UNITED STATE DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT KNOXVILLE

IRENE JENKINS, Plaintiff, V. NOVARTIS PHARMECEUTICALS CORP., Defendant.	)))))))	No. 3:11-CV-342 (CAMPBELL/SHIRLEY)

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

MEMORANDUM AND ORDER

These cases are before the undersigned pursuant to 28 U.S.C. § 636, the Rules of this Court, and the orders of the District Judge. Now before the Court is Novartis Pharmaceuticals Corporation's Daubert 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. This Daubert motion has been filed in both of the cases captioned above. This Memorandum and Order, however, addresses the testimony of Dr. James Vogel. Dr. Vogel is only expected to offer testimony on behalf of Plaintiff Thorn.

On June 14, 2012, the parties appeared before the Court to address this motion. The parties and the Court agreed that the Court would decide the Daubert challenge to the testimony of James M. Vogel, on the papers. The parties have submitted their materials on this issue to the Court, and the Court has completed its review. For the reasons stated below, Novartis's

objection and challenge to James M. Vogel, M.D., will be **GRANTED IN PART** and **DENIED IN PART**.

I. BACKGROUND

Both Plaintiff Jenkins and Plaintiff Thorn ("the Plaintiffs") underwent treatment for cancer in the late 1990s and early 2000s. Plaintiffs were prescribed Aredia by their physicians.[1] It is undisputed that Novartis was in the business of manufacturing, marketing, distributing, promoting, testing, labeling, and selling Aredia. The Plaintiffs allege that they suffered from osteonecrosis of the jaw caused by Aredia, and they argue that Novartis should be held liable for their personal injuries under theories of strict liability and negligence. Novartis disputes both general causation and specific causation.

The parties agree that Aredia is a bisphosphonate and the principal pharmacological action of Aredia is inhibition of bone resorption. Bisphosphonates are approved by the Food and Drug Administration ("FDA") for prevention and treatment of osteoporosis. Aredia and Zometa are "FDA-approved intravenous bisphosphonate drugs typically prescribed by oncologists to prevent bone pain, fracture and other skeletal complications in patients with cancer that has metastasized to bone." [MDL No. 3:06-MD-1760, Doc. 4695 at 2].

At the time of his initial report in these cases, James M. Vogel, M.D., ("Dr. Vogel"), had been a practicing physician in the field of hematology and medical oncology for thirty-five years. In his report, Dr. Vogel estimates that he is visited by eighty to one hundred patients per week. Dr. Vogel primarily sees patients with "solid tumors," predominately of breast and lung

[1] Plaintiff Jenkins currently has a pending motion to amend her Complaint. The motion requests leave to add an allegation that she was also prescribed and took Zometa. Plaintiff Thorn's Complaint [Doc. 1] does not allege use of Zometa, nor has she moved to amend her Complaint in this case.

etiologies, as well as patients with hematologic malignancies involving multiple myeloma, lymphoma, and leukemia. In this case, Dr. Vogel was retained by Plaintiff Thorn's counsel and asked to, *inter alia*: explain his experience prescribing bisphosphonate drugs; provide an opinion as to whether or not bisphosphonate drugs cause ONJ; review internal Novartis documents and provide an opinion as to whether hematologists and medical oncologists were fully informed of the risk of ONJ in patients prescribed bisphosphonates; and discuss measures for reducing and preventing ONJ in bisphosphonate patients.

Novartis challenged Dr. Vogel's testimony in its 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. [Doc. 42 in Case No. 3:11-CV-342, Doc. 26 in Case No. 3:11-CV-373]. After briefing on this challenge was complete, the parties reached an agreement partially resolving the challenges to Dr. Vogel's testimony. The parties stated their agreement as:

> a. Based upon plaintiffs' agreement, Dr. Vogel would <u>not</u> present opinion testimony that:
>
> i. Pretreatment dental screenings could prevent ONJ;
>
> ii. Aredia labels violate FDA regulations;
>
> iii. Novartis had an improper intent, motive, or "state of mind" during relevant events.
>
> b. The Court will take under advisement Dr. Vogel's opinion that the August 2004 Zometa label was inadequate because it did not say that ONJ may occur "spontaneously," as opposed to following an invasive dental procedure. [Novartis] asserts that Dr. Vogel has not disclosed this opinion in his expert report. Plaintiff Thorn asserts that Dr. Vogel has disclosed this opinion. Plaintiff will submit the transcript of Dr. Vogel's expert testimony from the *Brodie* trial, Dr. Vogel's expert report, and an explanation of the opinion Dr. Vogel intends to

assert at the trial in *Thorn*. If the Court finds that this opinion was not disclosed in Dr. Vogel's expert report, plaintiffs must supplement his expert report and offer Dr. Vogel for a limited deposition.

[Doc. 99 in 3:11-CV-342 at 3; Doc. 103 in 3:11-CV-373 at 3 (emphasis added)].[2] Thus, the Court now turns to the remaining, pending issues, as agreed upon by the parties above.

II. ANALYSIS

The issues before the Court involve application of both the Federal Rules of Evidence and the Federal Rules of Civil Procedure. The Court will apply each in turn.

A. Federal Rule of Evidence 702

Federal Rule of Evidence 702 governs the admission of expert testimony. It provides:

> If 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, 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.

The Court finds that Dr. Vogel is qualified to offer testimony regarding his experience prescribing bisphosphonates and treating ONJ. His expertise as a medical doctor specializing in hematology and his experience in these areas is more than sufficient, and there appears to be no dispute on this point. As the parties' agreement reflects, Dr. Vogel's expertise is limited with regard to certain topics. The Court finds that the parties' agreement that Dr. Vogel will not testify as to pretreatment dental screenings as a ONJ prevention measure, Aredia labels violating

[2] Novartis further agreed to defer its challenge to Dr. Vogel's opinions regarding irrelevant scientific and/or medical articles published after Plaintiff Thorn ceased pamidronate therapy until trial.

