UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	))))	**MDL No. 16-2740** **SECTION: "H" (5)**
This document relates to: Elizabeth Kahn, 16-17039	))	

ORDER AND REASONS

Before the Court is a Motion to Exclude Testimony of Michael Kopreski (Doc. 10938). The Court held oral argument on the Motion on October 7, 2020. For the following reasons, the Motion is **DENIED**.

BACKGROUND

Plaintiffs in this multidistrict litigation ("MDL") are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel,[1] that Plaintiffs were administered for the treatment of breast cancer or other forms of cancer. Among these companies are Defendants sanofi-aventis U.S. LLC and Sanofi U.S. Services Inc. (collectively, "Sanofi" or "Defendants"). Plaintiffs allege that the drug caused permanent alopecia—in other words, permanent hair loss. Plaintiffs bring claims of failure to warn, negligent misrepresentation, fraudulent misrepresentation, and more. The first bellwether trial was held in September 2019, and the second is set for February 1, 2021.

In the instant Motion, the second bellwether plaintiff, Elizabeth Kahn ("Plaintiff"), moves to exclude the testimony of Dr. Michael Kopreski, who formerly worked as the head of oncology pharmacovigilance at Sanofi. As the

[1] Docetaxel is the generic version of Taxotere.

parties explain, Dr. Kopreski served as a 30(b)(6) witness for Sanofi. In the first bellwether trial, the Plaintiffs' Steering Committee (the "PSC") asked Sanofi to produce a 30(b)(6) witness to identify cases of "persisting alopecia" in patients from "TAX 316," a term with great significance in this MDL.[2]

TAX 316 was a 1997 Sanofi clinical trial testing the efficacy of Taxotere in the treatment of adjuvant breast cancer. As part of the trial, 744 patients were given a Taxotere regimen that included Taxotere, Adriamycin, and Cyclophosphamide. Researchers called this the "TAC" arm of the study. The other arm of the study was a control/comparator arm—the "FAC" arm. In this arm, patients received a chemotherapy agent called Fluorouracil instead of Taxotere. The participants were followed for 10 years after their treatment. During this period, researchers tracked ongoing adverse events, including alopecia. The study, as reported to the FDA, concluded that roughly 4 percent of the Taxotere patients—29 of the 744—experienced "ongoing alopecia."

After reviewing the TAX 316 data for purposes of the 30(b)(6) deposition, however, Dr. Kopreski reported that only 6 of the patients who received Taxotere experienced "persistent alopecia as defined by Judge North" in this MDL.[3] Consistent with the Master Complaint, Magistrate Judge Michael

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[2] Doc. 11149-19 at 8. Specifically, in a deposition notice dated August 31, 2018, the PSC designated the following as subject matter for the deposition: "The identify of each patient, by reference number, who reportedly experienced persisting alopecia while enrolled as a participant in the TAX316 and/or TAX301/GEICAM and/or NABHOLTZ Phase II Study of Docetaxel, Doxorubicin, and Cyclorubicin as First-Line Chemotherapy for Metastatic Breast Cancer studies, *so that it can be determined whether each such patient is included in Table 1*." *Id.* (emphasis added). In Table 1, the PSC listed certain adverse event reports "regarding persisting alopecia" associated with Taxotere. *Id.* at 4–5. Similarly, in a deposition notice dated November 20, 2018, the PSC designated the following as subject matter for the deposition: "The findings regarding alopecia as a TEAE [Treatment Emergent Adverse Event] persisting into the 10-year follow-up period in TAX316 as provided in the Clinical Study Report on September 9, 2020, *so that it can be determined whether each such patient is included in Table 2*." Doc. 10938-9 at 13 (emphasis added). In Table 2, the PSC listed certain adverse event reports "regarding persisting alopecia" associated with Taxotere. *Id.* at 4–5.

[3] Doc. 10938-10 at 22.

North had ruled that "[f]or all purposes of the [30(b)(6)] deposition, the term 'persistent alopecia' shall mean that which remains six months after chemotherapy ended and without resolution."[4]

Leading up to the first bellwether trial, the PSC filed a motion seeking to exclude the testimony of Sanofi's expert witnesses who relied upon Dr. Kopreski. The PSC took issue with Dr. Kopreski's finding that only 6, or 1 percent, of the TAX 316 patients suffered persistent alopecia. The PSC argued that this conflicted with what Sanofi reported to the FDA, which was that 4 percent of the TAX 316 patients suffered ongoing alopecia.

Denying the motion, the Court reasoned that the expert witnesses reasonably relied on Dr. Kopreski's analysis. The Court noted that Dr. Kopreski had been deposed three times, and the depositions spanned six days and more than 25 hours. Accordingly, the Court allowed the experts to testify. Notably, Dr. Kopreski did not testify live in that trial. Instead, counsel played excerpts of videotaped deposition testimony for the jury.

