

#0021
06-06-14

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FILED

JUN 06 2014

JUDGE JESSICA R. MAYER

-and-

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*Attorneys for Defendant
Novartis Pharmaceuticals Corporation*

BARBARA BARWELL, Individually and as
Executrix of the Estate of George W. Barwell,
Jr.,

Plaintiff,

v.

NOVARTIS PHARMACEUTICALS
CORPORATION,

Defendant.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION – MIDDLESEX COUNTY
Docket No.: MID-L-9866-07-MT

CIVIL ACTION
In Re Zometa[®] / Aredia[®] Litigation
CASE NO. 278

**ORDER GRANTING DEFENDANT
NOVARTIS PHARMACEUTICALS
CORPORATION'S
MOTION TO EXCLUDE
TESTIMONY OF DR. TALIB NAJJAR**

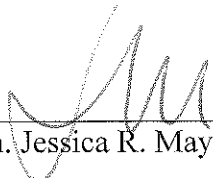
THIS MATTER having been opened by the Court by Sils Cummis & Gross P.C.,
attorneys for defendant Novartis Pharmaceuticals Corporation (“NPC”), seeking an order
granting NPC’s Motion to Exclude the Testimony of Dr. Talib Najjar, and the Court having
reviewed the papers submitted and arguments of counsel, and for good cause shown;

IT IS on this 6th day of June 2014, ORDERED as follows:

1. NPC’s motion be and hereby is granted, *for the reasons set forth in the court's memorandum of decision dated June 6, 2014;*
2. Dr. Najjar shall be precluded from testifying; and

3. A copy of this Order be ^{permitted to be} served upon all counsel of record within seven (7) days of the date hereof.

OPPOSED



Hon. Jessica R. Mayer, J.S.C.

This motion was:

Opposed

Unopposed

#0019

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SUPERIOR COURT OF NEW JERSEY
LAW DIVISION – MIDDLESEX COUNTY
Docket No.: MID-L-9866-07-MT

CIVIL ACTION
In Re Zometa[®] / Aredia[®] Litigation
CASE NO. 278

**ORDER GRANTING DEFENDANT
NOVARTIS PHARMACEUTICALS
CORPORATION'S MOTION FOR
SUMMARY JUDGMENT ON
PLAINTIFF'S CLAIMS AND
DISMISSING PLAINTIFF'S
COMPLAINT WITH PREJUDICE**

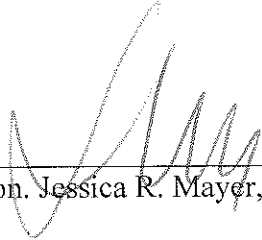
THIS MATTER having been opened by the Court by Silks Cummis & Gross P.C.,
attorneys for defendant Novartis Pharmaceuticals Corporation ("NPC"), seeking an order
granting NPC's Motion for Summary Judgment on Plaintiff's Claims, and the Court having
reviewed the papers submitted and arguments of counsel, and for good cause shown;

IT IS on this 6th day of June 2014, ORDERED as follows:

1. NPC's motion be and hereby is granted *for the reasons set forth in
the court's memorandum of decision dated June 6, 2014*

2. Plaintiff's case is hereby dismissed with prejudice; and
3. A copy of this Order be served ^{with certified} upon all counsel of record within seven (7) days of the date hereof.

OPPOSED



Hon. Jessica R. Mayer, J.S.C.

This motion was:

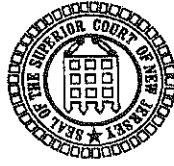
Opposed

Unopposed

SUPERIOR COURT OF NEW JERSEY

FILED
JUN 06 2014
JUDGE JESSICA R. MAYER

CHAMBERS OF
JESSICA R. MAYER, J.S.C.



MIDDLESEX COUNTY COURT HOUSE
P.O. Box 964
NEW BRUNSWICK, NJ 08903-0964

NOT FOR PUBLICATION WITHOUT
THE APPROVAL OF THE COMMITTEE ON OPINIONS

*Memorandum of Decision on Defendant's
Motion to Exclude Testimony of
Plaintiff's Expert Dr. Talib Najjar*

Barwell v. Novartis Pharmaceuticals Corp., Docket No. MID-L-9866-07-MT
(In re: Zometa[®]/Aredia[®] Litigation, Case No. 278)

For Defendant: Joe Hollingsworth, Esq., Katherine Latimer, Esq., and Neil S. Bromberg, Esq.,
Hollingsworth, LLP
Beth S. Rose, Esq. and Charles J. Falletta, Esq., Sills Cummis & Gross P.C.

