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Nos. 09-6147, 09-6272, 09-6274

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

PUNNOSE K. THOMAS,

Plaintiff-Appellant,

PATRICIA MELAU, individually and as personal
representative of Edwin Melau, deceased,

Plaintiff-Appellant,

TERRY ANDERSON,

Plaintiff-Appellant,

ON APPEAL FROM THE
UNITED STATES DISTRICT
COURT FOR THE MIDDLE
DISTRICT OF TENNESSEE

v.

NOVARTIS PHARMACEUTICALS
CORPORATION,

Defendant-Appellee.

_____ /

Before: MARTIN, BOGGS, and COOK, Circuit Judges.

BOYCE F. MARTIN, JR., Circuit Judge. Punnose Thomas, Edwin Melau, and Terry Anderson appeal the decisions of the district court granting summary judgment in favor of Novartis Pharmaceuticals Corporation and prohibiting their treating physicians from offering expert testimony on the cause of their injuries. We **AFFIRM**.

These cases arise out of a series of lawsuits filed by individuals who developed osteonecrosis of the jaw, a severe bone disease affecting the jaw, allegedly as a result of taking Zometa and Aredia. Zometa and Aredia are prescription bisphosphonate¹ drugs produced by Novartis that are given intravenously, most often to patients with cancerous conditions. The drugs are effective at preventing pathological fractures, spinal cord compression, and other bone pains. Although the Food and Drug Administration approved both drugs, many individuals claim to have developed osteonecrosis of the jaw as a result of receiving this medication. Osteonecrosis of the jaw results in the gums being eaten away until the bone is exposed.

Thomas, Melau, and Anderson each filed a separate lawsuit against Novartis alleging that they developed osteonecrosis of the jaw as a result of the Zometa infusions they received. The Judicial Panel on Multidistrict Litigation transferred these cases to the Middle District of Tennessee for consolidated proceedings.

To establish general causation, whether Zometa can cause osteonecrosis of the jaw, the plaintiffs retained experts. To establish specific causation, whether Zometa caused each individual plaintiff's osteonecrosis of the jaw, the plaintiffs planned to offer non-retained expert testimony from their treating physicians. However, the district court granted Novartis's motions to exclude the expert testimony of these treating physicians. And, because there was no evidence to establish specific causation, granted Novartis's motions for summary judgment.

II.

¹Bisphosphonates are a class of drugs that derive their name from their chemical structure, which contains two phosphonate groups (PO_3) covalently bonded to a carbon atom.

We review a district court's decision to exclude expert testimony for abuse of discretion. *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 668 (6th Cir. 2010). "A district court abuses its discretion if it bases its ruling on an erroneous view of the law or a clearly erroneous assessment of the evidence." *Ky. Speedway, LLC v. Nat'l Assoc. of Stock Car Auto Racing, Inc.*, 588 F.3d 908, 915 (6th Cir. 2009).

Under *Daubert* and its progeny, district courts must exercise a gatekeeping role in screening the reliability of expert testimony to keep "junk science" away from juries. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 147 (1993). Consistent with this directive, Federal Rule of Evidence 702 provides that:

If scientific, technical, or other specialized knowledge will assist the trier of fact 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 methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

This rule gives district courts broad discretion to determine whether a putative expert's testimony would be inadmissible junk science or instead would be testimony falling within the "range where experts might reasonably differ." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 153 (1999); *Gen. Elec. Co. v. Joiner*, 552 U.S. 136, 146 (1997). "Thus, we will not substitute our own judgment for that of the district court and will reverse an evidentiary decision only where we are left with a definite and firm conviction that [the district court] committed a clear error of judgment." *In re Scrap Metal Litig.*, 527 F.3d 517, 528 (6th Cir. 2008) (internal quotation marks and citation omitted); see also *Nolan v. Memphis City Sch.*, 589 F.3d 257, 265 (6th Cir. 2009) (holding that

“[b]road discretion is given to district courts in determinations of admissibility . . . and those decisions will not be lightly overturned”).

Generally a treating physician can provide expert testimony regarding a patient’s illness, the appropriate diagnosis, and the cause of the illness even if the physician is not among the world’s foremost authorities on the matters. *See Gass v. Marriott Hotel Servs., Inc.*, 558 F.3d 419, 426 (6th Cir. 2009); *Fielden v. CSX Transp., Inc.*, 482 F.3d 866, 870 (6th Cir. 2007). However, a treating physician’s testimony is still subject to the requirements in *Daubert*. Before permitting a physician to testify, the district court must be persuaded that (1) the reasoning or methodology underlying his or her testimony is scientifically valid; and (2) he or she has properly applied that reasoning or methodology to the facts at issue to aid the trier of fact. *See Gass*, 558 F.3d at 426; *In re Scrap Metal Antitrust Litig.*, 527 F.3d at 529-30 (“The task for the district court in deciding whether an expert’s opinion is reliable is not to determine whether it is correct, but rather to determine whether it rests upon a reliable foundation, as opposed to, say, unsupported speculation.”).

