

UNITED STATES COURT OF APPEALS June 17, 2009

FOR THE TENTH CIRCUIT

Elisabeth A. Shumaker
Clerk of Court

EDWARD RONWIN,

Plaintiff-Appellant,

v.

BAYER CORPORATION, an Indiana
corporation, doing business as Bayer
Pharmaceutical Division,

Defendant-Appellee.

No. 08-8089
(D.C. No. 2:01-CV-00172-WFD)
(D. Wyo.)

ORDER AND JUDGMENT*

Before **KELLY, McKAY**, and **BRISCOE**, Circuit Judges.

Edward Ronwin appeals pro se the district court's grant of summary judgment in favor of Bayer Corporation on his claims for negligence, strict liability, and breach of implied warranty. Exercising jurisdiction under 28 U.S.C. § 1291, we affirm.

* After examining the briefs and appellate record, this panel has determined unanimously that oral argument would not materially assist the determination of this appeal. *See* Fed. R. App. P. 34(a)(2); 10th Cir. R. 34.1(G). The case is therefore ordered submitted without oral argument. This order and judgment is not binding precedent, except under the doctrines of law of the case, res judicata, and collateral estoppel. It may be cited, however, for its persuasive value consistent with Fed. R. App. P. 32.1 and 10th Cir. R. 32.1.

Background

Dr. Ronwin filed a complaint against Bayer in September 2001, alleging that he was injured by cerivastatin, a prescription drug in the “statin” family that was manufactured and sold by Bayer under the name “Baycol.” The United States Food and Drug Administration (FDA) first approved Baycol for the treatment of high cholesterol in 1997. Plaintiff began taking Baycol for that purpose on or about January 10, 2001, when he was almost 77 years old. He alleges that a short time later he began experiencing a number of physical symptoms, including pain in his left shoulder, thighs, and back, blurred vision, and gait problems. He stopped taking Baycol on or about August 8, 2001. He claims that his blurred vision and gait problems receded after he ceased taking Baycol, but that his other symptoms persisted. Dr. Ronwin was diagnosed in 2003 with a torn left rotator cuff, which he had surgically repaired.

Bayer voluntarily removed Baycol from the market on August 8, 2001, citing a risk of rhabdomyolysis¹ as a serious, potentially fatal adverse effect of the drug. Dr. Ronwin and thousands of other plaintiffs sued Bayer, claiming that various injuries resulted from their ingestion of Baycol.² As of 2003, Bayer had

¹ “Rhabdo[myolysis] is an acute, fulminating, potentially fatal disease of the skeletal muscle, which entails destruction of skeletal muscle.” *In Re Baycol Prods. Litig.*, 218 F.R.D. 197, 201 n.1 (D. Minn. 2003).

² Plaintiff originally filed his complaint in state court in Wyoming. Bayer removed the case to the United States District Court for the District of Wyoming. (continued...)

settled close to 1,000 of the claims involving Baycol. *See In re Baycol Prods. Litig.*, 218 F.R.D. 197, 210 (D. Minn. 2003).

In support of his claims, plaintiff proffered his own expert testimony and the expert testimony of Dr. Raul G. Reyes, as summarized in expert reports submitted to the district court. After discovery was completed, Bayer filed a summary judgment motion arguing there was no evidence establishing that Baycol caused plaintiff to suffer any injury. More specifically, Bayer contended that plaintiff's proffered expert testimony was inadmissible under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), because neither witness was qualified to offer an expert opinion and their methodologies were not reliable. The district court granted Bayer's motion, excluding plaintiff's proffered expert testimony and granting summary judgment in favor of Bayer on all claims.