For Plaintiff: John J. Vecchione, Esq., John J. Vecchione, PLLC
Michael L. Rosenberg, Esq., Seeger Weiss LLP

Dated: June 6, 2014

The court issues this opinion in response to the motion filed on behalf of Defendant Novartis Pharmaceuticals Corporation ("Defendant" or "NPC") to exclude the specific causation testimony of Talib A. Najjar, D.M.D., M.D.S., Ph.D. ("Dr. Najjar"), offered on behalf of Plaintiff Barbara Barwell, individually and as Executrix of the Estate of George W. Barwell, Jr. ("Plaintiff").

Plaintiff offers the expert opinion of Dr. Najjar in support of her allegation that Zometa[®] caused her husband, George W. Barwell, Jr. ("Mr. Barwell"), to develop osteonecrosis of the jaw ("ONJ"). Dr. Najjar's opinion was based on his review of Mr. Barwell's medical and dental

records, and his experience in treating patients with ONJ. Dr. Najjar is certified as a practitioner with the American Board of Oral and Maxillofacial Surgery, American Board of Oral and Maxillofacial Pathology, and the American Board of Oral Medicine.

The court, in addressing Defendant's motion to exclude the testimony of this case specific expert, reviewed the report of Dr. Najjar, related exhibits, deposition testimony, and the written arguments of counsel.¹

Defendant challenges Dr. Najjar's testimony on the grounds that he failed to perform a proper differential diagnosis in concluding that Mr. Barwell "suffered from Bisphosphonate Induced Osteonecrosis of the Jaw ("BIONJ") from his treatment with Zometa® for his lung cancer."² The court finds that Dr. Najjar failed to perform a differential diagnosis. Additionally, the court rules that Dr. Najjar's report shall be excluded as net opinion.

Analysis

I. Failure of Dr. Najjar to Perform a Differential Diagnosis

N.J.R.E. 702, which governs the admissibility of scientific expert testimony in New Jersey, provides that:

[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or 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.

[Id.]

To admit expert testimony under N.J.R.E. 702, three basic requirements must be satisfied:

¹ The court did not conduct a hearing pursuant to N.J.R.E. 104 as both parties agreed, in writing, to waive such a hearing.

² Novartis Pharmaceuticals Corporation's Memorandum Of Law In Support Of Motion To Exclude Testimony of Plaintiff's Expert Dr. Talib Najjar ("Def. Mem.") at 1; Expert Report of Dr. Talib Najjar, D.M.D., M.D.S., Ph.D. ("Najjar Report"), attached as Exhibit 18 to the Certification of Charles Falletta dated May 1, 2014 ("Falletta Cert.") at 1.

(1) the intended testimony must concern a subject matter that is beyond the ken of the average juror; (2) the field testified to must be at a state of the art such that an expert's testimony could be sufficiently reliable; and (3) the witness must have sufficient expertise to offer the intended testimony.

[Creanga v. Jardal, 185 N.J. 345, 355 (2005) (quoting Kemp ex. Rel. Wright v. State, 174 N.J. 412, 424 (2002).]

At issue in this case is the second requirement—whether Dr. Najjar's expert testimony is "sufficiently reliable." To satisfy this element, "the proponent of the expert testimony is required to demonstrate that the expert's opinion or theory is generally accepted within the scientific community." Creanga, supra, 185 N.J. at 355 (internal quotations omitted). The role of the trial judge is to "assess the soundness of the proffered methodology." Kemp, supra, 174 N.J. at 426. The expert's opinion is supported by a sound methodology if the trial judge determines that the expert performed an adequate differential diagnosis in reaching his conclusion. See generally Creanga, supra, 185 N.J. at 357-58. The New Jersey Supreme Court defines differential diagnosis as "a medical construct for determining which one of two or more diseases or conditions a patient is suffering from, by systematically comparing and contrasting their symptoms." Id. at 355 (internal citations omitted).

To perform a proper differential diagnosis, an expert is required to conduct a two-part analysis. Feit v. Great West Life and Annuity Ins. Co., No. 07-1481, 2008 LEXIS 6849 at 21-22 (3rd Cir. Mar. 31, 2008); Creanga, supra, 185 N.J. at 356. First, an expert must "rule in *all plausible causes* for the patient's condition by compiling a comprehensive list of hypotheses that might explain the set of salient clinical findings under consideration." Creanga, supra, 185 N.J. at 356 (internal citations omitted) (emphasis added). Though an expert need only determine "which of the competing causes are *generally* capable of causing the patient's symptoms," a failure "to consider a plausible hypothesis that would explain the condition" results in an

improperly conducted differential diagnosis. *Id.* In addition to ruling in all plausible causes of the patient's condition, the expert:

must rule out those causes that did not produce the patient's condition by engaging in a process of elimination, eliminating hypotheses on the basis of a continuing examination of the evidence so as to reach a conclusion as to the most likely cause of the findings in that particular case. (internal quotations omitted)

[*Id.*]

To satisfy this second step, the expert must "employ[] sufficient diagnostic techniques to have good grounds for his or her conclusion." *Id.* (citations omitted) After reviewing all of the materials provided to the court, it is clear that Dr. Najjar did not perform a proper differential diagnosis.

