FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MARYLOU PRIMIANO; CHARLES PRIMIANO, *Plaintiffs-Appellants,* v. YAN COOK; STRYKER CORPORATION; ROBERT J. TAIT M.D., *Defendant,* HOWMEDICA OSTEONICS CORPORATION, *Defendant-Appellee.*	No. 06-15563 D.C. No. CV-03-00373-JCM/PAL OPINION

Appeal from the United States District Court
for the District of Nevada
James C. Mahan, District Judge, Presiding

Argued and Submitted February 13, 2008
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Before: Dorothy W. Nelson, Andrew J. Kleinfeld, and
Michael Daly Hawkins, Circuit Judges.

Opinion by Judge Kleinfeld

COUNSEL

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OPINION

KLEINFELD, Circuit Judge:

We address admissibility under *Daubert*[1] of medical testimony.

[1]*Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

I. Facts

Marylou Primiano has suffered a miserable ordeal since she had elbow surgery. The question raised by her litigation[2] is whether her ordeal resulted from a defective product, the artificial elbow Howmedica Osteonics Corporation manufactured. The district court granted summary judgment against her and dismissed her case, but that result could not have occurred had her medical expert's testimony been considered. His testimony would have established a genuine issue of material fact, because he thought the plastic bearing between the metal parts of the artificial elbow wore out so quickly that it must have been defective. The district court ruled that his testimony was inadmissible, leaving Primiano with inadequate evidence to establish a genuine issue of fact. The question before us is whether excluding Primiano's expert's testimony was an abuse of discretion.

Ms. Primiano, an active 36-year-old woman, fell in her kitchen and broke her elbow. The injury, serious for anyone, was especially serious for her, because she has had rheumatoid arthritis for years. Unlike osteoarthritis, a degenerative process of wear and tear on the joints, rheumatoid arthritis is a chronic inflammatory disease of the connective tissue in the joints.[3] Her physician, Robert J. Tait, M.D., performed surgery April 18, 2000, two days after her fall. He replaced her elbow joint with a device made by the defendant, Howmedica, consisting of titanium pieces to replace the bone and polyethylene components to prevent the metal from rubbing against metal.

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[2]The complaint also names Mr. Primiano as a plaintiff, for his derivative claim for loss of consortium etc., and names Stryker Corporation as owner of Howmedica Osteonics Corporation, Robert J. Tait M.D., the surgeon who operated on Ms. Primiano, and Yan Cook, a Howmedica sales representative. Only the Primianos' appeal challenging the summary judgment and exclusion of evidence in favor of Howmedica is before us.

[3]*Blakiston's Gould Medical Dictionary* 1353 (3d ed. 1972).

Two thirds of the way through surgery, Dr. Tait discovered that Howmedica had made a mistake in the packing and shipping, so even though he was replacing Ms. Primiano's right elbow, the humeral component (the humerus is the arm bone running from the elbow to the shoulder) sent to him was labeled for the left arm. He consulted Howmedica's representative ("Did I kill him? No, I didn't.") with Ms. Primiano's arm open on the table and was told that the components are symmetrical, identical in every respect except that the locking pin goes in the opposite side of the left humeral component, so the component he had could be used. The hole had to be drilled in Ms. Primiano's bone from the inside instead of the outside, but the artificial joint would be equally functional. Dr. Tait completed the operation, and it appeared to be a success.

But by July, Ms. Primiano's elbow squeaked, and by December, Dr. Tait could hear the metal-on-metal contact, which he confirmed in an x-ray. In February, Dr. Tait performed a second surgery addressing the evident failure of the implant and risk of metallosis (a destructive immune response of the body to flecks of metal shaved off by metal-on-metal contact), replacing the humeral component with a longer one. He used Howmedica's left arm humeral component again, though the long instead of the standard, to avoid having to redrill the remaining bone. He observed massive metallosis and "severe polyethylene wear" on the bearing surrounding the pin. Again, the surgery appeared to go fine. But the next month, Ms. Primiano was having trouble controlling her arm and the joint had a "cracking" sound. She obtained a second opinion from an orthopedic surgeon who concluded that the components appeared "to be adequately fixed and in good position." But in June her problems with the joint had not gone away, so she consulted a third orthopedic surgeon, who recommended a third surgery. In July this surgeon replaced her Howmedica device with one from its competitor, Zimmer. That surgeon performed a fourth surgery the next April to cor-

rect loosening. A pin backed out of position, so she needed yet another surgery, her fifth, in September.

