

FOR PUBLICATION

**UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

<p>LINDA MESSICK, <i>Plaintiff-Appellant,</i></p> <p>v.</p> <p>NOVARTIS PHARMACEUTICALS CORPORATION, <i>Defendant-Appellee.</i></p>	<p>No. 13-15433</p> <p>D.C. No. 3:12-cv-00693-SI</p> <p>OPINION</p>
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Appeal from the United States District Court
for the Northern District of California
Susan Illston, Senior District Judge, Presiding

Argued and Submitted
February 3, 2014—Seattle, Washington

Filed April 4, 2014

Before: Raymond C. Fisher, Ronald M. Gould,
and Morgan Christen, Circuit Judges.

Opinion by Judge Gould

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SUMMARY*

Expert Testimony

The panel reversed the district court's summary judgment in favor of Novartis Pharmaceuticals Corporation because the district court improperly excluded expert testimony.

Plaintiff offered Dr. Richard Jackson's testimony on osteonecrosis of the jaw and bisphosphonate-related osteonecrosis of the jaw generally ("BRONJ"), and on the causal link between plaintiff's bisphosphonate treatment and later development of BRONJ.

The panel held that the district court erred by excluding the causation testimony offered by the plaintiff's expert, Dr. Jackson, when it found the testimony to be irrelevant and unreliable. The panel held that Dr. Jackson's testimony indicated that plaintiff's bisphosphonate use was a substantial factor in her development of BRONJ, so the testimony was relevant. The panel also held that the testimony was reliable where Dr. Jackson testified a medical condition was a substantial causative factor. The panel concluded that Dr. Jackson's expert testimony created a genuine issue of material fact regarding the specific causal link between plaintiff's bisphosphonate treatment and her development of osteonecrosis of the jaw.

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

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OPINION

GOULD, Circuit Judge:

We consider when a district court should exclude expert testimony at trial. Linda Messick contends that the district court erred by excluding the causation testimony offered by her expert, Dr. Richard Jackson, when it found the testimony to be irrelevant and unreliable. Examining the district court's exclusion of expert testimony for an abuse of discretion, we conclude that Dr. Jackson's testimony was improperly excluded, and we reverse and remand.

I

In August 2000, Linda Messick was diagnosed with breast cancer. In response to her development of osteoporosis after chemotherapy and steroid therapy, Messick was treated with the drug Zometa from May 7, 2002 to November 14, 2002. Zometa is a bisphosphonate, a class of drug commonly used to treat multiple myeloma. Such drugs are used to reduce or eliminate the possibility of skeletal-related

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degeneration and injuries to which cancer patients are particularly susceptible. Novartis Pharmaceuticals Corporation (“Novartis”) produces Zometa, which was approved by the FDA in 2001 and 2002 for treating hypercalcemia of malignancy and other conditions.

After Messick encountered several dental problems, two oral specialists examined her in November 2005 and discovered osteonecrosis near three of her teeth. Both doctors treated her under the assumption that she was suffering from bisphosphonate-related osteonecrosis of the jaw (“BRONJ”), a condition recognized by the American Association of Oral and Maxillofacial Surgeons (“AAOMS”). According to the AAOMS, a BRONJ diagnosis is appropriate for patients with (1) current or previous treatment with bisphosphonates, (2) exposed bone in the maxillofacial region that has lasted for more than eight weeks, and (3) no history of radiation therapy to the jaw. Other potential causes of osteonecrosis of the jaw (“ONJ”) may include: periodontal and dental disease, osteomyelitis, corticosteroid use, cancer, radiation therapy, compromised immunity, and trauma. While ONJ may be caused by many factors, the AAOMS’s diagnostic definition of BRONJ sets out its unique features: it lasts more than eight weeks and is not related to radiation therapy. Messick’s BRONJ healed between March and October 2008, about three years after diagnosis. She and her husband brought suit against Novartis for strict products liability, negligent manufacture, negligent failure to warn, breach of express and implied warranty, and loss of consortium.

To support her claims, Messick offered Dr. Jackson’s testimony on ONJ and BRONJ generally, and on the causal link between her bisphosphonate treatment and later development of BRONJ. Dr. Jackson graduated from the

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University of the Pacific's School of Dentistry in 1974, completed his oral and maxillofacial surgery residency in 1982, and became Board Certified in oral maxillofacial surgery in 1984. He belongs to several dental and oral maxillofacial professional groups, and has published and lectured on a variety of topics over many years. Dr. Jackson has extensive experience diagnosing and treating ONJ, including ONJ in patients who had been treated with bisphosphonates, and he is the primary oral and maxillofacial surgeon managing ONJ in the Sacramento area.

While the action was pending in Multi-District Litigation proceedings, Novartis filed a motion to exclude the specific causation testimony of Messick's experts and a motion seeking summary judgment. After the case was remanded and transferred, the district court granted those motions, and Messick appeals the exclusion of Dr. Jackson's causation testimony and the ensuing grant of summary judgment to Novartis.