Applicable Law and Standards of Review

In this diversity action "the substantive law of the forum state governs the analysis of the underlying claims, including specification of the applicable standards of proof, but federal law controls the ultimate, procedural question

²(...continued)

In January 2002 the case was conditionally transferred by the Judicial Panel on Multidistrict Litigation to the United States District Court for the District of Minnesota (hereafter "MDL case"). After pretrial proceedings were completed, including briefing on Bayer's summary judgment motion, plaintiff's case was transferred back to the district court in Wyoming in 2007.

whether [summary judgment] is appropriate.” *Specialty Beverages, L.L.C. v. Pabst Brewing Co.*, 537 F.3d 1165, 1175 (10th Cir. 2008). Thus, we apply federal law in reviewing de novo the district court’s grant of summary judgment in this case. *See Hollander v. Sandoz Pharm. Corp.*, 289 F.3d 1193, 1214 (10th Cir. 2002). Summary judgment is appropriate “if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c).

The district court’s grant of summary judgment in favor of Bayer rested on two antecedent rulings. First, the district excluded the testimony of both of plaintiff’s experts. “The admissibility of expert testimony is governed by Rule 702 of the Federal Rules of Evidence.” *United States v. Benally*, 541 F.3d 990, 994 (10th Cir. 2008), *cert. denied*, 129 S. Ct. 1020 (2009).

We review de novo the question of whether the district court performed its gatekeeper role and applied the proper legal standard in admitting an expert’s testimony. We then review for abuse of discretion the trial court’s actual application of the gatekeeper standard in deciding whether to admit or exclude an expert’s testimony.

Miller v. Pfizer, Inc., 356 F.3d 1326, 1335 (10th Cir. 2004) (quotation and brackets omitted). In reviewing a district court’s application of the second step of this standard, we afford substantial deference to a court’s exclusion of expert opinion evidence under *Daubert*. *Hollander*, 289 F.3d at 1204. “Under the abuse

of discretion standard, a trial court's decision will not be disturbed unless the appellate court has a definite and firm conviction that the lower court made a clear error of judgment or exceeded the bounds of permissible choice in the circumstances." *Id.* (quotation omitted).³

In its second ruling leading to its grant of summary judgment, the district court held that, under Wyoming law, plaintiff was required to present expert testimony in order to establish that Baycol caused his injuries. Plaintiff does not challenge the district court's application of Wyoming law in deciding this issue.

Exclusion of Expert Testimony

The proponent of expert testimony bears the burden of showing that its proffered expert's testimony is admissible. *Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 970-71 n.4 (10th Cir. 2001). F.R.E. 702 "imposes upon the trial judge an important 'gate-keeping' function with regard to the admissibility of expert opinions." *Ralston*, 275 F.3d at 969. In this role, a district court should apply a two-step analysis, determining first whether an expert is qualified to render an opinion by "knowledge, skill, experience, training, or education," and

³ Plaintiff contends that we should apply a de novo standard of review to the district court's exclusion of expert testimony because the court's evidentiary ruling served as the definitive ground for its grant of summary judgment. The Supreme Court rejected a similar argument in *General Electric Co. v. Joiner*, 522 U.S. 136, 142-43 (1997), holding that a district court's decision on the admissibility of expert testimony is reviewed for an abuse of discretion, even where that ruling is "outcome determinative" for purposes of summary judgment.

second, whether the expert's opinions are "reliable" under *Daubert*. *Id.* (quoting F.R.E. 702). "Reliability is determined by assessing whether the reasoning or methodology underlying the testimony is scientifically valid." *Hollander*, 289 F.3d at 1204 (quotation omitted).

Trial courts generally apply four factors in assessing the reliability of an expert's methodology:

(1) whether the opinion at issue is susceptible to testing and has been subjected to such testing; (2) whether the opinion has been subjected to peer review; (3) whether there is a known or potential rate of error associated with the methodology used and whether there are standards controlling the technique's operation; and (4) whether the theory has been accepted in the scientific community.

Id. at 1205. These factors are nonexclusive, "and district courts applying *Daubert* have broad discretion to consider a variety of other factors." *Id.* But

[r]egardless of the specific factors at issue, the purpose of the *Daubert* inquiry is always the same: to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.

Id. at 1205-06 (quotation and brackets omitted).

