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No. 11-5053

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

**In re: AREDIA AND ZOMETA PRODUCTS
LIABILITY LITIGATION**

**CLARISSA SIMMONS, substituted on behalf
of James Simmons, deceased,**

Plaintiff-Appellant,

v.

**NOVARTIS PHARMACEUTICALS
CORPORATION,**

Defendant-Appellee.

FILED

Jun 05, 2012

LEONARD GREEN, Clerk

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

BEFORE: BOGGS, SUHRHEINRICH and COOK, Circuit Judges.

SUHRHEINRICH, Circuit Judge. Plaintiff Clarissa Simmons (“Plaintiff”), widow and personal representative of James Simmons (“Simmons”), appeals the decisions of the district court granting summary judgment in favor of Defendant Novartis Pharmaceuticals Corporation (“NPC” or “Defendant”) and prohibiting Simmons’s treating physicians and retained expert from offering expert testimony on the cause of Simmons’s injury in this product-liability action. We AFFIRM.

I. Background

A. Facts

Simmons developed osteonecrosis of the jaw (ONJ), a severe bone disease affecting the jaw,¹ allegedly as a result of using the prescription medications Zometa and Aredia, drugs produced by NPC. For thirty-five years, Simmons smoked a pack of cigarettes a day. In November 2000, Simmons was diagnosed with lung cancer. In 2002, the cancer metastasized to Simmons's bones, and he was prescribed Zometa to treat it. In May 2003, Simmons developed renal insufficiency and was switched to Aredia. Zometa and Aredia are FDA-approved intravenous bisphosphonate drugs² prescribed for the prevention and treatment of skeletal related events, such as bone fractures and spinal cord compression, in patients suffering from certain types of cancer that has metastasized to the bone. They are also prescribed for the treatment of another complication of cancer, hypercalcemia of malignancy, a potentially fatal elevation of calcium in the blood.

From 1999 to November 2002, Simmons was treated by dentist Dr. Mohamed Zamaludin. In October 2002, Simmons began complaining of pain in his right lower jaw, and saw Zamaludin in November. On February 28, 2003, he visited an oral surgeon, Dr. E. Ross Meyer. Dr. Meyer determined that all that remained of Tooth 29 was its root, which was infected and needed to be removed. Tooth 29 was removed on March 5, 2003. This is the location where Simmons experienced his jaw problems.

¹ONJ "results in the gums being eaten away until the bone is replaced." *Thomas v. Novartis Pharm. Corp.*, (6th Cir.) 443 F. App'x 58, 60.

²"Bisphosphonates are a class of drugs that derive their name from their chemical structure, which contains two phosphonate groups . . . , covalently bonded to a carbon atom." *Thomas*, 443 F. App'x at 60.

In July 2003, Simmons began experiencing jaw pain again. In July 2004, he began treatment with Dr. George Obeid, an oral and maxillofacial surgeon. A biopsy on his jaw showed the presence of osteomyelitis, an infection of the jaw bone.

In April 2006, Simmons filed this product-liability action.

B. Plaintiff's Experts

1. Dr. Obeid

Plaintiff offered Dr. Obeid as a “non-retained” expert.³ Dr. Obeid is a board-certified oral and maxillofacial surgeon. He is head of the Department of Oral and Maxillofacial Surgery at Washington Hospital Center in Washington, D.C. Dr. Obeid is also a member of the American Association of Oral Maxillo Surgeons.

Dr. Obeid opined in his deposition testimony that he found a “very close association” between ONJ and bisphosphonates. Dep. at 16. Dr. Obeid testified that he considers himself an expert in osteomyelitis⁴ as it relates to the oral maxillofacial region. Dep. at 24-25. Dr. Obeid testified that bisphosphonates such as Aredia and Zometa do not metabolize and thus can accumulate in the body and cause problems. He opined that leaving Simmons on his Aredia treatment “compounded the issue” and worsened his jaw condition. Dr. Obeid stated that although Simmons needed to have certain teeth extracted, because he was receiving the Zometa and Aredia bisphosphonate treatment, Dr. Obeid “could not predict with certainty the outcome of the procedure” and was concerned that he “might expose new bone and make his condition worse.” *Id.* at 43. Dr.