In each of these cases the district court held that the treating physicians could not give expert opinion testimony on the issue of specific causation. In reaching these conclusions, the district court relied in part on the physicians’ statements that they did not consider themselves to be experts about osteonecrosis of the jaw. While a witness’s self-assessment may be relevant, ultimately the district court—and not the individuals testifying—must determine whether the proposed testimony is sufficiently reliable and relevant to be admitted. We have previously explained that “[t]he ‘*ipse dixit*’ of the expert’ is alone not sufficient to permit the admission of an opinion.” *Tamraz*, 620 F.3d at 671. In this situation, the *Daubert* gate does not automatically slam shut when an individual

disclaims being an expert, just as a witness's statements that he or she is an expert do not automatically guarantee that he or she will be allowed to provide expert testimony. *See Watson v. United States*, 485 F.3d 1100, 1106 (10th Cir. 2007). In both situations, regardless of what the putative expert says about his or her qualifications, the district court must consider whether his or her proposed testimony meets the requirements of Rule 702 and the relevant *Daubert* factors in each particular case. This is partly because, as the Tenth Circuit noted, it would not benefit the legal system to exclude qualified individuals who modestly state that they do not believe themselves to be experts in favor of more savvy individuals who make their livings providing expert testimony. *Id.* However, while a putative expert's self-assessment is not dispositive as to whether he or she meets the requirements of Rule 702, it is one factor that district courts may consider when determining if his or her testimony is sufficiently reliable.

With this background we proceed to consider whether the district court abused its discretion by prohibiting the treating physicians from giving expert testimony in these cases.

A. Expert Opinion in *Thomas*.

The district court held that Thomas's treating physician, Dr. Johnson, could not give an expert opinion as to specific causation. As the proponent of the expert testimony, Thomas bore the burden of establishing that Dr. Johnson's testimony met the requirements of Rule 702. *See, e.g., Sigler v. Am. Honda Motor Co.*, 532 F.3d 469, 478 (6th Cir. 2008). Dr. Johnson appears to have used some form of a differential diagnosis, or differential etiology, which we have previously recognized is a proper basis for determining the cause of a medical condition when done properly. *E.g., Tamraz*, 620 F.3d at 674; *Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 178 (6th Cir. 2009).

However, the district court held that Thomas failed to establish that Dr. Johnson's experience and medical expertise gave him an appropriate basis for determining the cause of Thomas's osteonecrosis of the jaw.

Thomas argues that the district court improperly relied exclusively on Dr. Johnson's candid deposition remarks that he does not consider himself to be an expert in osteonecrosis of the jaw in deciding that he did not meet the requirements of Rule 702. While relevant to the district court's analysis, that self-assessment is, standing alone, insufficient to conclude that Dr. Johnson may not give expert testimony on specific causation. However, because Thomas failed to adequately establish the reliability of Dr. Johnson's opinion, we cannot conclude that the district court's decision excluding his testimony was an abuse of discretion.

Dr. Johnson is unquestionably an experienced oral surgeon with many years of practice and training. He treated other patients with osteonecrosis of the jaw, and has read literature and attended conferences on osteonecrosis of the jaw. However, Thomas failed to make the connection between Dr. Johnson's experience and bisphosphonate-induced osteonecrosis of the jaw. *Cf., e.g., Thomas v. City of Chattanooga*, 398 F.3d 426, 432 (6th Cir. 2005) (explaining that expert witnesses relying primarily on their experience must explain how they have applied that experience to reach their opinions). Because Thomas relied on Dr. Johnson to give an expert opinion on the cause of his osteonecrosis of the jaw, it is not enough to show that Dr. Johnson can recognize and treat osteonecrosis of the jaw. While Dr. Johnson's experience may provide a basis for giving expert testimony regarding certain issues relating to osteonecrosis of the jaw, Thomas failed establish that

Dr. Johnson meets the requirements to give an expert opinion regarding the cause of osteonecrosis of the jaw.

Thomas argues that Dr. Johnson is qualified to opine on the cause of his osteonecrosis of the jaw because a treating physician needs to be able to distinguish the cause of the disease. The treatment usually used for osteonecrosis of the jaw would actually worsen conditions in those suffering from bisphosphonate-induced osteonecrosis of the jaw. Because the cause of the osteonecrosis is central to determining the best course of treatment, and Dr. Johnson can treat osteonecrosis of the jaw, Thomas argues that Dr. Johnson, therefore, must be able to determine the cause of the condition. While this inferential chain shows the importance of correctly determining the cause of the osteonecrosis, it does nothing to establish that Dr. Johnson can in fact, reliably determine the cause of a patient's osteonecrosis of the jaw. Therefore, we cannot conclude that the district court abused its discretion by holding that Dr. Johnson was unqualified to give expert testimony on specific causation even if the cause of the condition is relevant to determining the best course of treatment.

B. Expert Opinions in *Melau*.

The district court also held that Melau's treating physicians, Dr. Siegel and Dr. Svalina, could not provide expert opinions regarding specific causation. In addition to the statement by Dr. Siegel that he did not consider himself to be an expert in osteonecrosis of the jaw, the district court noted that Dr. Siegel did not form an opinion to a reasonable degree of medical certainty as to whether Melau had osteonecrosis of the jaw at the time he was treating Melau. Dr. Siegel also stated at his deposition that he did not have his own opinion to a reasonable degree of medical certainty about

Melau's condition, but relied on the opinion of Melau's other doctors. Based on these statements we cannot conclude that the district court abused its discretion by holding that Melau failed to establish the reliability of Dr. Siegel's opinion.

