

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF TENNESSEE  
AT KNOXVILLE

SANDRA THORN,	)	
	)	
Plaintiff,	)	
	)	No. 3:11-CV-373
v.	)	(CAMPBELL/SHIRLEY)
	)	
NOVARTIS PHARMACEUTICALS CORP.,	)	
	)	
Defendant.	)	

**MEMORANDUM AND ORDER**

This case is before the undersigned pursuant to 28 U.S.C. § 636, the Rules of this Court, and referral of the District Judge. Now before the Court is Novartis Pharmaceuticals Corporation’s *Daubert* Motion to Exclude Causation Testimony of Plaintiff’s Experts in the *Thorn* Case [Doc. 31]. The Court now addresses Novartis’s challenge to the testimony of Eric Carlson, D.M.D., and J. Michael McCoy, D.D.S.

**A. Eric Carlson, D.M.D.**

Novartis argues that Dr. Carlson, an oral surgeon who treated Plaintiff from August 2004 to until February 2005, is not qualified to testify as to specific causation in this case because he lacks the requisite “knowledge, skill, experience, training or education.” Fed. R. Evid. 702. In fact, Novartis argues that the Plaintiff cannot demonstrate that Dr. Carlson even has a causation opinion. [Doc. 32 at 24]. Novartis alleges that “[P]laintiff has failed to provide any testimony from Dr. Carlson . . . that Aredia was the cause of her alleged ONJ.” [Id.]. To the extent Dr. Carlson does offer a causation opinion, Novartis maintains that Dr. Carlson simply diagnosed the

Plaintiff's condition not its origin. Novartis also argues that Dr. Carlson failed to engage in differential diagnosis. [Id.].

Plaintiff responds by noting that Novartis does not challenge Dr. Carlson's qualifications and arguing that Dr. Carlson is more than qualified to testify as to causation of ONJ. Plaintiff states that Dr. Carlson has previously testified regarding ONJ causation in other Aredia cases on Novartis's behalf. [Doc. 46 at 4]. Thus, Plaintiff contends Novartis has poor standing for questioning Dr. Carlson's qualifications in the instant case.

With regard to causation, Plaintiff states that Dr. Carlson "has already testified on causation about Ms. Thorn, and uses her case in his lectures around the country." [Id.]. With regard to differential diagnosis, Plaintiff states that Dr. Carlson examined the Plaintiff, obtained a medical history, noted "bone exposure," noted a history of Aredia use, and reviewed her panoramic radiograph and CT scans. [Id. at 6]. He arrived at a differential diagnosis of: (1) Aredia-induced osteonecrosis; (2) rule out multiple myeloma. [Id.]. Plaintiff notes that two days after arriving at this diagnosis Dr. Carlson, along with Dr. High, performed resection of the Plaintiff's jaw and placed a titanium plate. [Id.]. Dr. Carlson's pre- and post- operative diagnosis was "Aredia-induced osteonecrosis of mandible." [Doc. 45-10 at 34]. Dr. Carlson reiterated this diagnosis in operative notes for a later procedure on February 11, 2005. [Id. at 32].

Dr. Carlson is an oral surgeon, certified by the American Board of Oral and Maxillofacial Surgeons and is a member of the American College of Oral and Maxillofacial Surgeons. [See Doc. 45-14 at 19].<sup>1</sup> He has practiced as a board-certified oral and maxillofacial surgeon since 1991. [Id.]. Dr. Carlson is a professor and chairman of the Department of Oral and

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<sup>1</sup> The parties indicated to the Court that they did not take Dr. Carlson's deposition specifically for use in this case. They have, instead, filed trial testimony from Fussman v. Novartis Pharm. Corp., 1:06-CV-149 (M.D.N.C. Nov. 17, 2010), to demonstrate the nature and type of testimony Dr. Carlson would offer. The parties have not indicated that this testimony has changed or been altered in the almost three years since it was originally given.