Primiano sued Howmedica, Dr. Tait, and others in state court for negligence, strict liability, breach of warranty, and loss of consortium.[4] Howmedica removed the case to federal court based on diversity. All that is before us now is the products liability case.

In the summary judgment papers, Howmedica's experts, an orthopedic surgeon and a chemist, provided opinions that the polyethylene was as it should be, and the rapid failure of the prosthesis and excessive wear on the polyethylene components resulted from "malalignment of the prosthesis" along with increased risk of complication because of Ms. Primiano's rheumatoid arhtritis and her age. The product literature distributed to physicians said that the prosthesis would not restore function to the level expected with normal healthy bone, and was vulnerable to excessive loading from activity. Evidently, younger patients such as Ms. Primiano may do worse because they are more active. The manufacturer's literature says "[w]hile the expected life of the total elbow replacement components is difficult to estimate, it is finite."

Primiano's expert witness, Arnold-Peter Weiss, M.D., declared that the polyethylene bushing had worn through in less than eight months, "not a usual or expected circumstance." Though finite, the typical lifespan of elbow prostheses "far exceeds" how long this one lasted. Dr. Weiss testified in his deposition that although wear starts immediately, elbow prostheses last as long as ten or fifteen years, even twenty, and the earliest he had seen them wear out was around five to eight years, varying with the patient's activity level. Though misalignment could cause excessive wear, he had looked at the x-rays and found no significant misalignment.

[4]Primiano's complaint says that she is not suing Dr. Tait for malpractice, just as an agent of Howmedica in selling the prosthesis.

Nor would ordinary daily activity produce such extraordinarily rapid wear. Nor could he find technically inappropriate use of the prosthesis by Dr. Tait. His opinion was that the extraordinarily rapid wear was caused by abrasive wear and generation of debris from movement of the titanium against the polyethylene. And he concluded that the prosthesis failed to perform in a manner reasonably to be expected by a surgeon using it, because it failed too early.

The district court granted defendants' motion to exclude Dr. Weiss's testimony as not meeting the *Daubert* standard and granted summary judgment. The court concluded that Dr. Weiss's testimony would not be helpful to the jury. The judge reasoned: "Well, I mean it's like res ipsa loquitur, the elbow failed. Now, why did it fail? Maybe it was malpractice, maybe it was Dr. Tait." The evidence of rapid wear "doesn't make it defective." "I think [Dr. Tait's] opinion is weakened by the fact that he didn't see the plaintiff. He didn't examine her. He didn't talk to her." "[T]here's no peer review . . . no publication . . . there's got to be an objective source that he relies on." The court rejected plaintiff's argument, that testimony that the premature failure was not attributable to overuse, medical malpractice, "her physiology," or other factors external to the device, would assist the jury.

II. Analysis

We review summary judgment de novo.[5] The substantive question the jury would have to answer, in this diversity case arising out of state tort law, is established by Nevada law. The question whether evidence is admissible, though, is governed by federal law. The Federal Rules of Evidence "govern proceedings in the courts of the United States."[6] That is generally true in diversity cases because the Federal Rules of Evidence

[5]*Carmen v. San Francisco Unified Sch. Dist.*, 237 F.3d 1026, 1029 (9th Cir. 2001).

[6]Fed. R. Evid. 101.

are statutes enacted by Congress.[7] Though there are exceptions, such as state substantive law in the guise of an evidentiary rule,[8] no exception applies here.

[1] Ms. Primiano's burden was to establish a defect in the manufacture of the artificial elbow. In Nevada, "those products are defective which are dangerous because they fail to perform in the manner reasonably to be expected in light of their nature and intended function."[9] A plaintiff need not "produce direct evidence of a specific product defect [or] negate any alternative causes of the accident."[10] An "unexpected, dangerous malfunction" suffices.[11]

[2] Federal Rule of Evidence 702 controlled admissibility of Dr. Weiss's opinion. That rule establishes several requirements for admissibility: (1) the evidence has to "assist the trier of fact" either "to understand the evidence" or "to determine a fact in issue"; (2) the witness has to be sufficiently qualified to render the opinion:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and

[7]*Sims v. Great Am. Life Ins. Co.*, 469 F.3d 870, 878-79 (10th Cir. 2006).

