UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

RUTH DOPSON-TROUTT and FRANK TROUTT

Plaintiffs,

v. **Case No: 8:06-cv-1708-T-24EAJ**

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant.

ORDER

This matter comes before the Court on the *Daubert* Motion to Exclude Certain Testimony of Plaintiffs' Expert Dr. Robert Marx (Doc. 67) filed by the Defendant, Novartis Pharmaceuticals Corporation ("Novartis") and the response (Doc. 76) filed by the Plaintiffs. The Court conducted a hearing on March 8, 2013.

I. Background

The instant products liability case involves Aredia and Zometa, drugs manufactured by Novartis. Ms. Dopson-Troutt was diagnosed with breast cancer in 1997, and while undergoing treatment, received infusions of both Aredia and Zometa. She reported having a tooth extracted in 2004 while receiving Zometa infusions. Ms. Dopson-Troutt then developed osteonecrosis of the jaw ("ONJ"), a condition in which part of the jawbone essentially dies.

Marx is a board-certified oral and maxillofacial surgeon at the University of Miami. He was one of the first physicians to allege a connection between bisphosphonates, such as Aredia and Zometa, and osteonecrosis of the jaw, and is widely cited on these topics in medical literature. By way of the instant motion, Novartis challenges the following "discrete aspects" of Marx's proposed expert testimony:

(a) opinions regarding Novartis's "intent, motives or state of mind" when the company was responding to the evidence regarding its product and osteonecrosis of the jaw;

(b) his belief that certain dental procedures – screening before treatment with Aredia and Zometa, and avoidance of invasive procedures during such treatment – can help prevent what Marx refers to as bisphosphonate-induced osteonecrosis of the jaw (henceforth, "BIONJ");

(c) criticism of the clinical trials of Aredia and Zometa;

(d) his contention that some of the patients in those trials had BIONJ;

(e) general causation opinions based on adverse event reports he has not reviewed; and

(f) opinions as to the biological mechanism that allegedly causes ONJ.[1]

II. Standards

In *Daubert v. Merrill Dow*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), the Supreme Court admonished trial courts to fulfill a gatekeeping role in the presentation of expert testimony. Federal Rule of Evidence 702 ("Rule 702") provides that:

> If scientific ... 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.

To guide district courts' assessments of the reliability of an expert's testimony, the Supreme Court has identified four factors that district courts should consider when assessing the reliability of an expert's testimony: (1) whether the expert's methodology has been tested or is

[1] In its motion, Novartis sets forth one additional category of testimony that it wishes to preclude: "general causation opinions not disclosed by plaintiffs previously in this case." (Doc. 67 at 2). However, Novartis never identifies any such testimony or makes any argument in regard to it. Accordingly, this order will not address that issue.

capable of being tested; (2) whether the theory or technique used by the expert has been subjected to peer review and publication; (3) whether there is a known or potential error rate of the methodology; and (4) whether the technique has been generally accepted in the relevant scientific community. See *id*. at 593–94, 113 S.Ct. 2786. At the same time, the Court has emphasized that these factors are not exhaustive and are intended to be applied in a "flexible" manner. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999).

From the reference to "scientific knowledge" and the condition that it "will assist the trier of fact," the Supreme Court, in *Daubert*, interpreted Rule 702 to require that expert testimony on scientific matters have the following inter-connected attributes:

- that it be "scientific," having a "grounding in the methods and procedures of science";
- that it bear the hallmarks of "knowledge," which "connotes more than subjective belief or unsupported speculation"; and
- that it "assist the trier of fact" or "fit" a matter at issue, meaning that it expresses scientific knowledge as to the proposition for which it is offered.

Daubert, 509 U.S. 579, 592, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). Expert testimony need not purport to reveal a known certainty, but it must be derived by the "scientific method," which requires that it be supported by appropriate validation based on what is known. *Id*.

III. Analysis

This Court adopts the analysis of Judge Presnell in his March 28, 2013 order granting in part and denying in part the *Daubert* motion to exclude certain testimony of Plaintiffs' expert Dr. Robert Marx entered in *Guenther v. Novartis*, Case No: 6:08-cv-Orl-31DAB, Doc. No. 101. The motions and responses in both cases are essentially identical.

Initially, it should be noted that the MDL court has already addressed several of these

issues. (Doc. 67-1). Specifically, the MDL court allowed Marx's testimony regarding the usefulness of pre-treatment dental screenings and avoidance of invasive dental procedures (category "b" above) and the alleged causal connection between Aredia/Zometa and ONJ (categories "e" and "f"). Novartis has not offered any basis for this Court to revisit those rulings.

Novartis does raise one argument specifically to Ms. Dopson-Troutt in regard to category "b". Novartis contends that Marx's opinions about dental pre-screenings and avoidance of invasive dental procedures are not relevant in the instant case because there are no dental records or testimony, other than that of Ms. Dopson-Troutt , as to the state of Ms. Dopson-Troutt's oral condition when she began taking Aredia and Zometa and it would be speculation to conclude that pre-screening would have shown need for any dental procedures. Assuming that Plaintiffs' counsel is able to demonstrate relevance at trial, Marx will be permitted to offer his opinions regarding the pre-screenings and invasive dental procedures.

As for the clinical trials (categories "c" and "d"), Plaintiffs' counsel asserted at the hearing that, contrary to the representations of defense counsel, Marx does not intend to opine about the way in which Novartis designed or conducted those trials. Instead he intends to discuss what occurred during those trials, and specifically to offer his opinion, based on medical records, as to whether some of the participants in those trials developed BIONJ. This appears to fall within his area of expertise, and his testimony on this point will be permitted.

Finally, in regard to Marx's opinions regarding Novartis's intent, motive, and state of mind (category "a", Plaintiffs' counsel appears to agree that such a topic would not be a proper topic for expert testimony. Accordingly, no such testimony will be permitted.

In consideration of the foregoing, it is hereby

ORDERED that the *Daubert* Motion to Exclude Certain Testimony of Plaintiffs' Expert

Dr. Robert Marx (Doc. 67) is **GRANTED IN PART and DENIED IN PART** as set forth above.

DONE and **ORDERED** in Tampa, Florida on April 3rd, 2013.

Susan C. Bucklew

SUSAN C. BUCKLEW
United States District Judge

Copies furnished to: Counsel of Record