Maxillofacial Surgery at the University of Tennessee Medical Center in Knoxville. [Id. at 18]. He directs the residency program in oral and maxillofacial surgery and the fellowship in oral, head, and neck oncologic surgery. [Id.]. Dr. Carlson also serves as the chief of the hospital service in oral and maxillofacial surgery. [Id.].

The Court finds that, pursuant to Rule 701, Dr. Carlson may testify as to matters relating to his treatment of Plaintiff's ONJ and oral symptoms, including swelling and pain in the jaw. For example, Dr. Carlson may testify regarding his findings, examination, treatment, and diagnosis of Plaintiff's ONJ. Dr. Carlson may also offer his opinion as to the origin of Plaintiff's ONJ based upon his differential diagnosis. To the extent a discussion of the Plaintiff's condition may, to a degree, entail testimony covered by Rule 702, the Court finds that this testimony is sufficiently reliable under Rule 702 and that Dr. Carlson is qualified to offer such testimony under Rule 702.

The Court of Appeals has held that a "medical-causation opinion in the form of a doctor's differential diagnosis is reliable and admissible," where the doctor: (1) objectively obtains the nature of the patient's injuries, to the extent possible; (2) "rules in" one or more causes of the injury using a valid methodology; and (3) engages in "standard diagnostic techniques by which doctors normally rule out alternative causes" to reach a conclusion as to which cause is most likely. Best v. Lowe's Home Centers, Inc., 563 F.3d 171, 179 (6th Cir. 2009) (quoting In re Paoli Railroad Yard PCB Litig., 35 F.3d 717 (3d Cir. 1994)).

The Court finds, first, that Dr. Carlson objectively obtained the nature of the Plaintiff's injuries. Dr. Carlson performed two oral surgeries on the Plaintiff to insert and then remove a mandible plate. [Doc. 45-10 at 19, 27, 32, 33, 35, 36]. In advance of and as follow-up to these surgeries, Dr. Carlson examined the Plaintiff on numerous occasions. [Id. at 77- 92]. The Court

finds that Dr. Carlson objectively obtained the nature of the Plaintiff's injuries through numerous examinations and by performing two oral surgeries.

The Court further finds that Dr. Carlson "ruled in" one or more causes of the injury using a valid methodology. Dr. Carlson considered the Plaintiff's history of cancer along with her use of Aredia. [Doc. 45-10 at 78]. He considered the Plaintiff's cancer treatments with Dr. Antonucci, and the prescriptions given by Dr. High. [Id.]. He also reviewed Plaintiff's oral extraction history. [Id.]. After considering this information, Dr. Carlson formed his impression that the Plaintiff suffered from osteonecrosis induced by Aredia. [Id. at 79]. He ruled out multiple myeloma. [Id.].

Finally, the Court finds that Dr. Carlson engaged in "standard diagnostic techniques by which doctors normally rule out alternative causes" to reach a conclusion as to which cause is most likely. Dr. Carlson used the diagnostic techniques of physical examination, both in surgery and during patient visits, coupled with self-reports of symptoms. He also considered numerous medical records from the Plaintiff's other treating sources including pathology reports, radiology reports, and notes from her cancer treatment. [See e.g., 45-10 at 3, 8-12, 52-74]. The Court finds that Dr. Carlson engaged in standard, appropriate diagnostic techniques to rule out other diagnoses.

Based upon the foregoing, the Court finds that Dr. Carlson used differential diagnosis to conclude that the Plaintiff suffered from Aredia-induced osteonecrosis. Dr. Carlson may testify regarding his treatment of the Plaintiff and the differential diagnosis he performed. At this juncture and based upon the evidence before the Court, the undersigned finds that Novartis has not demonstrated that Dr. Carlson's causation testimony should be excluded at trial. Any short-

comings Novartis perceives in Dr. Carlson's findings may be addressed at trial through rigorous cross-examination.

**B. J. Michael McCoy, D.D.S.**

Novartis also argues that the testimony of Dr. McCoy should also be excluded. Dr. McCoy is an oral pathologist who treated Plaintiff from August 2004 until February 2005. In support of this request, Novartis argues simply:

Because Dr. McCoy, a pathologist, was not deposed, plaintiff has no basis to say he ever performed a differential diagnosis identifying a cause for her jaw injury. There is no evidence in the records to suggest that Dr. McCoy is an expert in ONJ or its causes.

