

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF OKLAHOMA

HELEN E. SHRUM,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case Number CIV-12-1057-C
	)	
NOVARTIS PHARMACEUTICALS	)	
CORPORATION,	)	
	)	
Defendant.	)	

**ORDER**

Plaintiff developed a jaw condition after taking Aredia and Zometa while being treated for bone cancer. Subsequently, Plaintiff filed this lawsuit against Defendant Novartis Pharmaceuticals Corporation, the manufacturer of Aredia and Zometa, alleging that Defendant's drugs caused her to develop osteonecrosis of the jaw ("ONJ"). Plaintiff has designated Dr. James Baker, one of her treating oral surgeons, as a case-specific expert to testify as to causation.<sup>1</sup> Defendant now asks the Court to exclude Dr. Baker's causation testimony on the grounds that Dr. Baker lacks the appropriate qualifications and did not use a reliable methodology in concluding that Aredia and Zometa were the cause of Plaintiff's ONJ.

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<sup>1</sup> In her Response to Defendant's Motion, Plaintiff withdrew the designations of Drs. Sehorn, Hornbuckle, Toma, and Chohan as case-specific causation experts. (Pl.'s Resp. to Def.'s Daubert Mem., Dkt. No. 13-33, at 2 n.1.) Thus, only Defendant's challenge to Dr. Baker's qualifications and methodology is at issue.

Federal Rule of Evidence 702 allows “[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education,” to “testify in the form of an opinion . . . 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.

Thus, to be admissible under Rule 702, the witness must be qualified as an expert and the testimony must be both relevant and reliable. See Bitler v. A.O. Smith Corp., 400 F.3d 1227, 1232 (10th Cir. 2004); see also Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 591 (1993). On the issue of causation, the Court agrees with Defendant that Dr. Baker is not qualified to testify as an expert and that his methodology is unreliable.

First, this case is unusual in that the purported expert, Dr. Baker, testified at deposition that he had not actually been retained by Plaintiff as an expert witness, understood that he was merely a fact witness, and did not consider himself an expert on ONJ or bisphosphonate drugs like Aredia or Zometa. (Def.’s Mem. in Support of Daubert Mot. to Exclude Causation Test., Dkt. No. 13-23, Ex. 35 at 7-8, 13-14.) Despite this testimony, Plaintiff insists that Dr. Baker is qualified to give case-specific opinion testimony on the cause of her ONJ. As support, Plaintiff points to Dr. Baker’s experience as a board certified oral and maxillofacial surgeon, his clinical practice, his treatment of other patients with bisphosphonate induced ONJ, his review of the relevant medical literature, and a talk he gave to the oncology group at his medical center on the topic of bisphosphonate induced ONJ. Plaintiff’s evidence, however, is unpersuasive. Although Dr. Baker’s experience presumably qualifies him to

testify as an expert with respect to the treatment or diagnosis of ONJ, it does not necessarily qualify him to testify as to the cause of Plaintiff's ONJ. See Tamraz v. Lincoln Elec. Co., 620 F.3d 665, 673 (6th Cir. 2010) (“The ability to diagnose medical conditions is not remotely the same . . . as the ability to deduce . . . in a scientifically reliable manner, the causes of those medical conditions.” (internal citation omitted)).<sup>2</sup> And, as Dr. Baker himself admitted, he is not “an expert in the etiology of ONJ.” (Def.’s Daubert Mem., Ex. 35 at 53.)<sup>3</sup>

Moreover, even if Dr. Baker was qualified to testify as to the cause of Plaintiff's ONJ, his opinion testimony must still be excluded as unreliable. Dr. Baker claims he performed a differential diagnosis for Plaintiff (Pl.’s Resp. to Def.’s Daubert Mem. at 5-6), a method of determining causation some courts have deemed scientifically reliable. See Tamraz, 620 F.3d at 674; Goebel v. Denver & Rio Grande W. R.R. Co., 346 F.3d 987, 999 (10th Cir. 2003) (“Whatever the merits of differential diagnosis in the abstract, the district court correctly determined, based on our precedent in Hollander [v. Sandoz Pharms. Corp.], 289 F.3d 1193, 1210 (10th Cir. 2002)], that it can admit a differential diagnosis that it concludes is reliable if general causation has been established.”). A physician renders a differential