[8]*See Feldman v. Allstate Ins. Co.*, 322 F.3d 660, 666 (9th Cir. 2003); *Wray v. Gregory*, 61 F.3d 1414, 1417 (9th Cir. 1995) (per curiam).

[9]*Allison v. Merck & Co.*, 878 P.2d 948, 952 (Nev. 1994) (internal quotation marks omitted); *Ginnis v. Mapes Hotel Corp.*, 470 P.2d 135, 138 (Nev. 1970) (internal quotation marks omitted).

[10]*Stackiewicz v. Nissan Motor Corp., USA*, 686 P.2d 925, 927 (Nev. 1984).

[11]*Id.* at 928.

> methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.[12]

Though *Daubert* is sometimes loosely spoken of as though it established the court's "gatekeeping" function, that is not quite right. Trial courts have always had a gatekeeping function for opinion evidence. *Daubert* held that Federal Rule of Evidence 702 replaces the old *Frye*[13] gatekeeping test, "general acceptance in the particular field," with a different test which is, in some respects, more open to opinion evidence.[14]

[3] The requirement that the opinion testimony "assist the trier of fact" "goes primarily to relevance."[15] For scientific opinion, the court must assess the reasoning or methodology, using as appropriate such criteria as testability, publication in peer reviewed literature, and general acceptance, but the inquiry is a flexible one.[16] Shaky but admissible evidence is to be attacked by cross examination, contrary evidence, and attention to the burden of proof, not exclusion.[17] In sum, the trial court must assure that the expert testimony "both rests on a reliable foundation and is relevant to the task at hand."[18] *Kumho Tire Co. v Carmichael* holds that the *Daubert* framework applies not only to scientific testimony but to all expert testimony.[19] It emphasizes, though, that the "test of reliability is 'flexible' and *Daubert*'s list of specific factors neither nec-

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[12]Fed. R. Evid. 702.

[13]*Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923).

[14]*Daubert*, 509 U.S. at 588 ("Nothing in the text of [Rule 702] establishes 'general acceptance' as an absolute prerequisite to admissibility."); *id.* at 589 ("That austere standard, absent from, and incompatible with, the Federal Rules of Evidence, should not be applied in federal trials.").

[15]*Id.* at 591.

[16]*Id.* at 592-4.

[17]*Id.* at 596.

[18]*Id.* at 597.

[19]*Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999); *see also White v. Ford Motor Co.*, 312 F.3d 998, 1007 (9th Cir. 2002).

essarily nor exclusively applies to all experts or in every case."[20] The "list of factors was meant to be helpful, not definitive,"[21] and the trial court has discretion to decide how to test an expert's reliability as well as whether the testimony is reliable,[22] based on "the particular circumstances of the particular case."[23]

[4] We further interpreted *Daubert* on remand.[24] In that case, the evidence proffered was scientific epidemiological evidence, of insufficient reliability for admissibility. We took pains to point out that the problem was methodology, not the conclusion to which the evidence would lead. "[T]he test under *Daubert* is not the correctness of the expert's conclusions but the soundness of his methodology."[25] Under *Daubert*, the district judge is "a gatekeeper, not a fact finder."[26] When an expert meets the threshold established by Rule 702 as explained in *Daubert*, the expert may testify and the jury decides how much weight to give that testimony.

Testimony by physicians may or may not be scientific evidence like the epidemiologic testimony at issue in *Daubert*. The classic medical school texts,[27] *Cecil*[28] and *Harrison*,[29] explain that medicine is scientific, but not entirely a science.

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[20]*Kumho Tire*, 526 U.S. at 141.

[21]*Id.* at 151.

[22]*Id.* at 152.

[23]*Id.* at 150.

[24]*Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1313 (9th Cir. 1995).

[25]*Id.* at 1318.

[26]*United States v. Sandoval-Mendoza*, 472 F.3d 645, 654 (9th Cir. 2006).

[27]Jock Murray, *Neurology Texts for Internists*, 123 Annals of Internal Med. 477, 477-79 (1995).

[28]*Cecil Textbook of Medicine* 1 (James B. Wyngaarden & Lloyd H. Smith Jr. eds., 17th ed. 1985).

[29]*Harrison's Principles of Internal Medicine* 3 (Dennis L. Kasper et al. eds., 16th ed. 2005).

