

FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LISA STILWELL,

Plaintiff-Appellant,

v.

SMITH & NEPHEW, INC., a
corporation,

Defendant-Appellee.

No. 05-15000

D.C. No.

CV-03-01322-SRB

OPINION

Appeal from the United States District Court
for the District of Arizona
Susan R. Bolton, District Judge, Presiding

Argued and Submitted
December 5, 2006—San Francisco, California

Filed April 11, 2007

Before: Myron H. Bright,* Dorothy W. Nelson, and
Marsha S. Berzon, Circuit Judges.

Opinion by Judge Bright

*The Honorable Myron H. Bright, Senior United States Circuit Judge
for the Eighth Circuit, sitting by designation.

COUNSEL

Joseph W. Charles, Glendale, Arizona, briefed and argued for the appellant.

Raymond R. Cusack and Stephen T. Portell, Tucson, Arizona, briefed for the appellee. Mr. Portell argued for the appellee.

OPINION

BRIGHT, Circuit Judge:

Plaintiff and appellant Lisa Stilwell (“Stilwell”) sustained two broken legs in a 1995 automobile accident. During her surgical treatment and recovery, doctors twice implanted a Russell-Taylor metal reconstruction nail (“RT nail”) to stabilize a compound subtrochanteric fracture of her right femur.¹ These two nails failed during the healing process, causing Stilwell pain, suffering, and disability. She brought this action against the defendant and appellee Smith & Nephew, Inc., manufacturer of the devices. Stilwell asserted claims based on strict liability, negligence, and breach of warranty. The district court rejected her claims for lack of proof of causation and ordered summary judgment in favor of Smith & Nephew.

¹The RT nail takes its name from its co-designers, Doctors Thomas Russell and John Taylor.

Stilwell asserts a single issue on appeal. She argues that the district court erred by barring the expert testimony of a metallurgist, Arun Kumar, Ph.D., under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and its progeny. Stilwell relied on the expert opinion to prove causation and, after the court's Rule 702 order, conceded that she could not prevail. We conclude that the court wrongly excluded the testimony but, after reviewing the record, affirm the grant of summary judgment for Smith & Nephew because evidence of record, including Kumar's deposition testimony and reports, does not demonstrate that any alleged defects were a cause of the delayed healing of Stilwell's fractured leg.

I.

In 1995, when Stilwell suffered a compound subtrochanteric fracture resulting in distal displacement and shortening of her right leg, doctors first attempted to repair her fractured femur with an Omega screw and side plate.² But—after twice replacing loose screws in the side plate in March 1995 and May 1996—they determined that the bone had not fused and the hardware had failed. Stilwell's doctors replaced the screw and plate in March 1998 with an RT nail, which failed and was replaced with a similar device three years later, in April 2001.³ In November 2002 doctors determined the second nail had failed and replaced it with a different device.

²A compound subtrochanteric fracture occurs when the shaft of the femur fractures below the hip joint, causing the bone to protrude through the skin. *See* STEDMAN'S MEDICAL DICTIONARY 712, 1720, 1878 (27th ed. 2000); *see also* Subtrochanteric fractures, WHEELESS' TEXTBOOK OF ORTHOPAEDICS, available at http://www.whelessonline.com/ortho/subtrochanteric_fractures (last visited Feb. 12, 2007).

³An intermedullary nail, also called a rod, aligns and stabilizes a fractured bone. It is inserted in the bone marrow canal of the femur and held in place by screws. *See* Intramedullary Nailing of Femoral Shaft Frx, WHEELESS' TEXTBOOK OF ORTHOPAEDICS, available at http://www.whelessonline.com/ortho/intramedullary_nailing_of_femoral_shaft_frx (last visited Feb. 12, 2007).

Stilwell, asserting that the RT nails failed in April 2001 and November 2002 because they were defectively designed or manufactured, sought compensation from Smith & Nephew. She hired Kumar to examine the two devices removed from her leg and determine why they had failed. Kumar's *curriculum vitae* indicates that he specializes in the “[f]ailure analysis of metallic and non-metallic . . . materials and electronic components” and has “[e]xtensive experience in metallurgical failure analysis of . . . medical implants.” He received a bachelors of science in physics, chemistry, and math; a bachelors of engineering in metallurgical engineering; a masters of science in engineering, with an emphasis in metallurgy and metal processing; and finally a doctorate in engineering. Kumar's *c.v.* also lists numerous memberships in professional societies, relevant work and teaching experience, and publications.