Plaintiff's Proffered Expert Testimony

Plaintiff proffered Dr. Reyes and himself as expert witnesses on causation. Although Dr. Reyes is a surgeon with over fifty years of experience, he admitted in his deposition that he had never prescribed statin drugs and that he was unaware of any published medical literature linking statins, or Baycol in

particular, to rotator cuff injuries. After reviewing a small portion of plaintiff's medical records, Dr. Reyes submitted an expert report concluding that:

The medical records clearly reveal that Dr. Ronwin suffered a left shoulder rotator cuff tear which required corrective surgery and, in view of the undisputed propensity of Baycol to disrupt body function along with an absence of any other traumatic event in Dr. Ronwin's case, it is my medical opinion that in view of the lack of medical history of any injury to this shoulder that there is a high probability that this injury was caused by Baycol ingestion for a period of seven (7) months.

Aplee. App., Vol. I at 286.⁴

Dr. Ronwin purports to be an expert on the biochemical composition of Baycol and its effect on the human body. He received B.S. and M.S. degrees in chemistry in 1949 and 1950, and a Ph.D. in biochemistry in 1952. He worked in the fields of chemistry and biochemistry until 1971, during which time he authored or co-authored numerous published scientific papers. He entered law school in 1971, then practiced law for twenty years. At the time he submitted his expert report in opposition to Bayer's summary judgment motion, Dr. Ronwin had not actively worked as a scientist in more than 30 years, but he had maintained his memberships in three major scientific societies, he continued to read scientific publications, and he taught one chemistry overview course in 2001.

⁴ With respect to plaintiff's other claimed injuries, Dr. Reyes's expert report concluded only that his symptoms "may be related to his ingestion of Baycol." Aplee. App., Vol. I at 286.

In his expert report Dr. Ronwin concluded that the injuries he suffered “are related to and caused by [his] ingestion of Baycol whose chemical structure can give rise to flouride ion which can, in turn, cause injury to numerous body components, proteins and tissues including the protein collagen in tendons and in rotator cuff tendons.” Aplee. App., Vol. II at 509. In support of this theory, he cited a book and a number of scientific papers addressing the effects of flouridated drinking water on various parts of the human body. In addition to these writings, he also based his opinion on his “general store of personal, biochemical knowledge.” *Id.* at 507.

Expert Qualifications

Applying the first step of the Rule 702 analysis, the district court held that Drs. Reyes and Ronwin were not qualified by their knowledge, skill, experience, training, or education to testify regarding a causal connection between Baycol ingestion and plaintiff’s shoulder injury. The court noted Dr. Reyes’s lack of any practical experience or training with respect to Baycol or statins in general and Dr. Ronwin’s “lengthy departure from active research, publication, and teaching.” Aplee. App., Vol. II at 803. A district court has “wide discretion” in determining whether a witness’s experience is sufficient to qualify him as an expert. *United States v. Arney*, 248 F.3d 984, 991 (10th Cir. 2001). Dr. Ronwin contends that Dr. Reyes’s extensive orthopedic surgery experience qualifies him to opine on the cause of plaintiff’s rotator cuff tear. But we have specifically rejected the

contention that surgical experience alone is sufficient to qualify an expert to testify regarding an issue “not within the reasonable confines of her subject area.” *Ralston*, 275 F.3d at 970 (holding district court did not abuse its discretion in excluding testimony by board-certified orthopedic surgeon where she had no practical, research, or publication experience regarding the subject matter of her proffered expert testimony, *see id.* at 969-70). Nor did the district court abuse its discretion in holding that Dr. Ronwin’s relevant practical experience in biochemistry was too stale to qualify him to give an expert causation opinion in this case. *See Meyerhoff v. Michelin Tire Corp.*, 70 F.3d 1175, 1182 (10th Cir. 1995) (upholding exclusion of expert testimony based, in part, on proffered witness’s absence from the relevant industry for over 30 years). Applying the proper standard, we cannot conclude that the district court abused its discretion in concluding that Drs. Reyes and Ronwin were not qualified to testify regarding whether Baycol caused plaintiff’s injuries.

