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 after a hearing on the *Daubert* Motion to Exclude Certain Testimony of Plaintiffs' Expert Dr. Suzanne Parisian (Doc. 68) filed by the Defendant, Novartis Pharmaceuticals Corporation ("Novartis") and the Memorandum in opposition (Doc. 83) 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. In 2004, Ms. Dopson-Troutt reported having a tooth extracted while receiving Zometa infusions. She then developed osteonecrosis of the jaw ("ONJ"), a condition in which part of the jawbone essentially dies.

Dr. Suzanne Parisian is an M.D. and a board-certified pathologist who worked for the Food and Drug Administration ("FDA") for four years in the area of regulation of medical devices. She

is the founder of a regulatory and medical consulting firm that specializes in matters involving FDA regulations.

In the instant motion, Novartis first seeks to exclude all of Parisian's testimony on the grounds that the Plaintiffs have not established that her opinions are admissible under *Daubert* and Federal Rule of Evidence 702. Failing that, Novartis argues that Parisian should be precluded from offering testimony in the following areas: (a) corporate conduct; (b) legal conclusions; (c) regulatory compliance; (d) the issue of whether Novartis violated FDA rules or regulations with respect to its development, marketing, labeling, and monitoring of Aredia and Zometa; (e) ONJ causation or diagnosis and so-called "regulatory causation"; (f) her opinions regarding labeling; (g) her opinions regarding the state of mind of Novartis or the FDA; (h) her opinion that Novartis failed to act "reasonably" or follow unspecified industry standards; (i) Novartis's alleged failure to adequately monitor the safety of clinical trial patients; (j) ghostwriting and company funding of publications; and (k) other "irrelevant, unfairly prejudicial, and confusing testimony."

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 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. at 592. 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. Suzanne Parisian entered in *Guenther v. Novartis*, Case No: 6:08-cv-456-Orl-31DAB, Doc. No. 102. The motions and responses in both cases are essentially identical.

Although Novartis asserts in its motion that the entirety of Parisian's testimony should be excluded for failure to meet the *Daubert* standard, Doc.68 at 1, it never squarely addresses the topic. Insofar as Novartis truly intended to question Parisian's qualifications to offer any testimony whatsoever, the Court finds that Parisian is generally qualified by virtue of, *inter alia*, her tenure with the FDA and her professional experience in the field of regulatory approval to offer opinions regarding the four broad subject areas described in her expert report (Doc. 41-19): (1) the role, process and functions of the FDA and the responsibilities of pharmaceutical drug sponsors; (2) Novartis' conduct regarding New Drug Application approvals and post-approval of Aredia and Zometa; (3) Novartis's pharmacovigilance efforts, investigation of ONJ and interactions with the FDA; and (4) Novartis's communication of ONJ risks to health care providers.

The majority of Novartis's motion is spent protesting allegedly objectionable testimony offered by Parisian in other trials or in depositions taken in other cases. At this juncture, the Court cannot determine whether the Plaintiffs will even seek to have Parisian repeat such testimony in this case, much less whether that testimony, in context, would be permitted.

The Plaintiffs have stipulated that, unless Novartis opens the door, Parisian will not be asked to testify regarding the following areas as to which Novartis has raised concerns: corporate state of mind (category "g" above"), industry standards (category "h"), monitoring of clinical trials (category "i"), and ghostwriting (category "j"). Thus, the motion is moot as to those categories.

Similarly, in regard to category "e", the Plaintiffs also stipulate that they will not ask Parisian to testify about medical causation. However, Plaintiffs' counsel stated that he may seek to have Parisian testify regarding what Novartis refers to as "regulatory causation." This line of

inquiry involves 21 C.F.R. § 201.57, an FDA regulation having to do with drug labels, and which provides in pertinent part that:

> [T]he labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established.

21 C.F.R. § 201.57(c)(6)(i). Novartis argues that allowing Parisian to testify regarding its compliance with that regulation is effectively the same as allowing her to testify regarding medical causation, allowing her to make an end run around her stipulation. (In other words, Novartis contends that to opine as to whether the label should have been revised, Parisian would need to discuss whether there was a causal association between Zometa and ONJ, which is essentially the same as discussing whether there was a causal relationship between Zometa and ONJ.) Plaintiffs' counsel responds that "causal association" is an FDA term, rather than a medical term, and that Parisian as an FDA compliance expert should be permitted to testify in regard to that term. Aside from its origin, however, Plaintiffs' counsel offers nothing to meaningfully distinguish "causal association" from medical causation, at least in terms of the expertise required to analyze it. On this record, Parisian will not be permitted to offer opinions regarding any alleged "causal association" between ONJ and Aredia or Zometa.

Novartis's remaining points requires less discussion. Assuming that Parisian's assessment of Novartis's "corporate conduct" (category "a") has some relevance to the instant case, she will be permitted to testify to it, assuming that her opinions are otherwise properly supported. Obviously, Parisian will not be permitted to offer legal conclusions (category "b"), *see, e.g., Cook ex rel. Estate of Tessier v. Sheriff of Monroe County, Fla.*, 402 F.3d 1092, 1113 (11th Cir. 2005), but an opinion is not objectionable just because it embraces an ultimate issue to be decided by the trier of fact, F.R.E. 704(a).

Finally, regulatory compliance (category "c"), alleged violations of FDA rules or regulations in regard to Zometa (category "d") and drug labeling (category "f") all appear to fall within Parisian's area of expertise. Subject to the usual requirements, such as relevance and evidentiary support, Parisian will be permitted to offer expert testimony in these areas. Any other concerns Novartis has in regard to "irrelevant, unfairly prejudicial and confusing testimony" (category "k") can be addressed at trial or cured by way of cross-examination.

In consideration of the foregoing, it is hereby

ORDERED that the *Daubert* Motion to Exclude Certain Testimony of Plaintiffs' Expert Dr. Susan Parisian (Doc. 68) is **GRANTED IN PART and DENIED IN PART** as set forth above.

DONE and **ORDERED** in Tampa, Florida on April 2, 2013.

Susan C. Bucklew

SUSAN C. BUCKLEW
United States District Judge

Copies furnished to: Counsel of Record