II

We review a ruling on the admissibility of expert testimony for an abuse of discretion, *Primiano v. Cook*, 598 F.3d 558, 563 (9th Cir. 2010), but review *de novo* the "construction or interpretation of . . . the Federal Rules of Evidence, including whether particular evidence falls within the scope of a given rule." *United States v. Durham*, 464 F.3d 976, 981 (9th Cir. 2006) (citations omitted).

The substantive issue here arises under the Federal Rules of Evidence and California state products liability law. Federal Rule of Evidence 702 governs expert testimony:

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A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

(a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and

(d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Although Rule 702 should be applied with a “liberal thrust” favoring admission, *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 588 (1993), it requires that “[e]xpert testimony . . . be both relevant and reliable,” *Estate of Barabin v. AstenJohnson, Inc.*, 740 F.3d 457, 463 (9th Cir. 2014) (alteration and omission in original) (quoting *United States v. Vallejo*, 237 F.3d 1008, 1019 (9th Cir. 2001)).

The relevancy bar is low, demanding only that the evidence “logically advances a material aspect of the proposing party’s case.” *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995) (“*Daubert II*”). Relevancy depends on the particular law at issue because “[e]xpert opinion testimony is relevant if the knowledge

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underlying it has a valid connection to the pertinent inquiry.” *Primiano*, 598 F.3d at 565. Here, California state products liability law requires only that a plaintiff show that the defendant’s conduct was “more likely than not” a substantial factor in causing the injury in order to prove specific causation. *See Saelzler v. Advanced Grp.* 400, 23 P.3d 1143, 1152 (Cal. 2001).

The district court excluded Dr. Jackson’s testimony as irrelevant because of its view that his “differential diagnosis only determines that Ms. Messick’s ONJ is *related* to her bisphosphonate use, and he admits that a diagnosis of BRONJ does not mean that bisphosphonates *caused* her ONJ.” The district court applied too high a relevancy bar without reference to California law. While Dr. Jackson never explicitly stated that Messick’s bisphosphonate use caused her BRONJ, he did say it was at least a substantial factor in her development of BRONJ. Specifically, Dr. Jackson equated Messick’s use of bisphosphonates leading to BRONJ with the oxygen necessary to start a fire. Although one might imagine more targeted testimony, Dr. Jackson’s testimony indicates that Messick’s bisphosphonate use was a substantial factor in her development of BRONJ, so his testimony is relevant.

The district court also abused its discretion in finding Dr. Jackson’s testimony to be unreliable. The reliability threshold requires that the expert’s testimony have “a reliable basis in the knowledge and experience of the relevant discipline.” *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 149 (1999) (citation and alterations omitted). The court must determine “whether the reasoning or methodology underlying the testimony is scientifically valid.” *Daubert*, 509 U.S. at 592–93.

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We recently acknowledged the district court’s duty to “act as a ‘gatekeeper’ to exclude junk science that does not meet Federal Rule of Evidence 702’s reliability standards.” *Barabin*, 740 F.3d at 463 (quoting *Ellis v. Costco Wholesale Corp.*, 657 F.3d 970, 982 (9th Cir. 2011)). To aid courts in exercising this gatekeeping role, the Supreme Court has suggested a non-exclusive and flexible list of factors that a court may consider when determining the reliability of expert testimony, including: (1) whether a theory or technique can be tested; (2) whether it has been subjected to peer review and publication; (3) the known or potential error rate of the theory or technique; and (4) whether the theory or technique enjoys general acceptance within the relevant scientific community. *Daubert*, 509 U.S. at 592–94.

We and our sister circuits have held that a reliable differential diagnosis may form the basis of an expert’s causation testimony. *See Clausen v. M/V NEW CARISSA*, 339 F.3d 1049, 1057 (9th Cir. 2003); *see also Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904 (7th Cir. 2007) (noting that “[a] differential diagnosis satisfies a *Daubert* analysis if the expert uses reliable methods”); *McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233, 1252 (11th Cir. 2005) (detailing a reliable differential diagnostic process); *Goebel v. Denver & Rio Grande W. R.R. Co.*, 346 F.3d 987, 999 (10th Cir. 2003); *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 202 (4th Cir. 2001) (holding that an expert’s opinion based on a differential diagnosis is generally admissible); *Hardyman v. Norfolk & W. Ry. Co.*, 243 F.3d 255, 260 (6th Cir. 2001) (“Differential diagnosis . . . is a standard scientific technique of identifying the cause of a medical problem”); *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1208 (8th Cir. 2000) (“[A] medical opinion about causation, based upon a proper differential diagnosis, is sufficiently reliable to

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satisfy *Daubert*.”); *Baker v. Dalkon Shield Claimants Trust*, 156 F.3d 248, 253 (1st Cir. 1998) (stating that “‘differential diagnosis’ is a standard medical technique”); *Ambrosini v. Labarraque*, 101 F.3d 129, 140 (D.C. Cir. 1996) (describing the appropriate use of differential diagnosis to prove specific causation); *McCulloch v. H.B. Fuller Co.*, 61 F.3d 1038, 1043–44 (2d Cir. 1995); *In re Paoli R.R. Yard PCD Litig.*, 916 F.2d 829, 862 (3d Cir. 1990).¹