Methodologies

The district court also excluded plaintiff’s experts’ testimony on the independent basis that their methodologies failed to satisfy any of the four *Daubert* factors and were therefore not scientifically valid or reliable. First, we reject plaintiff’s argument that his experts’ theories have been peer reviewed. His primary contention, however, is that the district court erred in choosing to apply the *Daubert* factors. Specifically, he argues that, because of the short time that

Baycol was sold, there will never be sufficient research to support a causation conclusion, and further that “[t]he first several victims of a new toxic tort should not be barred from having their day in court simply because the medical literature, which will eventually show the connection between the victims’ condition and the toxic substance, has not yet been completed.” Aplt. Opening Br. at 18 (quoting *Hollander*, 289 F.3d at 1211). The record belies plaintiff’s assertions: *thousands* of plaintiffs filed suits asserting that Baycol caused their injuries; the district court in the MDL case *required* each plaintiff to submit an expert report in support of his claim of causation; and plaintiff’s case had been pending for seven years at the time the district court excluded his proffered expert testimony. We cannot conclude that the district court exceeded the bounds of permissible choice in deciding to apply the four *Daubert* factors in assessing the reliability of Dr. Reyes’s and Dr. Ronwin’s methodologies.

Because the district court has discretion to consider a variety of factors [in] assessing reliability under *Daubert*, and because, in light of that discretion, there is not an extensive body of appellate case law defining the criteria for assessing scientific reliability, we are limited to determining whether the district court’s application of . . . *Daubert* manifests a clear error of judgment or exceeds the bounds of permissible choice in the circumstances.

Hollander, 289 F.3d at 1206.

Plaintiff asserts that the district court should have admitted Dr. Reyes’s testimony, despite its failure to satisfy any of the *Daubert* factors, because a reasonable differential diagnosis may be sufficient to validate a causation

opinion.⁵ *See id.* at 1211-12.⁶ Bayer argues that Dr. Reyes did not do a differential diagnosis ruling out all other plausible causes of his shoulder injury, including those that were identified by plaintiff's own treating physicians. Plaintiff responds that Dr. Reyes implicitly did such an analysis with respect to degenerative changes and his advanced age as likely causes of his rotator cuff tear. He asserts that Dr. Reyes reviewed his medical records related to the shoulder injury and was aware of his age, therefore Dr. Reyes must have considered and ruled out these other factors as the cause of his injury, as opposed to simply ignoring or overlooking them. But plaintiff admits that Dr. Reyes did not rule out a third potential cause, and he fails to show that Dr. Reyes ruled in Baycol as a scientifically plausible cause based upon reliable evidence. We conclude that the district court did not abuse its discretion in failing to admit Dr. Reyes's expert testimony based upon his "implicit" differential diagnosis.

⁵ Dr. Ronwin does not contend that *he* performed a differential diagnosis, or even that he would be qualified to do so.

⁶ "Differential diagnosis' refers to the process by which a physician 'rules in' all scientifically plausible causes of the plaintiff's injury. The physician then 'rules out' the least plausible causes of injury until the most likely cause remains. The remaining cause is the expert's conclusion." *Hollander*, 289 F.3d at 1209 (citation and quotation omitted). We have emphasized that the remaining cause must have been "ruled in" as scientifically plausible based upon reliable evidence. *See id.* at 1211. And this court has recognized that deficiencies in a particular differential diagnosis can support a district court's decision to exclude expert testimony. *See id.* at 1212.

Absent indicia of reliability based upon the *Daubert* factors or a valid differential diagnosis, all that is left to support plaintiff's experts' causation conclusions is their own *ipse dixit*. See *Gen. Elec. Co.*, 522 U.S. at 146 (“[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.”). The district court did not abuse its discretion in excluding plaintiff's proffered expert testimony.