Kumar issued his first report in August 2003. He conducted three non-destructive tests on the RT nails and concluded that they “fractured due to fatigue.” He noted that fatigue was “of a low stress, high cycle type,” and that “sharp corners of the rod at the intersection of the slant screw hole and the outer diameter surface of the implant create[d] a high stress concentration area, enabling fatigue cracks to initiate at low stress levels.” He concluded that “[t]his constitutes a design/manufacturing defect, since the sharp corners could be ground and polished for a smoother transition between the two intersecting surfaces.”

Smith & Nephew first deposed Kumar in February 2004. Kumar responded repeatedly that his expertise was in metallurgy, as opposed to medicine or biomechanical engineering. He did, however, express his opinion regarding the potential life of intermedullary nails:

Q. Are you saying that the intermedullary nails, which are the subject matter of this lawsuit,

would never fail if there was never any union [of the bones]?

A. I really don't know the answer to that because I haven't done any testing to prove that, but in the absence of the defect that I will point out to you, that will be the case.

Kumar also repeated the conclusion of his first report, that further grinding and polishing could have extended the endurance limit of the RT nails he examined.

Kumar's second report, delivered in April 2004, included the findings of a series of destructive tests that he conducted on the RT nails, in the presence of an expert hired by Smith & Nephew. He compared his findings to the manufacturer's specifications and found that "[a] large variation in edge radius can be seen from one side to the other; the fatigue cracks had emanated at the sharper radius surface for both rods." Kumar explained:

The sharper radii measurements were 0.0003 inch and 0.00125 inch, way below the minimum requirement of the part drawing of 0.010 inch. This is a manufacturing defect and the sharper radius at the edge created a higher stress concentration factor, resulting in premature fatigue fracture of the rods. The variation in the radius around the slant hole is also a manufacturing defect and shows poor quality control during manufacturing.

As he did in his first report, Kumar concluded that the RT nails suffered from correctable defects that shortened their life.

Smith & Nephew again deposed Kumar in May 2004. He responded "out of [his] area of expertise" to a number of questions designed to explore his knowledge of internal fixa-

tion devices like the RT nail, such as, "Would you agree that as long as bone healing progresses normally an implant such as the type of nails we have in question will not undergo fatigue failure?" One exchange in particular characterizes the tension between Smith & Nephew and Kumar:

Q. With respect to these nails, though, would you agree that it's race in time; you either get union of the bone or you get fatigue failure of the nail?

A. Again, I'm not an expert in that area where one designs this for the union or nonunion [of bones]. I am looking at the failure from a metallurgical standpoint only.

Q. So in other words, we have deposed two of Lisa Stilwell's orthopedic surgeons, Dr. Kramer and Dr. Reinhert [sic]. Both of them have testified under oath that based upon their experience as orthopedic surgeons there is a race in time that takes place. You either get union or healing of the fracture or you're going to have fatigue failure of the rod.

I take it you would not disagree with that or is that outside your area of expertise?

A. That's their expertise and I cannot comment on that.

Q. So with respect to the measurements that you took, Doctor, where you have the .0003 you can't tell me if that caused the rod to fail a week before it would have failed, two weeks before it would have failed or three weeks before it failed? You can't put a quantitative distinction on that?

A. That's correct.

Kumar could not comment beyond his abstract knowledge of metals:

Q. So you can't tell me whether or not the nail as designed met the criteria for which it was designed in being used as an implant to treat a subtrochanteric fracture?

A. Correct.

According to his own testimony, he could examine the RT nail only as an object composed of metal; he did not attempt to testify regarding its design as a medical device.

Armed with Kumar's reports and deposition testimony, Smith & Nephew moved to bar his testimony. The company argued that he was unqualified to testify regarding the design, manufacture, or use of the RT nail. His expertise as a metallurgist, the company continued, should not qualify him to testify regarding whether a medical device made of metal failed due to a design or manufacturing defect. Finally, the company argued that his opinion that further grinding and polishing could have extended the life of the RT nail was without scientific basis.

The district court, applying *Daubert*, concluded that Kumar "acknowledged that he lacked the expertise to determine whether the nails served the biomechanical purpose for which they were designed." His "concern[] only with metallurgical issues," the court continued, rendered "his opinions about the defectiveness of the RT nails for use in bone healing . . . speculative, albeit speculation spawned from his testing relating to the metallurgical integrity of the nails." Because the dispute, as the court described it, was not whether the RT nail would suffer fatigue failure but rather whether the device was designed to fail only after it succeeded in supporting a union of the fractured bone, the court excluded Kumar's testimony.