A. Dr. Najjar Did Not "Rule In" Avastin^{®3} As a Potential Cause of Mr. Barwell's Alleged BIONJ

Dr. Najjar failed to complete the first step of a differential diagnosis because he did not consider all alternative causes of Mr. Barwell's alleged ONJ. Under New Jersey case law, "[a] reliably performed differential diagnosis includes considering plausible alternative causes." *Lewis v. Airco*, No. A-3509-08T3 (App. Div. July 15, 2011) (slip op. at 72). Mr. Barwell was treated with Avastin[®] from February 2006 to May 2006, and again from June 2007 to September 2007.⁴ Thus, Dr. Najjar's failure to even consider Avastin[®], a known cause of ONJ⁵, as a cause

³ Zometa[®] and Avastin[®] are two different drugs used to treat different medical conditions. Zometa[®], also known as zoledronic acid, "is in a class of medications called bisphosphonates. Bisphosphonates work by slowing bone breakdown, increasing bone density (thickness), and decreasing the amount of calcium released from the bones into the blood." MedlinePlus, *Zoledronic Acid Injection*, NATIONAL INSTITUTES OF HEALTH, <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a605023.html> (last visited June 4, 2014). Zometa[®] is not a cancer drug. Avastin[®] is an angiogenesis inhibitor. National Cancer Institute at the National Institutes of Health, *National Cancer Institute FactSheet*, ANGIOGENESIS INHIBITORS, <http://www.cancer.gov/cancertopics/factsheet/Therapy/angiogenesis-inhibitors> (last visited May 29, 2014). "Angiogenesis plays a critical role in the growth and spread of cancer... Angiogenesis inhibitors [such as Avastin[®]] interfere with various steps [in the tumor growth process]." Avastin[®] is a cancer drug. *Id.*

⁴ Def. Mem. at 2.

⁵ U.S. Food and Drug Admin., *Safety Information, AVASTIN[®] (BEVACIZUMAB)*, <http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm275758.htm> (last visited May 29, 2014).

of Mr. Barwell's alleged ONJ renders his differential diagnosis incomplete and inherently flawed.

Recently, the American Association of Oral and Maxillofacial Surgeons ("AAOMS") released a report stating that while the AAOMS previously favored the term bisphosphonate-related osteonecrosis of the jaw ("BRONJ"), it now "favors the term **medication-related osteonecrosis of the jaw (MRONJ)** ... to accommodate the growing number of osteonecrosis cases involving the maxilla and mandible associated with other ... antiangiogenic therapies," such as Avastin®.⁶ Even if Dr. Najjar failed to read the reports and medical journals alleging an association between Avastin® and ONJ, the Postmarketing Experience section of the Avastin® label, posted on the website for the United States Food and Drug Administration ("FDA") lists "Osteonecrosis of the jaw" as an adverse reaction.⁷ In fact, Avastin® labels dating back to September 2011 included ONJ as an adverse reaction, prior to Dr. Najjar's issuance of his expert report.⁸ Since 2011, the FDA, the manufacturer of Avastin®, and authors of medical journals identify Avastin® as a possible cause of ONJ. Therefore, Dr. Najjar's failure to consider Avastin® as a cause of Mr. Barwell's alleged ONJ renders his differential diagnosis incomplete.

It is undisputed that Dr. Najjar knew Mr. Barwell treated with Avastin®. In his expert report, dated December 13, 2013, Dr. Najjar wrote that Mr. Barwell "was treated with a chemotherapy regimen of carboplatin, Taxol and *Avastin*" (emphasis added).⁹ Dr. Najjar's

⁶ Reply Certification of Charles Falletta dated May 22, 2014 ("Falletta Rep.") Exhibit 2 at 1. The court recognizes that the AAOMS report was released after Dr. Najjar issued his expert report and after Dr. Najjar was deposed in this case. However, the citations in the AAOMS report alleging an association between bevacizumab and ONJ predated Dr. Najjar's report and deposition. Falletta Rep. Exhibit 2 at 23. Thus, a link between bevacizumab and ONJ was known in the medical community before Dr. Najjar prepared his expert report and was deposed in Mr. Barwell's case.

⁷ HIGHLIGHTS OF PRESCRIBING INFORMATION, *Avastin*® (bevacizumab), http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/125085s2851bl.pdf (12/2013).

⁸ HIGHLIGHTS OF PRESCRIBING INFORMATION, *Avastin*® (bevacizumab), http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/125085s2251bl.pdf (September 2011).