³The district court excluded a number of non-retained experts. On appeal, Plaintiff protests only the exclusion of Dr. Obeid.

⁴Osteomyelitis is an acute or chronic bone infection.

Obeid testified that a 2003 article by Dr. Robert Marx⁵ and a 2004 article by Dr. Salvatore Ruggerio recommended conservative treatment given uncertainty whether the jaw bone would heal after an invasive procedure. Dep. at 44-45. In addition, in January 2005, Plaintiff and Simmons contacted Dr. Marx, who advised against extracting any remaining teeth. Dep. at 46.

2. Dr. Gutman

Plaintiff retained Dr. Edward Gutman also on the issue of specific causation. Dr. Gutman is an experienced oral surgeon. He has written numerous publications and given many presentations on dental issues and serves as a consultant to the Maryland State Board of Dental Examiners. Dr. Gutman testified that based on what he had read, it was his opinion “with a reasonable degree of dental certainty” that “the majority of people on bisphosphonate who have an invasive procedure will develop ONJ.” Dep. at 170. He stated that Simmons’s ONJ could have been prevented through prophylactic treatment and avoiding an extraction while on Aredia and Zometa.

C. Procedural History

On April 19, 2006, Simmons and Plaintiff brought this product-liability action in Maryland state court, alleging that NPC’s prescription cancer drugs Aredia and Zometa caused Simmons to develop ONJ and loss of consortium as to Clarissa. NPC removed the action to the United States District Court for the District of Maryland based on federal diversity jurisdiction. The Judicial Panel on Multidistrict Litigation transferred the action under 28 U.S.C. § 1407 to the United States District Court for the Middle District of Tennessee (“MDL court”) and assigned it to Chief Judge Todd Campbell. After transfer to the MDL court, Plaintiff voluntarily dismissed Novartis Corporation.

⁵Dr. Marx was subsequently retained as one of Plaintiff’s experts, but solely on the issue of general causation.

After Simmons died of lung cancer on April 11, 2007, Clarissa was substituted as the personal representative of his jaw injury claims in this survival action.

NPC moved to exclude, *inter alia*, the testimony of Drs. Obeid and Gutman, on the issue of causation. NPC also moved for summary judgment.

On December 7, 2010, the MDL court granted Defendant's motion for summary judgment on all of Plaintiff's claims. The court granted the motion to exclude any testimony by Dr. Obeid as to the cause of Simmons's injury. The court held that "Dr. Obeid has no admissible specific causation expert testimony to be offered," R. 101 at 5, because Plaintiff failed to point to any opinion of Dr. Obeid, "under oath and to a reasonable degree of medical certainty" as to the cause of Simmons's ONJ. The court also noted that simply because Dr. Obeid told Simmons he had ONJ from the Aredia and Zometa drugs (and could diagnosis the medical condition) did not mean he was qualified to give an expert opinion as to specific causation. *Id.* at 6.

By a separate order dated December 7, 2010, the district court granted Defendant's motion to exclude Dr. Gutman's testimony, also finding that Dr. Gutman was not qualified to testify about the specific cause of Simmons's ONJ. R. 102. The court held that Gutman's opinion lacked the sound methodology and foundation required by *Daubert*. The court noted that Dr. Gutman admitted that his information was based solely on literature Plaintiff's counsel sent him and that, other than these articles, there was no methodology behind his opinion. R. 102 at 5.

Because Plaintiff no longer had proof of an essential element of her product-liability claim under Maryland law, i.e. specific causation, the district court granted summary judgment to

Defendant and dismissed the case. R. 103, 104.⁶

This appeal followed.