When an expert rules out a potential cause in the course of a differential diagnosis, the “expert must provide reasons for rejecting alternative hypotheses using scientific methods and procedures and the elimination of those hypotheses must be founded on more than subjective beliefs or unsupported speculation.” *Clausen*, 339 F.3d at 1058 (internal quotation marks and citation omitted); *Daubert II*, 43 F.3d at 1318 (requiring explanations based on “scientifically valid principles”). The district court abused its discretion in excluding Dr. Jackson’s opinion, which stated that a patient without cancer or exposure to radiation in the mouth area would not develop ONJ lasting for years without IV bisphosphonate treatments. It excluded the testimony because Dr. Jackson “never explained the scientific basis for this conclusion.” But Dr. Jackson repeatedly referred to his own extensive clinical experience as the basis for his differential diagnosis, as well as his examination of Messick’s records, treatment, and history. Medicine partakes of art as well as science, and there is nothing wrong with a doctor relying on extensive clinical experience when making a

¹ The Fifth Circuit is alone in not yet explicitly approving the use of differential diagnosis, although it suggested in a recent case that a differential diagnosis may be admissible to prove specific causation. See *Johnson v. Arkema, Inc.*, 685 F.3d 452, 467–68 (5th Cir. 2012).

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differential diagnosis. Dr. Jackson also relied on the AAOMS definition of BRONJ in reaching his diagnosis and causation conclusions, which itself persuasively uses the three elements to distinguish BRONJ from other ONJ or delayed healing conditions. These sources form an appropriate scientific basis for his opinions, and the district court abused its discretion in concluding otherwise. *See Primiano*, 598 F.3d at 567 (admitting expert's testimony with "sufficient basis in education and experience").

Although experts must provide scientifically sound reasons for excluding potential causes, we have consistently recognized the difficulties in establishing certainty in the medical sciences. *Id.* at 565 (stating that "medical knowledge is often uncertain" (quoting *United States v. Sandoval-Mendoza*, 472 F.3d 645, 655 (9th Cir. 2006))). The Supreme Court has similarly stressed that "it would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty; arguably, there are no certainties in science." *Daubert*, 509 U.S. at 590.

Given the difficulties in establishing a medical cause and effect relationship, "[c]ausation can be proved even when we don't know precisely *how* the damage occurred, if there is sufficiently compelling proof that the agent must have caused the damage *somehow*." *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1230 (9th Cir. 1998) (quoting *Daubert II*, 43 F.3d at 1314). Viewed in this context, it is perhaps unsurprising that the AAOMS stated in a 2009 position paper that "the current level of evidence does not fully support a cause-and-effect relationship between bisphosphonate exposure and necrosis of the jaws." But the paper goes on to explain that while "causality might never be proven, emerging experimental and epidemiologic studies have established a firm foundation for

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a strong association between monthly IV bisphosphonate therapy and the development of BRONJ.”

Because of that inherent uncertainty, we do not require that an expert be able to identify the sole cause of a medical condition in order for his or her testimony to be reliable. It is enough that a medical condition be a substantial causative factor. We hold that the district court abused its discretion in excluding Dr. Jackson’s causation testimony when it found that testimony to be unreliable largely because Dr. Jackson could not “determine in a patient who has multiple risk factors at one time which of those particular risk factors is causing [the ONJ].” Such an unduly exacting standard goes beyond the district court’s proper gatekeeping role.

Dr. Jackson’s testimony should be admitted as relevant and reliable. Remaining issues regarding the correctness of his opinion, as opposed to its relevancy and reliability, are a matter of weight, not admissibility. *Kennedy*, 161 F.3d at 1230–31. While the district court must act as a gatekeeper to exclude “junk science” under *Daubert*, Federal Rule of Evidence 702(a) includes within its scope all evidence that would “help the trier of fact . . . to determine a fact in issue.” A doctor using a differential diagnosis grounded in significant clinical experience and examination of medical records and literature can certainly aid the trier of fact and cannot be considered to be offering “junk science.”

III

Summary judgment is proper when the moving party shows “there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). A court must view the evidence in the light

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most favorable to the non-moving party, *Scott v. Harris*, 550 U.S. 372, 378 (2007), and “there must be evidence on which the jury could reasonably find for the plaintiff,” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986). We review the district court’s grant of summary judgement de novo. *Lust ex rel. Lust v. Merrell Dow Pharm., Inc.*, 89 F.3d 594, 596–97 (9th Cir. 1996).

Here, the district court based its grant of summary judgment entirely on the fact that Messick had no expert causation testimony once all of her experts had been excluded. The admissibility, correctly viewed, of Dr. Jackson’s expert testimony creates a genuine issue of material fact regarding the specific causal link between Messick’s bisphosphonates treatment and her development of ONJ. We reverse the district court’s grant of summary judgment.

REVERSED AND REMANDED.