⁹ Falletta Cert., Exhibit 18 at 1.

report listed several other possible causes for Mr. Barwell's alleged BIONJ such as osteomyelitis, multiple myeloma, and osteoradionecrosis of the jaw, among others.¹⁰ Yet nowhere in his report did Dr. Najjar "rule in" Avastin® as a possible cause of Mr. Barwell's alleged ONJ.¹¹ During his deposition, Dr. Najjar conceded that he did not consider Avastin® as a possible cause of decedent's jaw problems.

Q: You did not indicate in your report that you considered Mr. Barwell's treatment with Avastin as a possible cause of his jaw problems, correct?

A: That's true, because Avastin doesn't really cause necrosis per se, but it does cause delayed healing —¹²

Later in the deposition, Dr. Najjar admitted he did not consider Avastin® in his differential diagnosis:

Q: And can you rule out in Mr. Barwell's case that his treatment with Avastin caused him to develop osteonecrosis of the jaw?

A: I cannot—

...

A: I cannot rule it out, no. *I should add it to my differential.*¹³ (emphasis added)

Dr. Najjar explained that he did not consider Avastin® in his differential diagnosis because he thought Avastin® only contributed to "delayed healing on [sic] necrosis."¹⁴ Dr. Najjar did not provide any information—either in his expert report or his deposition—as to why he believed Avastin® only caused delayed healing of ONJ. Indeed, Dr. Najjar's deposition testimony, taken as a whole, undermined his conclusion that Avastin® only caused delayed healing of ONJ. First, Dr. Najjar admitted in his deposition that he saw "some of the reports" of

¹⁰ Id. at 1-2.

¹¹ Id.

¹² Deposition transcript of Dr. Talib Najjar dated January 29, 2014 (hereinafter "Najjar Dep.") at 87:14-20.

¹³ Najjar Dep. at 97:5-9, 11-12.

¹⁴ Id. at 89:17.

“patients receiving Avastin who did not take bisphosphonates and developed osteonecrosis of the jaw.”¹⁵ Second, Dr. Najjar admitted he did not read the label for Avastin®:

Q: Doctor, have you reviewed the label, the labeling for Avastin?

A: No, sir, I haven't.

Q: Are you aware, Dr. Najjar, that the labeling for Avastin identifies osteonecrosis of the jaw as a possible adverse reaction?

...

A: I really have no – I did search the Avastin on the Internet, and I don't think there was, at least in my search, there was only delaying healing on necrosis – no, I haven't seen anything, yeah.¹⁶

Third, Dr. Najjar agreed “that there are multiple articles in the medical literature talking about Avastin as an independent cause of osteonecrosis of the jaw.”¹⁷ Dr. Najjar's own testimony undercut his opinion that Mr. Barwell suffered specifically from bisphosphonate induced osteonecrosis of the jaw, and not medication-related osteonecrosis of the jaw.¹⁸

New Jersey case law requires “[a] reliably performed differential diagnosis” that “consider[s] plausible alternative causes.” Lewis, supra, No. A-3509-08T3 at 72. In Lewis v. Airco, the defendant argued that the plaintiff's expert failed to perform a differential diagnosis because he did not consider a possible alternative cause for plaintiff's illness. Id. at 73. Similar to Dr. Najjar, who did not consider Avastin® as a risk factor for Mr. Barwell developing ONJ, the expert in Lewis, “did not consider obesity as an ‘accepted’ risk factor” in causing the plaintiff's illness. Id. The Appellate Division in Lewis found the expert performed a proper differential diagnosis because the expert “testified that no studies existed to prove that obesity was a factor in developing the disease.” Id. at 72-73. In this case, Dr. Najjar testified at his deposition “that

¹⁵ Id. at 88:12-18.

¹⁶ Id. at 89:6-12, 14-18.

¹⁷ Id. at 96:22-25; 97:1-4.

¹⁸ Falletta Cert., Exhibit 18 at 1 and 2.

there are multiple articles in the medical literature talking about Avastin as an independent cause of osteonecrosis of the jaw,” while providing no evidentiary support for his opinion that it was Zometa® that caused Mr. Barwell’s alleged ONJ.¹⁹ Consequently, since Dr. Najjar failed to “rule in” Avastin® as a possible cause of Mr. Barwell’s alleged ONJ, his differential diagnosis is flawed.