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<sup>2</sup> See also In re Aredia & Zometa Prods. Liab. Litig., 483 F. App'x 182, 189 (6th Cir. 2012) (holding oral surgeon's experience might have qualified him to diagnose ONJ but not “to explain the etiology of [the plaintiff's] ONJ”), cert. denied, \_\_\_ U.S. \_\_\_, 133 S.Ct. 576 (2012); Thomas v. Novartis Pharms. Corp., 443 F. App'x 58, 62 (6th Cir. 2011) (same).

<sup>3</sup> Plaintiff also relies on Defendant's own designation of Dr. Baker as a non-retained expert. Defendant's designation is irrelevant to whether Dr. Baker is qualified to testify on the issue of causation. Defendant's designation only allows Defendant to elicit testimony from Dr. Baker with respect to Plaintiff's oral and dental condition during the time Dr. Baker treated her, his treatment of Plaintiff's ONJ, and the impact of Plaintiff's smoking and other treatments and medicines received, not the cause of Plaintiff's ONJ. (Pl.’s Resp. to Def.’s Daubert Mem. at 5.)

diagnosis when he or she “‘first ‘rule[s] in’ all scientifically plausible causes of the plaintiff’s injury’ and ‘then “rules out” the least plausible causes of injury until the most likely cause remains.’” Huerta v. BioScrip Pharmacy Servs., Inc., 429 F. App’x 768, 773 (10th Cir. 2011) (quoting Hollander, 289 F.3d at 1209). However, “[c]alling something a “differential diagnosis” . . . does not by itself answer the reliability question.” Id. (quoting Pluck v. BP Oil Pipeline Co., 640 F.3d 671, 678-79 (6th Cir. 2011)). To perform a reliable differential diagnosis, the expert must have made an accurate diagnosis, reliably ruled in all possible causes of the disease, and reliably ruled out the rejected causes. Id. Here, Dr. Baker failed to scientifically rule out the other potential causes of Plaintiff’s ONJ, such as smoking, chemotherapy, and periodontal disease, instead relying only on his experience as an oral surgeon and the failure of Plaintiff’s condition to respond to treatment to rule out these other potential causes. (Def.’s Daubert Mem., Ex. 35 at 63-64.) This is particularly insufficient in the Tenth Circuit, which has held that a differential diagnosis is most useful when the party relying on it has offered additional corroborating evidence. See Huerta, 429 F. App’x at 775; Goebel, 346 F.3d at 999; Hollander, 289 F.3d at 1210.

Thus, because Dr. Baker is not qualified to opine as to the specific cause of Plaintiff’s ONJ and did not use a scientifically reliable method in forming his opinion, his causation testimony must be excluded. Plaintiff has “concede[d] that to meet her burden of proof on case-specific causation, she must proffer expert testimony on the issue.” (Pl.’s Opposition to Def.’s Mot. for Summ. J. & for Sanctions, Dkt. No. 13-34, at 4.) As the only expert

testimony Plaintiff intended to rely upon was Dr. Baker's (id. at 5), summary judgment is appropriate for Defendant on all of Plaintiff's claims.

Sanctions, however, are not warranted. Defendant has not shown that it would have avoided the costs of Dr. Baker's second deposition or Defendant's Motion for Summary Judgment had Plaintiff not designated Dr. Baker as a retained expert. Dr. Baker's affidavit, opining that to a reasonable degree of medical certainty Defendant's drugs caused Plaintiff's ONJ, suggests Defendant would have sought to re-depose Dr. Baker, regardless of Plaintiff's designation error. Allowing Defendant to recover the cost of its entire Motion for Summary Judgment would be even more inequitable, as Defendant sought summary judgment not just on the basis of Dr. Baker's exclusion, but also on the merits of Plaintiff's failure to warn and warranty claims.