II. Analysis

A district court's grant of summary judgment is reviewed de novo. *Ky. Speedway, LLC, v. Nat'l Ass'n of Stock Car Auto Racing, Inc.*, 588 F.3d 908, 915 (6th Cir. 2009). Summary judgment is appropriate if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, "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)(2).⁷ Summary judgment is appropriate if the nonmoving party fails to make a showing sufficient to carry her burden of proof on an essential element of that party's case. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

A district court's decision to exclude expert testimony is reviewed for abuse of discretion, *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 668 (6th Cir. 2010) (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999), *cert. denied*, 131 S. Ct. 2454 (2011)), even when the decision results in summary judgment. *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 248 (6th Cir. 2001) (citing *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142-43 (1997)). "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*, 588 F.3d at 915 (internal quotation marks omitted).

⁶The district court noted that it had previously found that there were genuine issues of material fact as to whether Aredia or Zometa generally cause ONJ, and applied that ruling in this case. R. 103 at 2.

⁷The parties filed their briefs prior to the amended version of Rule 56 on December 1, 2010.

Federal Rule of Evidence 702 states:

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.

Fed. R. Evid. 702.⁸ It is the district court's duty to ensure that all expert evidence "rests on a reliable foundation." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993). Rule 702 gives district courts a "gatekeeping role" in screening the reliability of expert testimony. *Id.*; *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999). District courts are given "broad latitude" in making this assessment. *Kumho Tire*, 526 U.S. at 139 (citing *Gen. Elec.*, 522 U.S. at 143).

There is no dispute that the substantive law of Maryland applies. Under Maryland law, the plaintiff in a product-liability suit must show generally that the defendant's products could cause the injury and specifically that the defendant's products were the cause-in-fact (i.e. specific cause) of the injury. *Giddings v. Bristol-Myers Squibb Co.*, 192 F. Supp. 2d 421, 423 (D. Md. 2002). To satisfy this burden, expert testimony is usually required. *Id.*

A. Dr. Obeid

Plaintiff argues that the district court abused its discretion in concluding that Dr. Obeid did not offer any opinions on causation. As the district court noted, a treating physician's testimony is subject to Daubert. *See Gass v. Marriott Hotel Servs., Inc.*, 558 F.3d 419, 426 (6th Cir. 2009). Plaintiff was therefore required to demonstrate that Dr. Obeid's reasoning or methodology was scientifically valid and that he properly applied that reasoning or methodology to the facts at issue.

⁸The language of Fed. R. Evid. 702 was amended effective December 1, 2011. The changes are stylistic only.

Id. Plaintiff has not met that burden.

First, contrary to Plaintiff's assertion, Dr. Obeid never opined that Aredia and Zometa caused Simmons's ONJ. Plaintiff relies on Dr. Obeid's statement that he found "a very close association" between ONJ and bisphosphonates. However, Dr. Obeid also specifically acknowledged that he "didn't establish causation" in evaluating Simmons's ONJ. Dep. at 16. *See Nelson*, 243 F.3d at 253 (noting that "an association does not mean there is a cause and effect relationship" and that "[b]efore any inferences are drawn about causation, the possibility of other reasons for the association must be examined"). Plaintiff also claims that Dr. Obeid stated that he relied on case reports from Dr. Marx suggesting that Aredia would "compound[] the issue" of ONJ. Dep. at 33. However, Dr. Obeid clarified that he was not aware of any evidence suggesting that by continuing to use Aredia, Simmons's condition worsened. Dep. at 33. Furthermore, Dr. Obeid agreed that the present level of evidence did not support a cause-and-effect relationship between bisphosphonate exposure and ONJ. Dep at 36.⁹

Plaintiff also claims that Dr. Obeid's medical records "conclusively link" Simmons's ONJ with his use of Aredia and Zometa. Simmons's July 31, 2004, consult record from Dr. Obeid and his medical residents state "Biphosphonate induced osteonecrosis area." R. 78-6 at 2. On November 23, 2004, the note indicates that Simmons had exposed and necrotic bone. R. 78-8 at 2. However, it is not clear if Dr. Obeid himself created these medical records, and the diagnosis is merely an

⁹Dr. Obeid was responding to a statement found in a 2009 article. Furthermore, his counsel objected, stating that Dr. Obeid was offered as a fact witness and that the article went beyond the scope of anything he would have considered in 2003. Dep. at 36.