B. Dr. Najjar Did Not Rule Out Avastin® As a Potential Cause of Plaintiff’s Alleged ONJ

The medical community recognizes an association between Avastin® and ONJ.²⁰ Despite this recognition, Dr. Najjar only mentioned Avastin® in his expert report once, when he noted that Mr. Barwell was treated with the drug.²¹ Nowhere in his report did Dr. Najjar explain why he “ruled out” Avastin® as a cause of Mr. Barwell’s alleged ONJ. Interestingly, Dr. Najjar specifically ruled out osteoradionecrosis of the jaw (“ORNJ”) as a potential cause of Mr. Barwell’s ONJ. Dr. Najjar wrote that ORNJ did not cause Mr. Barwell’s jaw problems because the “patient’s jaw was not exposed to radiation according to his medical record.”²² Yet, Dr. Najjar did not provide a single reason in his report as to why Avastin® did not cause Mr. Barwell’s alleged BIONJ.²³

Thus, even if Dr. Najjar considered Avastin® as a cause of Mr. Barwell’s alleged ONJ—which he did not—the differential diagnosis performed by Dr. Najjar is inherently flawed. Once an expert “rules in” all possible causes of a plaintiff’s disease, he or she must “[r]ule out’ causes through a process of elimination whereby the last remaining potential cause is deemed the most likely cause [of injury].” *Feit, supra*, 3rd Cir. 2008 LEXIS 6849, at 21-22. To complete a proper differential diagnosis, “the expert witness must *demonstrate* what he or she did and that the

¹⁹ Najjar Dep. at 96:22-25; 97:1-4.

²⁰ See *supra*, Part I.A.

²¹ Falletta Cert., Exhibit 18 at 1.

²² *Id.* at 1-2.

²³ See Falletta Cert., Exhibit 18.

proper diagnostic procedures were followed when performing the diagnosis A court is justified in excluding evidence if an expert *utterly fails* ... to offer an explanation for why the proffered alternative cause was ruled out.” Creanga, supra, 185 N.J. at 357-58 (internal citations and quotations omitted). The only reason Dr. Najjar provided in his written report or deposition testimony for his failure to rule out Avastin® was his unsubstantiated belief that Avastin® only delayed healing.²⁴

This court has the:

discretion to exclude an opinion on specific causation where [t]he defendants pointed to some likely alternative cause and the expert offered no reasonable explanation as to why he or she still believed that defendant’s actions were a substantial factor in bringing about plaintiff’s illness. While an expert is not required to rule out all alternative possible causes of a plaintiff’s disease, ‘where a defendant points to a plausible alternative cause and the doctor offers no reasonable explanation’ for why he still concludes that the chemical was a substantial factor in bringing about the plaintiff’s disease, ‘that doctor’s methodology is unreliable.’

[Magistrini v. One Hour Martinizing Dry Cleaning, 180 F. Supp.2d 584, 609 (D.N.J. 2002) (internal citations omitted).]

Given that the FDA, the manufacturer of Avastin®, and authors of published medical articles indicate Avastin® as a possible cause of ONJ, Avastin® is a “plausible alternative cause” for Mr. Barwell’s alleged ONJ in this case.²⁵ However, Dr. Najjar utterly failed to provide a “reasonable explanation” for why he concluded that Zometa® “was a substantial factor in bringing about” Mr. Barwell’s alleged ONJ. The court finds that because Dr. Najjar “utterly failed” to rule out Avastin® as a cause of Mr. Barwell’s jaw problems, his differential diagnosis is flawed.

Because Dr. Najjar failed to both “rule in” and “rule out” Avastin® as a potential cause of Mr. Barwell’s alleged injury, his “methodology is unreliable,” and his opinion shall be excluded.

Magistrini, supra 180 F. Supp.2d at 609.

²⁴ See supra, Part I.A.

²⁵ Id.

II. Dr. Najjar Provided a Net Opinion

N.J.R.E. 703, which governs the basis of opinion testimony by experts in New Jersey, provides that:

[t]he facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

[Id.]

Under N.J.R.E. 703, “[a]n expert’s conclusion is considered to be a ‘net opinion,’ and thereby inadmissible, when it is a bare conclusion unsupported by factual evidence In other words, an expert must ‘give the why and wherefore of his or her opinion, rather than a mere conclusion.’” Creanga, supra, 185 N.J. at 360 (internal citations omitted); See also Pomerantz Paper Corp. v. New Community Corp., 207 N.J. 344, 372 (2011); Beadling v. William Bowman Assoc., 355 N.J. Super. 70, 87 (2002). Medical opinion testimony, such as the type presented in this case, “concerning the cause of an injury, ‘must be couched in terms of reasonable medical certainty or probability; opinions as to possibility are inadmissible.’” Creanga, supra, 185 N.J. at 360. After reviewing Dr. Najjar’s written report and deposition testimony, it is clear that his conclusion is a net opinion and therefore inadmissible.