[Doc. 32 at 6 (internal citations excluded)].

Plaintiff responds that Dr. McCoy is a board certified Professor of Oral and Maxillo surgery and Pathology at the University of Tennessee Medical Center-Knoxville, who also serves as a member of the University's Tumor Board and Oncology Service. [Doc. 46 at 6]. Plaintiff argues that Dr. McCoy reviewed Plaintiff's first biopsy and determined that no evidence of multiple myeloma appeared on the specimens. [Doc. 46 at 6 (citing 45-10 at 1-6)]. Plaintiff notes the Dr. McCoy also reviewed a second biopsy and, again, eliminated multiple myeloma as the cause of the osteonecrosis. [Id. at 7]. Finally, Dr. McCoy examined biopsy samples and found no evidence of malignancy. [Id.].

The Court has considered the parties' positions, the applicable standards stated herein, and Rules 701 and 702 of the Federal Rules of Civil Procedure. The Court finds that Dr. McCoy is well-qualified to offer testimony in this matter. Dr. McCoy was awarded his D.D.S. in 1973 and has completed an internship, residency, and additional post-graduate work. [Doc. 45-19 at

2-6]. In 1981, he became a fellow in the American Society of Oral and Maxillofacial Pathology, and in 1988, he became a fellow in the American Society of Oral and Maxillofacial Surgeons. [Id. at 7]. He has served as a professor in both the Department of Pathology and Department of Oral and Maxillofacial Surgery at the University of Tennessee Medical Center at Knoxville, [id. at 12], and is currently the Chief of Oral and Maxillofacial Pathology at the University of Tennessee Medical Center at Knoxville, [id. at 12-13].

The Court finds that Dr. McCoy can testify about his treatment of the Plaintiff. The Court finds that the evidence indicates an appropriate differential diagnosis was performed, and at this juncture, the evidence does not support excluding Dr. McCoy's causation testimony. The Court specifically finds that: (1) Dr. McCoy objectively obtained the nature of the Plaintiff's injuries through at least three pathology specimen examinations over a six-month period [Doc. 45-10 at 9-12];<sup>2</sup> (2) Dr. McCoy "ruled in" osteonecrosis as a cause of the injury and ruled out myeloma using a valid methodology [Id. at 6; see also Id. at 9-12]; and (3) Dr. McCoy engaged in "standard diagnostic techniques by which doctors normally rule out alternative causes" to reach a conclusion as to which cause is most likely, [see Id. at 6-12].

In so ruling, the Court notes that it has specifically reviewed the pathology report of September 1, 2004, cited by the Defendant [Doc. 32-33] and the pathology report of February 11, 2005, cited by the Defendant [Doc. 32-28].<sup>3</sup> The Court finds that the notation under "Clinical History and Diagnosis," which lists: osteonecrosis of mandible, multiple myeloma, orocutaneous fistula, and resection of the mandible and reconstruction, does not render Dr. McCoy's testimony excludable, because the final diagnosis in these pathology reports are "osteonecrosis consistent with bisphosphonate-induced necrosis" and "osteonecrosis, no viable

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<sup>2</sup> The same records are also found in Document 45-12.

<sup>3</sup> The same records are also found in Document 45-10 and Document 45-12.

bone identified.” To the extent Novartis contends that the “Clinical History” notation undercuts the weight of Dr. McCoy’s final diagnoses, this issue can be addressed through cross-examination at trial.

**C. Conclusion**

Accordingly, with regard to Eric Carlson, D.M.D., and J. Michael McCoy, D.D.S., Novartis’s *Daubert* Motion to Exclude Causation Testimony of Plaintiff’s Experts in the Thorn Case [Doc. 31] is **DENIED** to the extent stated above. Where appropriate, the Defendant may renew its objection to causation testimony at trial.

**IT IS SO ORDERED.**

ENTER:

s/ C. Clifford Shirley, Jr.  
United States Magistrate Judge