The court also granted summary judgment for Smith & Nephew. In addition to Kumar, Stilwell would have relied on the deposition testimony of three treating physicians, Quentin Kramer, M.D., Charles Reinert, M.D., and Mark Spangehl, M.D. Doctor Reinert expressed concern that Stilwell's "cigarette smoking is very deleterious to fracture healing," but that he "didn't see anything at surgery that would have made us think that she would be unable to heal." Doctor Spangehl agreed with the statement that "failure rates of these types of nails is relatively rare," but qualified it by testifying that "rare is sort of a relative thing because in most situations we get on with treatment but a year, two years, three years, that would sort of be within the time frame that . . . I wouldn't be surprised that it would fail." Without Kumar's testimony, however, Stilwell conceded that her remaining evidence could not propel her claim past summary judgment.

II.

We review a district court's decision to exclude testimony pursuant to Federal Rule of Evidence 702, as the rule of evidence is explained in *Daubert v. Merrell Dow* and its progeny, for abuse of discretion. *See United States v. Prime*, 431 F.3d 1147, 1152 (9th Cir. 2005). The district court's ruling is entitled to deference, even when the exclusion of expert testimony determines the outcome of a case. *See Cabrera v. Cordis Corp.*, 134 F.3d 1418, 1420 (9th Cir. 1998).

[1] Federal Rule of Evidence 702 permits testimony by experts qualified by "knowledge, skill, expertise, training, or education" to testify "in the form of an opinion or otherwise" based on "scientific, technical, or other specialized knowledge" if that knowledge will "assist the trier of fact to understand the evidence or to determine a fact in issue." FED. R. EVID. 702. The expert's testimony must be "based upon sufficient facts or data," "the product of reliable principles and methods," and the expert must "appl[y] the principles and methods reliably to the facts of the case." *Id.* In *Daubert* and

Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999), the Supreme Court described the district court’s “gatekeeping role,” and required that “all forms of expert testimony, not just scientific testimony” survive scrutiny under Rule 702. *White v. Ford Motor Co.*, 312 F.3d 998, 1007 (9th Cir. 2002).

[2] Rule 702 embodies “the twin concerns of ‘reliability’ . . . and ‘helpfulness.’ ” *United States v. Mitchell*, 365 F.3d 215, 234 (3d Cir. 2004); *see Hemmings v. Tidyman’s Inc.*, 285 F.3d 1174, 1184 (9th Cir. 2002) (“Whether testimony is helpful within the meaning of Rule 702 is in essence a relevancy inquiry.”). The test for reliability, however, “is not the correctness of the expert’s conclusions but the soundness of his methodology.”⁴ *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995) (“Daubert II”). And, reliable testimony must nevertheless be helpful. *See Daubert*, 509 U.S. at 591 (“‘Expert testimony which does not relate to any issue in the case is not relevant, and ergo, non-helpful.’ ” (quoting 3 Weinstein & Berger ¶ 702[02], p. 702-18.)). A court may exclude testimony that falls short of achieving either end.

III.

[3] The district court’s analysis in this case focused on the helpfulness, rather than reliability, of Kumar’s testimony. The court, however, mingled the analysis required by Federal Rule of Evidence 702 for the admissibility of expert testimony and Federal Rule of Civil Procedure 56 for summary judgment. Though summary judgment enquires whether there is a “genuine issue of material fact,” *Rivera v. Philip Morris, Inc.*, 395 F.3d 1142, 1146 (9th Cir. 2005), Rule 702’s analysis is ordi-

⁴Here Smith & Nephew suggests that Kumar misread the RT nail manufacturing drawing, and that the product did not deviate from the design specification. That argument does not, however, undermine the admissibility of the testimony under Rule 702 and thus we will not address it here. *See Daubert II*, 43 F.3d at 1318.

narily prospective. Expert testimony is helpful if it “*will* assist the trier of fact.” FED. R. EVID. 702 (emphasis added). Thus a district court may not exclude expert testimony simply because the court can, at the time of summary judgment, determine that the testimony does not result in a triable issue of fact. Rather the court must determine whether there is “a link between the expert’s testimony and the matter to be proved.” *United States v. Bighead*, 128 F.3d 1329, 1335 (9th Cir. 1997). The chain necessary to prevail on a claim may be weakened by the absence of other evidence or testimony, but that does not undermine the admissibility of Rule 702 evidence.