Accordingly, Novartis Pharmaceuticals Corporation's Daubert Motion to Exclude Causation Testimony of Dr. James Baker (Dkt. No. 13-22) is hereby GRANTED and Novartis Pharmaceuticals Corporation's Motion for Summary Judgment and for Sanctions (Dkt. No. 13-24) is hereby DENIED as to sanctions, but in all other respects is GRANTED. Defendant's remaining Daubert Motion to Exclude Testimony of Plaintiff's Experts Dr. Robert Fletcher, Dr. Keith Skubitz, Dr. James Vogel, Professor Wayne Ray, Dr. Suzanne Parisian, and Dr. Robert Marx (MDL 06-cv-383, Dkt. No. 4601) is thus MOOT. A Judgment shall enter accordingly.

IT IS SO ORDERED this 28th day of June, 2013.

A handwritten signature in black ink, appearing to read "Robin J. Cauthron", written over a horizontal line.

ROBIN J. CAUTHRON  
United States District Judge

**DeShazo, Anna**

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**Western District of Oklahoma[LIVE]**

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**ORDER granting [13-22] Novartis Pharmaceuticals Corporation's Daubert Motion to Exclude Causation Testimony of Dr. James Baker; granting in part and denied in part [13-24] Novartis Pharmaceuticals Corporation's Motion for Summary Judgment and for Sanctions; moot (MDL 06-cv-383, Dkt. No. 4601) Motion to Exclude Testimony of Plaintiffs Experts Dr. Robert Fletcher, Dr. Keith Skubitz, Dr. James Vogel, Professor Wayne Ray, Dr. Suzanne Parisian, and Dr. Robert Marx. Signed by Honorable Robin J. Cauthron on 6/28/13. (lg)**

**5:12-cv-01057-C Notice has been electronically mailed to:**

Miles L Mitzner [miles@mitzner.com](mailto:miles@mitzner.com), [kelsey@mitzner.com](mailto:kelsey@mitzner.com)

Thomas E Steichen [tom.steichen@mcafeetaft.com](mailto:tom.steichen@mcafeetaft.com), [julia.wallis@mcafeetaft.com](mailto:julia.wallis@mcafeetaft.com)

Vani R Singhal [vani.singhal@mcafeetaft.com](mailto:vani.singhal@mcafeetaft.com), [julia.wallis@mcafeetaft.com](mailto:julia.wallis@mcafeetaft.com)

Katharine R Latimer [Klatimer@hollingsworthllp.com](mailto:Klatimer@hollingsworthllp.com), [ecfzometa@hollingsworthllp.com](mailto:ecfzometa@hollingsworthllp.com)

Donald W Fowler (Terminated) [DFowler@spriggs.com](mailto:DFowler@spriggs.com)

Daniel A Osborn [dosborn@osbornlawpc.com](mailto:dosborn@osbornlawpc.com), [ecf@osbornlawpc.com](mailto:ecf@osbornlawpc.com), [ltrust@osbornlawpc.com](mailto:ltrust@osbornlawpc.com)

Philip M Busman [pbusman@HollingsworthLLP.com](mailto:pbusman@HollingsworthLLP.com)

**5:12-cv-01057-C Notice has been delivered by other means to:**

David E. Richman (Terminated)  
Rivkin Radler, LLP  
926 Rexcorp Plaza  
Uniondale, NY 11556

Jesse J. Graham , II(Terminated)  
Rivkin Radler, LLP  
926 Rexcorp Plaza  
Uniondale, NY 11556

Joe Gregory Hollingsworth (Terminated)  
Spriggs & Hollingsworth  
1350 I Street NW  
Washington, DC 20005

Philip Jeremy Miller (Terminated)  
Osborn Law, P.C.  
295 Madison Avenue  
39th Flr.  
New York, NY 10017

Robert Johnston (Terminated)  
Hollingsworth LLP  
1350 I Street, NW  
Washington, DC 20005

Russel Harrison Beatie , Jr(Terminated)  
Russel Harrison Beatie , LLP  
521 Fifth Avenue, Suite 1700  
New York, NY 10175

Yanika C. Smith-Bartley (Terminated)  
Baker, Donelson, Bearman, Caldwell & Berkowitz, PC-Nashville  
211 Commerce Street  
Suite 800  
Nashville, TN 37201

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