Similarly, the district court also did not abuse its discretion by holding that Dr. Svalina could not offer an expert opinion on specific causation. At several points in his deposition, Dr. Svalina made comments from which the district court could have concluded that he did not meet the requirements for giving an expert opinion on whether Zometa caused Melau's osteonecrosis. The court noted that Dr. Svalina said that he could not state to a reasonable degree of medical certainty which of the drugs Melau was taking caused his osteonecrosis of the jaw. Consistent with this admission, Dr. Svalina also explained that he could not confirm that Zometa was responsible for Melau's osteonecrosis to a reasonable degree of medical certainty. Additionally, Dr. Svalina remarked that he did not consider himself to be an expert regarding Zometa or the relationship between Zometa and osteonecrosis of the jaw. Therefore, like its decision to exclude Dr. Siegel's expert testimony on specific causation, the district court's decision to exclude Dr. Svalina's expert opinion was not an abuse of discretion.

C. Expert Opinion in *Anderson*.

It is much the same story for Dr. Swift, Anderson's treating physician. Anderson presented extensive evidence that Dr. Swift is an experienced maxillofacial surgeon who has treated several patients suffering from osteonecrosis of the jaw. Based on this evidence, as Novartis concedes, Dr. Swift is likely qualified to treat osteonecrosis of the jaw and could likely give an expert opinion regarding some issues relating to osteonecrosis of the jaw. However, this does not establish Dr.

Swift's ability to diagnose the cause of Anderson's osteonecrosis of the jaw, which is the salient issue his opinion was offered to establish. The lack of evidence showing Dr. Swift's expertise with diagnosing the causes of osteonecrosis of the jaw is consistent with his acknowledgment that he does not consider himself to be an expert in the causes of osteonecrosis of the jaw. Therefore, the district court did not abuse its discretion in concluding that Dr. Swift was unqualified to give an expert opinion regarding the cause of Anderson's osteonecrosis of the jaw.

Anderson also argues, like Thomas, that Dr. Swift is qualified to opine on the cause of his osteonecrosis of the jaw because a treating physician needs to be able to distinguish the cause of the disease. The treatment usually used for osteonecrosis of the jaw would actually worsen conditions in those suffering from bisphosphonate-induced osteonecrosis of the jaw. Because the cause of the osteonecrosis is crucial to determining the best course of treatment, Anderson argues that Dr. Swift therefore must be able to determine the cause. While this shows the importance of correctly determining the cause of the osteonecrosis, it does nothing to establish Dr. Swift's expertise in determining the cause. Therefore, we cannot conclude that the district court abused its discretion by holding that Anderson failed to establish sufficiently Dr. Swift's basis for giving an expert opinion on specific causation even if the cause of the condition is relevant to determining the best course of treatment.

III.

After holding that the treating physicians could not give expert opinions regarding specific causation, the district court granted summary judgment in favor of Novartis in each case. "We review the district court's grant of summary judgment de novo." *Stansberry v. Air Wisconsin*

Airlines Corp., – F.3d —, No. 09-2499, 2011 WL 2621901, at *3 (6th Cir. June 1, 2011) (citing *Bentkowski v. Scene Magazine*, 637 F.3d 689, 693 (6th Cir. 2011)). Summary judgment is appropriate where the pleadings, depositions, answers to interrogatories, admissions on file, and affidavits show “that there is no genuine dispute as to any material fact and that the movant is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(a). “The moving party has the initial burden of proving that no genuine issue of material fact exists,” and the court must draw all reasonable inferences in the light most favorable to the nonmoving party. *Vaughn v. Lawrenceburg Power Sys.*, 269 F.3d 703, 710 (6th Cir. 2001). When a motion for summary judgment is properly made and supported and the nonmoving party fails to respond with a showing sufficient to establish an essential element of its case, summary judgment is appropriate. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986).

Specific causation is an essential element of the tort pled, and without any admissible evidence to raise a question of fact as to whether Zometa caused each individual’s osteonecrosis of the jaw, the district court properly granted summary judgment in favor of Novartis in each case.

Although Melau argues on appeal that, even without an expert opinion on specific causation, other evidence creates a question of fact as to whether Zometa caused his osteonecrosis of the jaw, he did not argue this in his opposition to Novartis’s motion for summary judgment before the district court. Generally, we will not consider arguments raised for the first time on appeal. *See United States v. Ellison*, 462 F.3d 557, 560 (6th Cir. 2007). Therefore, because Melau did not properly present this argument to the district court, we will not consider it now.

IV.

The district court did not abuse its discretion in concluding that Thomas, Melau, and Anderson each failed to establish that their treating physicians were qualified to give expert opinions on the cause of their osteonecrosis of the jaw. Without evidence establishing this essential element of their cases, the district court properly granted summary judgment in favor of Novartis. Therefore, we **AFFIRM**.