[4] The court, by concentrating its analysis on the eventual merit of Stilwell’s claim, seemingly required Kumar’s testimony to establish not only the presence of an alleged defect but also causation.

Were it established that the nails were designed so that they would not fatigue prior to bone union as Dr. Kumar initially assumed, Dr. Kumar’s testimony might be relevant to the determination of whether an unreasonably dangerous defect caused Plaintiff’s injury. However, given that there is no dispute that the nails failed due to fatigue and Dr. Kumar’s lack of expertise about both the intended fatigue life of intermedullary nails used to treat fractures and about the biological factors that impact the effectiveness of intermedullary nails in the bone healing process, Dr. Kumar’s opinion does little to advance this Court’s inquiry.

The court, though explaining in great detail why Kumar’s testimony fell short of guaranteeing Stilwell would prevail, failed to demonstrate that a metallurgist’s testimony that the metal device was both poorly manufactured and could have been designed to last longer than it did is not relevant to this

products liability case. We thus reject the court's Rule 702 order.

IV.

[5] We turn next to the order granting summary judgment. Stilwell, faced with the exclusion of her lone expert, conceded defeat in the district court, resulting in a single page order granting Smith & Nephew's summary judgment motion. Nevertheless, the district court's Rule 702 order and the parties here have consistently focused on the merits of Stilwell's claim, and the ability of Kumar to support that claim.⁵ Though we determine that the district court's decision regarding the admissibility of Kumar's testimony cannot be sustained, we construe the court's order and the parties' appellate responses as an analysis of summary judgment. Accordingly, this is the rare case in which it is proper for us to exercise our discretion to consider a legal issue for the first time on appeal. *See Delange v. Dutra Const. Co.*, 183 F.3d 916, 919 n.3 (9th Cir. 1999); *Self-Realization Fellowship Church v. Ananda Church of Self-Realization*, 59 F.3d 902, 912 (9th Cir. 1995).

Our review of the grant of summary judgment is plenary, and we view the facts in the light most favorable to Stilwell, the non-moving party. *See Ward v. Circus Circus Casinos, Inc.*, 473 F.3d 994, 997 (9th Cir. 2007). Because we determine that the court erred by rejecting Kumar's testimony, we will consider his reports and deposition testimony in addition to the other record evidence.

Viewing the entire record we are convinced that the district

⁵In addition we note that at oral argument Stilwell provided this court with her argument against summary judgment. Counsel conceded that Stilwell relied only on Kumar and her treating physicians and discussed the testimony and evidence provided by each of those individuals. Stilwell's argument and the entire record at summary judgment are therefore before us.

court properly granted summary judgment for Smith & Nephew. Stilwell's argument is nebulous, but at oral argument her counsel contended that Kumar was the only appropriate expert because he could testify that the RT nails did not conform to some design specifications (ostensibly a manufacturing defect) and that alterations to their design could have extended their life by an unspecified period of time.⁶ Stilwell's counsel agreed that the RT nail was not designed to perform indefinitely, but also stated that it is "common sense, [that] you wouldn't put a piece of metal in there and expect it to break in a little over a year." Indeed, her counsel claimed that *no* expert could testify regarding the *expected* length of the healing process, and consequently the period of time the RT nail should perform, because only a treating physician could determine when an *individual* patient's injury had healed by examining x-ray films. Stilwell's argument thus asks us to blindly accept the RT nails' failure before her fracture healed as *prima facie* evidence that they were defective.

[6] Stilwell's argument against summary judgment cannot sustain her claims. Her complaint included counts sounding in negligence and strict liability. We apply state law to a products liability claim brought in federal district court pursuant to diversity jurisdiction. *See Adams v. Synthes Spine Co.*, 298 F.3d 1114, 1117 (9th Cir. 2002); *Kay v. Cessna Aircraft Co.*, 548 F.2d 1370, 1372 (9th Cir. 1977). Arizona permits tort claims against medical device manufacturers, *see Fiore v. Collagen Corp.*, 930 P.2d 477, 485 (Ariz. Ct. App. 1996), and adopts the Restatement (Second) of Tort's strict liability standard, *see State Farm Ins. Cos. v. Premier Manufactured Sys., Inc.*, 142 P.3d 1232, 1234 n.2 (Ariz. Ct. App. 2006); *Golonka v. General Motors Corp.*, 65 P.3d 956, 962 (Ariz. Ct. App. 2003). Absent a statute to the contrary, the state also adopts the Restatement's negligence standard. *See Calnimpewa v.*

⁶We are mindful that Smith & Nephew's expert, Dr. Wilson Hayes, contradicted Kumar's conclusion, but we interpret the factual dispute in Stilwell's favor, as we must at summary judgment.