Plaintiff claims that the district court erred in relying on counsel's characterization of Dr. Obeid as a fact witness. It does not matter here, because counsel's characterization does not affect our analysis in this case.

hypothesis, which does not satisfy *Daubert* and Rule 702. See *Tamraz*, 620 F.3d at 670-72.

Next, Plaintiff claims that, as reflected by their deposition testimony, Dr. Obeid told both her and her husband that Aredia and Zometa caused Simmons to develop ONJ. However, these statements represent the conclusions of Dr. Obeid's medical residents. Moreover, these are simply hypotheses. See *Tamraz*, 620 F.3d at 670.

Plaintiff also asserts that Dr. Obeid's "conservative treatment" of Simmons (i.e. the decision not to extract any teeth) demonstrates that he had a causation opinion. The record does not support this assertion. The record reflects that Dr. Obeid merely acquiesced in the Simmons's desire to forgo further extractions after Plaintiffs had spoken with Dr. Marx. Specifically, Dr. Obeid testified that because "he [Dr. Obeid] could not promise them good outcome . . . [he] agreed to that." Dep. at 46-47. This does not amount to an opinion on specific causation.

Absent an opinion regarding causation, the district court did not abuse its discretion in excluding Dr. Obeid's testimony.

Alternatively, Plaintiff contends that Dr. Obeid utilized a "differential diagnosis" to determine the cause of Simmons's jaw problems.¹⁰ This court recognizes "differential diagnosis" as an appropriate method for determining specific causation. *Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 178 (6th Cir. 2009). As part of "differential diagnosis" the expert must accurately diagnose the nature of the disease, reliably rule in the possible causes of it, and reliably rule out the rejected causes. See *Tamraz*, 620 F.3d at 674; *Best*, 563 F.3d at 179.

Again, the record does not support Plaintiff's claim. Dr. Obeid, who considers himself to

¹⁰The district court did not separately address the methodology or Dr. Obeid's qualifications.

be an expert in osteomyelitis in the mouth, Dep. at 24-25, testified that Simmons had osteomyelitis. Dep. at 39-40. However, nowhere in his testimony did Dr. Obeid rule out osteomyelitis as the sole cause of Simmons's ONJ. At most his testimony reflects that he adopted a "conservative course of treatment" based on the recommendations of Drs. Marx and Ruggiero (in their case reports) because none of the doctors "was sure whether the bone is going to heal after a procedure or not." Dep. at 44. In short, Plaintiff has not met her burden of demonstrating that Dr. Obeid employed a reliable methodology for ruling out osteomyelitis as a possible cure of the ONJ. See *Tamraz*, 620 F.3d at 674. The district court did not abuse its discretion in excluding any causation testimony from Dr. Obeid.

In addition, Plaintiff challenges the district court's conclusion that Dr. Obeid was not qualified to give an expert opinion as to causation. In support, she points to two publications and three presentations listed on his curriculum vitae. The two published case reports (which Plaintiff failed to file as part of her opposition to NPC's *Daubert* motion) are not helpful because as Dr. Obeid himself explained, he did not establish causation in those case reports, but simply a "very close association." Dep. at 16. Dr. Obeid also agreed with the statement in the 2009 position paper of the American Association of Oral and Maxillofacial Surgeons (AAOMS) that "the current level of evidence does not fully support a cause-and-effect relationship between bisphosphonate exposure and necrosis of the jaws." Dep. at 36. Dr. Obeid was apparently not asked (by either party) to explain his presentations, but he acknowledged in his deposition testimony that he had never been involved in any clinical trials regarding the drugs in question, had never served as a peer reviewer for any articles that involve ONJ, Dep. at 16, 27, and had never conducted any research on ONJ (or bisphosphonates) other than the two case reports. Dep. at 23. Furthermore, he stated that he is not

an expert or specialist in epidemiology, endocrinology, pharmacology, toxicology, radiology, or pathology. Dep. at 24.