"[M]edicine is not a science but a learned profession, deeply rooted in a number of sciences and charged with the obligation to apply them for man's benefit."[30] "Evidence-based medicine" is "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients."[31] "Despite the importance of evidence-based medicine, much of medical decision-making relies on judgment—a process that is difficult to quantify or even to assess qualitatively. Especially when a relevant experience base is unavailable, physicians must use their knowledge and experience as a basis for weighing known factors along with the inevitable uncertainties" to "mak[e] a sound judgment."[32]

When considering the applicability of *Daubert* criteria to the particular case before the court, the inquiry must be flexible. Peer reviewed scientific literature may be unavailable because the issue may be too particular, new, or of insufficiently broad interest, to be in the literature.[33] Lack of certainty is not, for a qualified expert, the same thing as guesswork.[34] "Expert opinion testimony is relevant if the knowledge underlying it has a valid connection to the pertinent inquiry. And it is reliable if the knowledge underlying it has a reliable basis in the knowledge and experience of the relevant discipline."[35] "[T]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony."[36] Reliable expert testimony

[30]*Cecil Textbook of Medicine*, *supra*, at 1.

[31]*Harrison's Principles of Internal Medicine*, *supra*, at 3.

[32]*Id.*

[33]*Clausen v. M/V New Carissa*, 339 F.3d 1049, 1056, 1060 (9th Cir. 2003).

[34]*Id.* at 1059.

[35]*Sandoval-Mendoza*, 472 F.3d at 654 (internal quotation marks and citation omitted).

[36]*White v. Ford Motor Co.*, 312 F.3d 998, 1007 (9th Cir. 2002) (internal quotation marks omitted).

need only be relevant, and need not establish every element that the plaintiff must prove, in order to be admissible.[37]

[5] We have some guidance in the cases for applying *Daubert* to physicians' testimony. "A trial court should admit medical expert testimony if physicians would accept it as useful and reliable," but it need not be conclusive because "medical knowledge is often uncertain."[38] "The human body is complex, etiology is often uncertain, and ethical concerns often prevent double-blind studies calculated to establish statistical proof."[39] Where the foundation is sufficient, the litigant is "entitled to have the jury decide upon [the experts'] credibility, rather than the judge."[40] We held in *United States v. Smith* that even a physician's assistant was qualified based on experience to offer his opinion.[41]

[6] Other circuits have taken similar approaches focusing especially on experience. The Sixth Circuit held that a district court abused its discretion by excluding a physician's testimony based on extensive, relevant experience even though he had not cited medical literature supporting his view.[42] Likewise the Third Circuit pointed out that a doctor's experience might be good reason to admit his testimony.[43] Thus under our precedents and those of other circuits, the district court in this case was pushing against the current, but that alone does not imply an abuse of discretion.

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[37]*See Stilwell v. Smith & Nephew, Inc.*, 482 F.3d 1187, 1192 (9th Cir. 2007).

[38]*Sandoval-Mendoza*, 472 F.3d at 655.

[39]*Id.*

[40]*Id.* at 656.

[41]520 F.3d 1097, 1105 (9th Cir. 2008).

[42]*Dickenson v. Cardiac & Thoracic Surgery of E. Tenn.*, 388 F.3d 976, 982 (6th Cir. 2004).

[43]*Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 406-07 (3d Cir. 2003).

[7] A close look at the foundation for Dr. Weiss's opinion, the nature of medical opinion, and the question posed by Nevada law does. Dr. Weiss is a board certified orthopedic surgeon and a professor at Brown University School of Medicine in the Division of Hand, Upper Extremity and Microvascular Surgery, department of Orthopedics. He has published over a hundred articles in peer-reviewed medical journals including several specifically on the elbow and at least one somewhat related to this case, "Capitellocondylar Total Elbow Replacement: A Long-Term Follow-up Study."[44] He has years of experience implanting various elbow prosthetics and has performed five to ten revisions of total elbow replacements that had been performed by other physicians. He has examined the various types of prosthetics available, and has maintained familiarity with the peer-reviewed literature. He testified that the very short lifespan of Ms. Primiano's artifical elbow is "outside of my review of the known literature." He conceded on cross examination that there was "no published peer-reviewed article that [I'm] aware of that states a strict minimum lifespan of a polyethylene component in a total elbow system," but explained that "I wouldn't expect any literature, because you don't see it. It's hard to write a paper about something that doesn't occur. I mean, this is really bizarre."

[8] A court would have to find that Dr. Weiss is "qualified as an expert by knowledge, skill, experience, training, or education"[45] to render an opinion on elbow replacements. The district court appears to have rejected the opinion based in part on two elements of Rule 702, whether his opinion would assist the trier of fact, and whether it was based upon sufficient facts or data.