FDA regulations, or Novartis's intent, motive, or "state of mind" during relevant events, is well-supported.

Accordingly, to the extent the Motion to Exclude objects to Dr. Vogel's testimony pursuant to Rule 702 of the Federal Rules of Evidence, it will be **GRANTED** as to the three lines of testimony discussed above – pretreatment dental screenings as a ONJ prevention measure, Aredia labels violating FDA regulations, or Novartis's intent – and it will be **DENIED** as to the other proposed testimony.

B. Disclosure of the Opinion Relating to Labeling and the Term "Spontaneous"

Novartis argues that Dr. Vogel failed to disclose an opinion which can be summarized as: Failure to use the term "spontaneous" on the bisphosphonate label rendered the 2004 Zometa label inadequate. Plaintiff Thorn maintains that this opinion was timely disclosed.

Rule 26 of the Federal Rules of Civil Procedure governs expert disclosures. Rule 26 requires that expert like Dr. Vogel provide a written report that includes: "(i) a complete statement of all opinions the witness will express and the basis and reasons for them; (ii) the facts or data considered by the witness in forming them; (iii) any exhibits that will be used to summarize or support them; (iv) the witness's qualifications, including a list of all publications authored in the previous 10 years; (v) a list of all other cases in which, during the previous 4 years, the witness testified as an expert at trial or by deposition; and (vi) a statement of the compensation to be paid for the study and testimony in the case."

In this case the parties do not dispute the timeliness of Dr. Vogel's first report, "Expert Report of James M. Vogel, M.D.," nor do they dispute the timeliness of Dr. Vogel's second report, "Rebuttal Report of James M. Vogel, M.D." Instead, Defendant argues that the opinion regarding the use of the term "spontaneous" in Zometa labeling was not included in either of the

reports. The Plaintiffs dispute the Defendant's position, and counsel for the Plaintiffs directed the Court to page forty of Dr. Vogel's first report, specifically to ¶¶ (b)(c).

The Court has reviewed the portions of paragraph forty cited to the Court, and the Court has further reviewed the entirety of paragraph forty and paragraph forty-one. The Court finds that these paragraphs do not disclose an opinion that failing to use the term "spontaneous" on the bisphosphonate label rendered the label inadequate.

In addition, the Court has reviewed the transcript of Dr. Vogel's testimony in Brodie v. Novartis, No. 4:10-CV-138 (E.D. Mo.), offered at trial on January 26, 2012. The Court initially finds that none of the attorneys who made an appearance in the trial transcript for Brodie are counsel of record in either of the cases pending before the undersigned. In addition, the Court finds that Dr. Vogel's brief reference that the 2004 Zometa label "didn't inform in terms of spontaneous development of ONJ" was the subject of an objection sustained by the Court but later allowed by the Brodie court. [Vogel Tr. at 25-26; 31]. The Court has considered the testimony provided in Brodie, but the Court finds that this opinion does not constitute sufficient disclosure in this case.

Accordingly, the Court finds the Zometa labeling opinion relating to using or failing to use the term "spontaneous" in 2004 Zometa labeling was/is not sufficiently disclosed in Dr. Vogel's expert reports. The Court, therefore, finds that Novartis's request that the Court order supplementation is well-taken, and it is **GRANTED**. The Court finds that if Plaintiff Thorn plans to use this opinion, Dr. Vogel must supplement his expert report with regard to this opinion

on or before **April 1, 2013**, and Plaintiff Vogel must offer Dr. Vogel for a limited supplemental deposition on or **before June 28, 2013**.[3]

III. CONCLUSION

In sum, the Court finds that James M. Vogel, M.D., is well-qualified to testify in this case to matters within his knowledge and experience. He will be precluded from offering testimony on pretreatment dental screenings as an ONJ prevention measure, Aredia labels violating FDA regulations, or Novartis's intent. Moreover, if Plaintiffs plan to offer the use of the term "spontaneous" in 2004 Zometa labeling, then they must supplement Dr. Vogel's disclosures and allow a deposition consistent with the Court's instructions above.

Accordingly, and for the reasons more fully stated above, the 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 **[Doc. 42 in Case No. 3:11-CV-342, Doc. 26 in Case No. 3:11-CV-373]** is **GRANTED IN PART** and **DENIED IN PART**, as stated above, with regard to the testimony of James M. Vogel, M.D.

IT IS SO ORDERED.

ENTER:

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

[3] However, as previously noted Plaintiff Thorn has, and her experts and her counsel have, repeatedly stated that she took only Aredia and not Zometa. [See, e.g., Ex. 3 from Oct. 4, 2012 hrg. (showing Ms. Thorn took only Aredia); Ltr. dated Jan. 18, 2012 from Sid Gilreath, counsel for Plaintiff Thorn (stating "Ms. Thorn . . . received monthly Aredia infusions . . . .")]. They have also failed to dispute Novartis's assertion of the same. [See, e.g. Novartis's Supp. Memo., Doc. 72 in No. 3:11-CV-373 ("Plaintiff Thorn asserts that she was only treated with Aredia . . . .")]. Accordingly, while the Court herein is ruling on the legal and Daubert issues presented, the Court is at a loss as to understand ultimate relevance of Dr. Vogel's testimony regarding labeling on Zometa – a drug that Plaintiff Thorn did not use – in the Thorn case.