First, Dr. Najjar failed to reach a conclusion that is “couched in terms of reasonable medical certainty or probability.” In reaching his conclusion, Dr. Najjar wrote, “[b]ased on the medical and dental records, *it appears* that Mr. Barwell suffered from Bisphosphonate Induced Osteonecrosis of the Jaw (“BIONJ”) from his treatment with Zometa for his lung cancer.”²⁶ (emphasis added). Dr. Najjar also wrote, “that Mr. Barwell *more likely than not* suffered from

²⁶ Falletta Cert., Exhibit 18 at 1.

Zometa induced BIONJ.”²⁷ (emphasis added) Even during his deposition, Dr. Najjar failed to reach a conclusion with the requisite medical certainty or medical probability:

Q: --so the record is clear, beginning in April of 2007 do you believe that Mr. Barwell, to a reasonable degree of medical certainty, suffered from bisphosphonate-induced osteonecrosis of the jaw?

A: Well, I think based on the medical record and also the description of the oral surgeon, which I happen to try to trust any oral surgeon because I’m sure they are qualified, they have indicated that he have [sic] bisphosphonate-induced necrosis of the jawbone. And based on his medication and what have you, so I would say that *most likely he does*—

....

Q: Did Mr. Barwell, based upon your review of the medical records, meet the diagnostic criteria for bisphosphonate-induced osteonecrosis of the jaw?

....

A: It *appear* [sic] he does, and he’s probably, you know, like, stage 1 disease. Um-hum.²⁸

Dr. Najjar’s conclusion that it “appears” or it is “more likely than not” that Mr. Barwell suffered from Zometa®-induced BIONJ is a far cry from expert testimony that is “couched in terms of reasonable medical certainty or probability.” State v. Freeman, 223 N.J. Super. 92, 116 (1988).

According to New Jersey case law:

it seems universally agreed that an expert medical opinion as to the cause of death, disease, or other physical condition is inadmissible if it is solely an unsupported conclusion of the witness, since however well qualified the witness is, and however scientific or abstruse the subject matter is, an opinion must have reference to the material facts of the case as reflected by the evidence.

[Vuocolo v. Diamond Shamrock Chems. Co., 240 N.J. Super. 289, 299. See also Dawson v. Bunker Hill Plaza Assoc., 289 N.J. Super. 309, 323 (1996) (stating that “[e]xpert testimony should not be received if it appears the witness is not in possession of such facts as will enable him [or her] to express a reasonably

²⁷ Id. at 2.

²⁸ Najjar Dep. at 133:22-25; 133:1-10, 20-33; 134:1-3. Significantly, Dr. Najjar rendered these vague and inconclusive opinions in response to questions posed by Plaintiff’s counsel.

accurate conclusion as distinguished from a mere guess or conjecture.”
(alternation in original)]

The court notes that “[c]are must be taken, however, to see that the incantation [‘with a reasonable degree of medical certainty’] does not become a semantic trap and the failure to voice it is not used as a basis for exclusion without analysis of the testimony itself.” Schulz v. Celotex Corp., 942 F.2d 204, 208 (3rd Cir. 1991) (internal citations omitted). However,

[s]ituations in which the failure to qualify the opinion have resulted in exclusion are typically those in which the expert testimony is speculative, *using such language as ‘possibility....’* Accordingly, while the particular phrase used should not be dispositive, it may indicate the level of confidence the expert has in the expressed opinion. Perhaps nothing is absolutely certain in the field of medicine, but the intent of the law is that if a physician cannot form an opinion with sufficient certainty so as to make a medical judgment, neither can a jury use that information to reach a decision.

[Id. at 208-09 (internal citations omitted) (emphasis added).]

That Dr. Najjar failed to state his conclusion to a “reasonable degree of medical certainty” is troubling. Even more problematic is that Dr. Najjar waived in his conclusion and used tentative words such as “appears” and “likely.” The usage of such words indicates to the court that Dr. Najjar was unable to form his opinion with “sufficient certainty.” Schulz, supra 942 F.2d at 209.

The court is further troubled by Dr. Najjar’s lack of certainty in this case after reading the case specific expert report authored by Dr. Najjar in another case, Estate of Laura Brown v. Novartis Pharmaceuticals Corp., Docket No. L-4971-10 (Law Div., Middlesex County). Significantly, Dr. Najjar’s expert report in this case and the Brown case were both dated December 13, 2013. Pursuant to Case Management Order (“CMO”) No. 33, dated October 3, 2013, specific causation expert reports were to be submitted on behalf of Plaintiff in this case as well as the plaintiff in the Brown case. According to CMO No. 35, dated March 18, 2014,

dispositive motions in both Barwell and Brown were to be filed on May 1, 2014. NPC filed motions to bar the case specific expert testimony of Dr. Najjar in both cases. However, the plaintiff in Brown took a voluntary dismissal, with prejudice, on May 12, 2014. Because the court received NPC's motion to bar Dr. Najjar's testimony in both cases, the court had an opportunity to compare and contrast Dr. Najjar's written reports in Brown and Barwell.