Plaintiff maintains that Dr. Obeid's opinions are also based on his own experience. As Plaintiff correctly notes, "the text of Rule 702 expressly contemplates that an expert may be qualified on the basis of *experience*." *Dickenson v. Cardiac & Thoracic Surgery of E. Tenn. P.C.*, 388 F.3d 976, 980 (6th Cir. 2004) (quoting Fed. R. Evid. 702 advisory committee's note (2000 Amendments) (emphasis added)). *See also Gass*, 558 F.3d at 427-28. Plaintiff's reliance on *Dickenson* and *Gass* is misplaced. As those courts explained, "[t]he exclusion of a medical doctor's professional opinion, rooted in that doctor's 'extensive relevant experience,' is 'rarely justified in cases involving medical experts as opposed to supposed experts in the area of product liability.'" *Gass*, 558 F.3d at 427 (quoting *Dickenson*, 388 F.3d at 982). Here, however, Dr. Obeid's own testimony reveals that his experience as an oral surgeon, while it may qualify him to diagnose Simmons's ONJ, did not prepare him to explain the etiology of Simmons's ONJ. *See Tamraz*, 620 F.3d at 673; *cf. Thomas v. Novartis Pharm. Corp.*, 443 F. App'x 58, 62 (6th Cir. 2011) (holding that the plaintiff "failed to make the connection between [the treating physician's] experience and bisphosphonate-induced osteonecrosis of the jaw" and "it is not enough to show that [the treating physician] can recognize and treat osteonecrosis of the jaw").

In short, Plaintiff failed to show that Dr. Obeid meets the requirements to give an expert opinion on the causation of his ONJ. The district court did not abuse its discretion by excluding Dr. Obeid's testimony.

B. Dr. Gutman

Plaintiff complains that the district court erred in concluding that Dr. Gutman lacked the

experience and knowledge necessary for a reliable evaluation of the etiology of Simmons's ONJ. However, as the district court found, the record reflects that Dr. Gutman had no knowledge of the etiologies of ONJ prior to meeting Simmons, and then gained only a limited familiarity based on literature supplied to him by Plaintiff's counsel.

As the district court found, Dr. Gutman testified in his deposition testimony that he has never treated any patients who were taking Aredia or Zometa or any other bisphosphonate, Dep. at 102, 140, 210, had never diagnosed a patient with ONJ, Dep at 162, 163, 303, or determined a cause of a patient's ONJ. Dep. at 303. Dr. Gutman stated that although he was previously aware, as part of "the general dental public" of the association of ONJ with Aredia and Zometa, it did not affect his practice. Dep. at 155-56. He stated that if he ever had such a patient, he would refer them to an oral surgeon. Dep. 156. In addition, Dr. Gutman admitted that he was not an expert on Zometa, Aredia, bisphosphonates, or ONJ, except as to Simmons's case. Dep. at 159-60.

As the district court also found, Dr. Gutman's testimony revealed that he had no independent expertise from any other source other than the six articles Plaintiff's counsel gave him, that these articles were the foundation of his opinion, and that there was no other methodology supporting his opinion. Dep. at 48, 54-55, 57-58, 59, 177, 179, 201, 303. Dr. Gutman stated that he has never written or edited any articles, abstracts, or books which address ONJ or bisphosphonates. Dep. at 45, 151. He has also never conducted any kind of laboratory or clinical study of Aredia or Zometa. Dep. at 162, 202.