Grant of Summary Judgment

Having excluded plaintiff's proffered expert testimony, the district court held that he presented no evidence demonstrating a causal link between his ingestion of Baycol and his alleged injuries. In reaching this conclusion, the court applied an earlier ruling in the MDL case that, because the Baycol litigation involves complicated causation issues, all plaintiffs were required to present expert testimony to prove injury and a causal connection. See *In re Baycol Prods. Litig.*, 321 F. Supp. 2d 1118, 1125-26 (D. Minn. 2004) (citing *Sayer v. Williams*, 962 P.2d 165, 167 (Wyo. 1998)).⁷ Plaintiff does not identify any error in the district court's conclusion that, absent expert testimony on causation, summary

⁷ In that decision the district court specifically addressed plaintiff's claims, stating that “[c]ontrary to Plaintiff Ronwin's assertions, whether Baycol caused such injuries is beyond the understanding and experience of a lay person, and will require a differential diagnosis.” *In re Baycol Prods. Litig.*, 321 F. Supp. 2d at 1126-27.

judgment was appropriate. But he argues that summary judgment should be reversed because the district court did not grant his request for oral argument on Bayer's motion. He contends that the court's failure to grant him an oral hearing is a violation of his rights under the First and Seventh Amendments.

Denial of Oral Argument

“The law is well-settled that summary judgment does not violate the Seventh Amendment.” *J.R. Simplot v. Chevron Pipeline Co.*, 563 F.3d 1102, 1117 (10th Cir. 2009). Nor does a “hearing” on a summary judgment motion necessarily require oral argument. “Rather, the parties’ right to be heard may be fulfilled by the court’s review of the briefs and supporting affidavits and materials submitted to the court.” *Gear v. Boulder Comm. Hosp.*, 844 F.2d 764, 766 (10th Cir. 1988). Plaintiff does not cite in his opening brief any case law holding that a district court’s grant of summary judgment without an oral hearing is constitutionally infirm, or otherwise denying a district court discretion to decide a summary judgment motion without oral argument.⁸

⁸ The cases from other circuits that plaintiff cites for the first time in his reply brief do not squarely support that proposition in the context of this case. Therefore, in addition to being tardy, they are not persuasive. *See Season-All Indus., Inc. v. Turkiye Sise Ve Cam Fabrikalari, A.S.*, 425 F.2d 34, 39-40 (3d Cir. 1970) (holding that summary judgment should not be granted on the briefs without oral argument unless court makes clear that affidavits must be filed with the briefs); *Ga. S. & Fla. Ry. Co. v. Atl. Coast Line R.R. Co.*, 373 F.2d 493, 496-98 (5th Cir. 1967) (addressing final judgment granted after court, without prior notice, converted motion to dismiss into summary judgment motion and

(continued...)

In *Gear* we addressed the sufficiency of the parties' written materials in the absence of an oral hearing:

[T]he district judge examined the briefs and supporting materials to evaluate the merits of the motion for summary judgment. Nothing in the record suggests that the issues and evidence presented in this case could not be addressed adequately in the form of written briefs with accompanying affidavits, depositions and similar exhibits. Based upon its review of the submitted materials, the court found that entry of judgment was appropriate because there was no genuine issue of fact, and the Defendant was entitled to judgment as a matter of law. Thus, the court satisfied the "hearing" requirement of Rule 56.

844 F.2d at 766. The same reasoning applies here. Plaintiff does not identify any legal or factual issue that he was unable to present sufficiently in his 71-page brief in response to Bayer's motion, such that oral argument was essential. We conclude that the district court's decision not to grant a hearing on Bayer's summary judgment motion was not an abuse of discretion. We therefore affirm the district court's grant of summary judgment in favor of Bayer.⁹

⁸(...continued)

granted summary judgment after preliminary injunction hearing); *Dredge Corp. v. Penny*, 338 F.2d 456, 461-62 (9th Cir. 1964) (holding that district court could not apply local rule to preclude oral argument); *see also Stump v. Gates*, 211 F.3d 527, 533 (10th Cir. 2000) (stating "court does not ordinarily review issues raised for the first time in a reply brief").

⁹ Plaintiff raises two additional "issues" in his opening brief, which we decline to address in detail. Whether Bayer "deliberately lie[d] to the court below" and whether Bayer is a "criminal organization," Aplt. Opening Br. at 2, have no bearing on the basis for the district court's grant of summary judgment in Bayer's favor.

Conclusion

The judgment of the district court is AFFIRMED.

Entered for the Court

Paul J. Kelly, Jr.
Circuit Judge