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[44]Andrew J. Weiland, Arnold-Peter C.Weiss, Robert P. Wills & J. Russell Moore, *Capitellocondylar Total Elbow Replacement: A Long-Term Follow-up Study*, 71 J. of Bone & Joint Surgery, 217, 217-22 (1989).

[45]Fed. R. Evid. 702.

[9] The district court thought Dr. Weiss's opinion would not assist the jury because Dr. Weiss could not say why the plastic part of the artificial elbow failed so quickly. The "will assist" requirement, under *Daubert*, "goes primarily to relevance."[46] What is relevant depends on what must be proved, and that is controlled by Nevada law. Nevada law establishes that "those products are defective which are dangerous because they fail to perform in the manner reasonably to be expected in light of their nature and intended function."[47] In Nevada, a plaintiff need not "produce direct evidence of a specific product defect [or] negate any alternative causes of the accident."[48] An "unexpected, dangerous malfunction" suffices.[49] Since Dr. Weiss, with a sufficient basis in education and experience, testified that the artificial joint "fail[ed] to perform in the manner reasonably to be expected in light of [its] nature and intended function," that was enough to assist the trier of fact. He did not have to know why it failed.

[10] The district court's other concerns, that Dr. Weiss never saw or talked to Ms. Primiano, and there was no publication supporting his opinion that the device failed extraordinarily early, both might be useful to the jury as impeachment, but neither furnished an adequate basis for excluding his opinion. What he most needed to see was what was inside her arm, not outside it, and he did. He saw the x-rays. He also saw the polyethylene from the implant installed in Primiano's first surgery. As for lack of a publication backing his opinion up, *Daubert* offers several reasons why an opinion unsupported by peer-reviewed publication may be admissible,[50] and Dr.

[46]*Daubert*, 509 U.S. at 591.

[47]*Allison v. Merck & Co.*, 878 P.2d 948, 952 (Nev. 1994) (internal quotation marks omitted); *Ginnis v. Mapes Hotel Corp.*, 470 P.2d 135, 138 (Nev. 1970) (internal quotation marks omitted).

[48]*Stackiewicz v. Nissan Motor Corp., USA*, 686 P.2d 925, 927 (Nev. 1984).

[49]*Id.* at 928.

[50]*Daubert*, 509 U.S. at 593.

Weiss furnished another one, that the phenomenon is so extraordinary that the specialists who publish articles do not see it in their practices.

[11] Dr. Weiss's background and experience, and his explanation of his opinion, leave room for only one conclusion regarding its admissibility. It had to be admitted. Once admitted, the opinion precluded summary judgment, because if the jury accepted it, then the Howmedica prosthesis "fail[ed] to perform in the manner reasonably to be expected."[51] His methodology, essentially comparison of what happened with Ms. Primiano's artificial elbow with what surgeons who use artificial elbows ordinarily see, against a background of peer-reviewed literature, is the ordinary methodology of evidence based medicine: "not a science but a learned profession deeply rooted in a number of sciences,"[52] "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients"[53] and "rel[ying] on judgment—a process that is difficult to quantify or even to assess qualitatively. Especially when a relevant experience base is unavailable, physicians must use their knowledge and experience as a basis for weighing known factors along with the inevitable uncertainties" to "mak[e] a sound judgment."[54]

[12] The jury may reject Dr. Weiss's opinion. It may conclude that Ms. Primiano's level of activity, or error by Dr. Tait in performing the surgery, caused the failure. Or it may conclude that the negligence that matters was in the packing and shipping department of Howmedica, when they sent the wrong pieces to the hospital. But those possibilities bear on

[51]*Allison*, 878 P.2d at 952.

[52]*Cecil Textbook of Medicine* 1 (James B. Wyngaarden & Lloyd H. Smith Jr. eds., 17th ed. 1985).

[53]*Harrison's Principles of Internal Medicine* 3 (Dennis L. Kasper et al. eds., 16th ed. 2005).

[54]*Id.*

the merits of Ms. Primiano's claim, not the admissibility of Dr. Weiss's opinion. Given that the judge is "a gatekeeper, not a fact finder,"[55] the gate could not be closed to this relevant opinion offered with sufficient foundation by one qualified to give it.

REVERSED.

[55]*Sandoval-Mendoza*, 472 F.3d at 654.