In the Brown report, issued the same day as Dr. Najjar issued the Barwell report, Dr. Najjar's conclusion was stronger. In Brown, Dr. Najjar wrote, "[b]ased on the medical and dental records, *I am reasonably certain* that Mrs. Brown suffered from pain and discomfort ... due to Bisphosphonate Induced Osteonecrosis of the Jaw ("BIONJ") due to her treatment with Zometa for her multiple myeloma."²⁹ (emphasis added) In the conclusion section of his report in the Brown case, Dr. Najjar wrote, "it is my opinion ... that Mrs. Brown suffered from Zometa induced BIONJ."³⁰ Contrasting these two case specific expert reports only heightens the lack of certainty with which Dr. Najjar rendered his opinions in the Barwell litigation.

Not only did Dr. Najjar render a speculative opinion, but he also failed to "give the why and wherefore" of his opinion, and instead stated a "mere conclusion" that is nothing more than inadmissible net opinion. State v. Townsend, 186 N.J. 473, 494 (2006). It is well-established law in New Jersey that "[t]he corollary of [Rule 703] is the net opinion rule, which forbids the admission into evidence of an expert's conclusions that are not supported by factual evidence or other data." Polzo v. County of Essex, 196 N.J. 569, 583 (2008) (internal quotations omitted) (reversed and remanded on other grounds). In Polzo, the New Jersey Supreme Court defined what constitutes net opinion and held:

²⁹ See Certification of Charles Falletta, dated May 1, 2014 in Support of Novartis Pharmaceutical's Motion to Exclude Testimony of Plaintiff's Expert Dr. Talib Najjar in Estate of Laura Brown v. Novartis Pharmaceuticals Corp., Docket No. L-4971-10 (Law Div., Middlesex County) (hereinafter "Falletta Cert. Brown"), Exhibit 28 at 1.

³⁰ Falletta Cert. Brown 28 at 3.

On its face, Dr. Kuperstein's report appears to provide no explanation for any of his conclusions: it does not provide the basis for his conclusion In sum, Dr. Kuperstein's opinion ... may suffer from the very ills that condemn a net opinion: it can be said to present a solely bald conclusion, without specifying the factual bases or the logical or scientific rationale that must undergird that opinion. If so, then the result is as simple as it is compelling: a net opinion alone is insufficient to sustain plaintiff's burden.

[Id. at 583-84.]

In his report in this case, Dr. Najjar stated that "Mr. Barwell's BIONJ's severity, complications and suffering are Zometa dosage and duration related."³¹ But nowhere in the report did he state why he reached this conclusion in Mr. Barwell's case. Thus, just as the New Jersey Supreme Court held in Polzo, Dr. Najjar's report provides "no explanation for any of his conclusions," and is thus "a net opinion ... which is insufficient to sustain plaintiff's burden." Polzo, *supra*, 196 N.J. at 584.

This multicounty litigation requires proof of the causal connection between Zometa[®] and ONJ for each specific plaintiff. Plaintiff must present expert testimony to satisfy her burden with respect to specific causation—i.e. whether Zometa[®] caused ONJ in *Mr. Barwell's specific case*. Leese v. Lockheed Martin, 2013 U.S. Dist. LEXIS 140566, at 21-22 (D.N.J., Sept. 30, 2013). The report presented by Dr. Najjar is not case specific. Comparing Dr. Najjar's report in the Barwell litigation to the report he prepared in the Brown matter revealed that the two reports were nearly identical—practically the same, word for word—except for slightly different phrasing in a few sentences.³² In fact, the only substantive difference between the two case specific expert reports was Dr. Najjar's ultimate opinion. In the Brown report, Dr. Najjar's conclusion was definitive and affirmative. Dr. Najjar was "reasonably certain" and "it [was his]

³¹ Falletta Cert., Exhibit 18 at 2.

³² Falletta Cert., Exhibit 18; Falletta Cert. Brown, Ex. 28. The court notes that the plaintiff's name is different in each report, as is the presentation of the facts.

opinion” that the plaintiff in Brown “suffered from Zometa induced BIONJ.”³³ In the Barwell report, Dr. Najjar’s language was inconclusive, stating “it appears” and “that Mr. Barwell more likely than not suffered from Zometa induced BIONJ.”³⁴ The fact that Dr. Najjar’s two expert reports are nearly identical demonstrated to this court that Dr. Najjar failed to reach a conclusion to a reasonable degree of medical certainty in Mr. Barwell’s *specific* case.