Plaintiff argues that Dr. Gutman is a dentist who is trained in oral surgery and is an expert in treating teeth and the mouth and diagnosing infections and other diseases. But this knowledge, standing alone, does not qualify him to evaluate the cause of Simmons's ONJ. *See, e.g., Sigler v.*

Am. Honda Motor Co., 532 F.3d 469, 478-79 (6th Cir. 2008) (holding that the district court properly excluded proposed expert's testimony because his evidence pertained to area in which he lacked expertise); *cf. Tamraz*, 620 F.3d at 673 (holding that the plaintiff conflated his proposed expert doctor's expertise in diagnosis with a doctor's expertise in etiology, remarking that "most treating physicians have more training in and experience with diagnosis than etiology"). In short, the district court did not err in concluding that Dr. Gutman's opinion lacks the sound methodology and foundation required under *Daubert*, when he had read only six articles on the subject provided to him by counsel, had performed no laboratory or clinical tests, and did not treat bisphosphonate patients.¹¹

The district court also did not abuse its discretion in excluding Dr. Gutman's specific-causation opinion as unreliable because it was not derived from scientifically valid principles but rather relied exclusively on the scientific literature provided by Plaintiff's counsel. Dr. Gutman made no attempt to verify this information, such as doing his own research for other articles, and then drawing an independent conclusion. As the district court noted, this court views with special caution expert testimony prepared solely for purposes of litigation, rather than flowing from an expert's line of scientific or technical work. *See Johnson v. Manitowoc Boom Trucks, Inc.*, 484 F.3d 426, 434-35 (6th Cir. 2007).

The district court correctly concluded that Dr. Gutman failed to perform a reliable differential

¹¹Plaintiff's reliance on *Streimer v. Biondo*, 873 N.Y.S.2d 515 (N.Y. Sup. Ct. 2008) (unpublished), is misplaced. The fact that other physicians have been found qualified to opine on ONJ causation does not establish Dr. Gutman's qualifications. It also appears that Plaintiff is somehow using this case to bolster her argument that because Dr. Gutman's reliance on the body of literature regarding the relationship between ONJ and bisphosphonates rests in large part on Dr. Ruggiero's expertise, Gutman was qualified to testify on causation. However, as she acknowledges in her brief, Dr. Ruggiero testified that no "cause and effect" relationship has been established between bisphosphonates and ONJ. Appellant's Br. 51.

diagnosis. Dr. Gutman conceded that he did not apply a differential diagnosis. Dep. at 223. Nonetheless, Plaintiff says that Dr. Gutman actually testified about other possible causes of Simmons's ONJ. But Dr. Gutman admitted that he did no research into alternative risk factors for ONJ. Dep. at 207. Dr. Gutman admitted that Simmons had osteomyelitis, and that osteomyelitis can cause ONJ, and he conceded that he did not rule out osteomyelitis and potential exacerbating factors such as smoking, chemotherapy, diabetes, anemia, and general dental health. Dep. at 223 (osteomyelitis); 224-25 (smoking); 240-45 (chronic suppurative osteomyelitis); 250-54 (chronic diffuse sclerosing osteomyelitis); 274-76, 283-84, 290-91 (corticosteroids and chemotherapy); 278-83, 284-90 (diabetes); 296 (general dental health).

Thus, we hold that the district court did not abuse its discretion in finding that Dr. Gutman was not qualified to testify about the specific cause of Simmons's ONJ in this case because his opinion lacks the sound methodology and foundation required by Fed. R. Evid. 702 and *Daubert*.

C. Summary Judgment

Because Plaintiff failed to demonstrate an essential element of her case, specific causation, the grant of summary judgment was appropriate. *See Celotex*, 477 U.S. at 322. *See Thomas*, 443 F. App'x at 64.

D. Alternative Argument

For the first time on appeal, Plaintiff offers statistical analysis that over 88 % of all cases of ONJ in individuals who have received bisphosphonates are caused by the bisphosphonates, proffered by Dr. Wayne Ray. She therefore argues that because Simmons had ONJ, and took Aredia and Zometa, she has submitted sufficient evidence to survive summary judgment. Because this issue was not presented to the district court, which means that the district court did not have an opportunity to

address the admissibility of Dr. Ray's testimony, we decline to address it. *See United States v. Ellison*, 462 F.3d 557, 560 (6th Cir. 2006).

III. Conclusion

For the foregoing reasons, as well as those found in the orders of the district court dated December 7, 2010, R. 101, 102, 103, the judgment of the district court is **AFFIRMED**.