Flagstaff Police Dep't, 30 P.3d 634, 639 (Ariz. Ct. App. 2001).

[7] Claims such as Stilwell's must rely on the allegation that a product is defective. *See Dart v. Wiebe Mfg., Inc.*, 709 P.2d 876, 878 n.1 (Ariz. 1985); *Wilson v. United States Elevator Corp.*, 972 P.2d 235, 256 (Ariz. Ct. App. 1998). The Arizona courts have described the myriad standards applied to determine whether a product is defective as a result of its design or manufacture. *See, e.g., Byrns v. Riddell, Inc.*, 550 P.2d 1065, 1068 (Ariz. 1976); *Gomulka v. Yavapai Mach. & Auto Parts, Inc.*, 745 P.2d 986, 988-89 (Ariz. Ct. App. 1987). Nevertheless, three classic premises predominate. A negligence claim begins with the assertion that a manufacturer produced a product that fails to meet "the purpose for which it is designed." *Campo v. Scofield*, 95 N.E.2d 802, 804 (N.Y. Ct. App. 1950) (quoted in *Morrow v. Trailmobile, Inc.*, 473 P.2d 780, 784 (Ariz. Ct. App. 1970)). Likewise, a strict liability claim arises when a product is in a "defective condition unreasonably dangerous," *Lunt v. Brady Mfg. Corp.*, 475 P.2d 964, 966 (Ariz. Ct. App. 1970), and the product "'fail[s] to perform as safely as an ordinary consumer would expect when used in an intended or reasonable manner'" (the consumer expectation test), or "'the benefits of a challenged design . . . outweigh the risk of danger inherent in the design'" (risk/benefit analysis). *Golonka*, 65 P.3d at 961-62 (quoting *Dart*, 709 P.2d at 879); *see Dart*, 709 P.2d at 878 (observing that the consumer expectation test encompasses manufacturing defect); *Restatement (Second) of Torts: Strict Liability* § 402A cmt. g (1965). ("The rule stated in this Section applies only where the product is, at the time it leaves the seller's hands, in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him.").

[8] Underlying all three potential standards for a defect is some understanding of the product's purpose. *See also Mather v. Caterpillar Tractor Corp.*, 533 P.2d 717, 719 (Ariz. Ct. App. 1975) ("The difference between the two theories of

liability in a defective design case is that under strict liability the manufacturer can be held liable despite its best efforts to make or design a safe product.”). But that is the evidence that Stilwell failed to provide in the district court. Her doctors testified that the RT nails implanted to stabilize her fractured femur failed, and Kumar testified regarding some design and manufacture improvements that could have, in his opinion, extended the life of the RT nail. Stilwell, though, has not pointed to any evidence, beyond her doctors’ impressions regarding the failure rate of the RT nail, to explain to a jury the intended duration of its use, which she conceded was not indefinite. To the contrary, Doctor Reinert expressed concern that Stilwell’s cigarette use would impede her healing and Doctor Spangehl stated that he would not be surprised if an intermedullary rod, like Stilwell’s, failed after one year, which is longer than the time expected for the healing process. (Stilwell’s first RT nail failed after three years and the second after twenty months.)

[9] Given the opportunity at oral argument, Stilwell again failed to explain the defect that formed the basis for her claim. She seemed to suggest that, at a minimum, the second RT nail should have performed for longer than it did, but she did not rely on any record evidence to support that contention. She has repeatedly reminded us that her treating physicians testified that a RT nail failure is rare, yet rarity does not indicate infallibility. Stilwell’s vague arguments regarding the expected life of the RT nail thus do not refute Smith & Nephew’s evidence that the RT nails performed as intended in this case. In sum, the addition of the rejected testimony of Kumar, if added to other evidence and considered in the light most favorable to Stilwell, does not establish that the RT nails in question caused any actionable harm to Stilwell.

V.

Accordingly we reject the district court’s order excluding the Kumar testimony but **AFFIRM** the court’s order granting summary judgment for Smith & Nephew.