After conducting a careful review of all the materials regarding Dr. Najjar’s expert report in the Barwell matter, the court:

cannot escape the conclusion that the opinions were nothing more than the expert’s personal views. Certainly the two-page summary report that the expert prepared is devoid of any clue as to its basis and lacks any suggestion about the expert’s support for the conclusion that he intended to offer at trial.

[Pomerantz, supra, 207 N.J. at 373.]³⁵

Given the uncertainty with which Dr. Najjar reached his conclusion regarding the cause of Mr. Barwell’s alleged BIONJ, the utter lack of evidentiary support for his conclusion, and the fact that his conclusion was not case specific, the court concludes that Dr. Najjar’s written report constitutes inadmissible net opinion.

III. Previous Use of Dr. Najjar as an Expert

As recently as March 2014, Dr. Najjar was permitted to testify as a specific causation expert in the Zometa® federal multidistrict litigation (“MDL”) under the Daubert standard. Daubert v. Merrell Dow Pharms., 509 U.S. 579; 113 S. Ct. 2786; 125 L. Ed.2d 469 (1993). See Rowland v. Novartis Pharms. Corp., 2014 U.S. Dist. LEXIS 44865, at 37 (W.D. Pa., Mar. 31,

³³ Falletta Cert. Brown, Exhibit 28 at 3.

³⁴ Falletta Cert., Exhibit 18 at 1 and 2.

³⁵ The court recognizes that the sufficiency of an expert report cannot be judged on the length of the report alone. However, this court has prior experience with case specific expert reports in this very multicounty litigation matter. In fact, this court allowed the case specific experts to survive defense motions to exclude such testimony in Bessemer v. Novartis Pharms. Corp., Docket No. L-1835-08 (Law Div., Middlesex County) and Meng v. Novartis Pharms. Corp., Docket No. L-7670-07 (Law Div., Middlesex County). Compared to the case specific expert reports that the court reviewed in prior Zometa®/Aredia® multicounty litigation matters, Dr. Najjar’s two-page report is the least compelling and briefest of any that this court has examined.


2014). Dr. Najjar also survived Daubert review in two recent decisions issued by the District Court for the Southern District of Ohio, Western Division. See Bowles v. Novartis Pharms. Corp., 2013 U.S. Dist. LEXIS 134350, at 15 (S.D. Ohio, Sept. 19, 2013), and Sheffer v. Novartis Pharms. Corp., 2013 U.S. Dist. LEXIS 25601, at 16 (S.D. Ohio, Sept. 18, 2013). Of particular interest to the court is the Sheffer decision, where Dr. Najjar survived an examination under Daubert even though he was unable to rule out the plaintiff's use of Avastin® in that case. Sheffer, *supra*, U.S. Dist. LEXIS 25601 at 14.

In Sheffer, Dr. Najjar “conclude[d], to a reasonable degree of medical certainty, that Sheffer developed ONJ as a result of her treatment with Zometa®. *Id.* at 12. The conclusion reached by Dr. Najjar in Sheffer is stronger than the conclusion reached by Dr. Najjar in the present matter. This court does not have access to Dr. Najjar's report or his deposition testimony in the Sheffer litigation. Therefore, it is not possible to know to what degree Dr. Najjar considered Avastin® as a cause of the plaintiff's alleged ONJ in Sheffer. The Sheffer court concluded that “Dr. Najjar's failure to conclusively rule out every possible alternative does not necessarily render his testimony deficient under Daubert.” *Id.* at 15.

However, Dr. Najjar did not merely fail to “rule out” Avastin® in the Barwell litigation. He also failed to consider, or “rule in,” Avastin® as a possible cause of Mr. Barwell's alleged ONJ. Dr. Najjar was also unable to support his rationale for not considering Avastin® as a cause of Mr. Barwell's alleged ONJ. And, even if Dr. Najjar did adequately consider Avastin®, he utterly failed to explain why he ruled out Avastin® as a potential cause of Mr. Barwell's jaw problems. These facts distinguish the present litigation from Sheffer and “render [Dr. Najjar's] testimony deficient” under N.J.R.E. 702 and N.J.R.E. 703.

IV. Conclusion

Therefore, the specific causation testimony of Dr. Najjar is inadmissible, and Defendant's Motion to Exclude Testimony of Dr. Talib Najjar is **GRANTED**. Without the requisite expert testimony to establish specific causation in this case, the court concludes no reasonable jury could find that any alleged failure to warn was a proximate cause of Mr. Barwell's injuries. Because the court has excluded Dr. Najjar's case specific causation testimony due to his flawed differential diagnosis and net opinion, summary judgment shall be entered in favor of NPC and the court shall dismiss Plaintiff's complaint. The court will enter orders memorializing the determinations in this memorandum.



JESSICA R. MAYER, J.S.C.