Now, for her trial, Plaintiff Kahn seeks to exclude the testimony of Dr. Kopreski himself, arguing that he offers expert opinions and testimony based upon materials provided to him by counsel for Sanofi. Defendants oppose her Motion, arguing that Dr. Kopreski is testifying as a fact witness.

LEGAL STANDARD

Federal Rule of Evidence 701 governs lay witness testimony. Rule 701 provides as follows:

> If a witness is not testifying as an expert, testimony in the form of an opinion is limited to one that is:
>
> (a) rationally based on the witness's perception;

[4] Doc. 3473 at 2.

> (b) helpful to clearly understanding the witness's testimony or to determining a fact in issue; and
>
> (c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702.[5]

Federal Rule of Evidence 702 governs expert witness testimony:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise 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.[6]

As the Fifth Circuit has explained, the difference between lay and expert witness testimony is that "lay testimony results from a process of reasoning familiar in everyday life, while expert testimony results from a process of reasoning which can be mastered only by specialists in the field."[7] Notably, "Rule 701 does not exclude testimony by corporate officers of business owners on matters that relate to their business affairs, such as industry practices."[8]

[5] FED. R. EVID. 701.
[6] FED. R. EVID. 702.
[7] United States v. Yanez Sosa, 513 F.3d 194 (5th Cir. 2008).
[8] Nat'l Hispanic Circus, Inc. v. Rex Trucking, Inc., 414 F.3d 546, 551–52 (5th Cir. 2005).

LAW AND ANALYSIS

Plaintiff argues that Dr. Kopreski is offering expert opinions even though Sanofi did not disclose him as an expert. Plaintiff avers that in evaluating the results of TAX 316, Dr. Kopreski used a methodology that he did not identify in an expert report. Plaintiff further argues that Dr. Kopreski is not qualified to opine on TAX 316. According to Plaintiff, Sanofi has failed to demonstrate that Dr. Kopreski knows how to assess clinical trial data.

In addition, Plaintiff argues that Dr. Kopreski is offering unreliable litigation-driven testimony. She emphasizes that Dr. Kopreski reviewed only information that counsel gave him, which included patient data for only the 29 TAX 316 patients who were classified as having "ongoing alopecia." He admittedly did not review the patient data for all 744 Taxotere patients in TAX 316. Lastly, Plaintiff takes issue with the fact that two of Sanofi's experts rely on Dr. Kopreski—namely, Dr. Janet Arrowsmith and Dr. John Glaspy. Plaintiff avers that these experts must be excluded, although she notes that she has filed separate motions relating to these experts.

In response, Sanofi characterizes Dr. Kopreski as a fact witness. Sanofi emphasizes that he offers testimony about information known or available to Sanofi and on matters squarely within his previous responsibilities at Sanofi. According to Defendants, Dr. Kopreski applied his pharmacovigilance experience to determine which cases of "ongoing alopecia" from TAX 316 should be considered cases of "persistent alopecia" for purposes of this MDL. Lastly, Sanofi points to the first bellwether trial and argues that the Court has already rejected the argument that Dr. Kopreski is unqualified to offer the testimony at issue. Sanofi contends that this Court has already determined that a jury is capable of understanding and weighing Dr. Kopreski's testimony.

After reviewing what Dr. Kopreski did in assessing the TAX 316 data, the Court concludes that he is a fact witness offering appropriate opinion testimony. The Court will explain his work. If a TAX 316 patient had alopecia at the time she withdrew from the TAX 316 study, her alopecia was recorded as "ongoing" for purposes of TAX 316. In this MDL, however, the Master Complaint alleges that permanent chemotherapy-induced alopecia is alopecia that persists six months after treatment. Dr. Kopreski then looked at the 29 reports of ongoing alopecia from the TAC arm of TAX 316 to see if any of these reports involved patients who were deemed to have "persistent alopecia" as defined by Judge North for the 30(b)(6) deposition. Dr. Kopreski did that work and determined that only 6 had persistent alopecia despite the study records showing that they had ongoing alopecia.

For example, Dr. Kopreski explained that a certain patient, Patient No. 15002, took Taxotere in August 1998.[9] Soon after this, she was withdrawn from the study after developing gastrointestinal mucositis. In September 1998, she began an alternative chemotherapy regimen that did not include Taxotere. At a follow up visit in November 1998, her alopecia was recorded as ongoing. After this, however, she was no longer followed as part of the TAX 316 study because she had changed her chemotherapy regimen. Therefore, after November 1998, no further alopecia assessments were made, and she was "lost to follow up."

Similarly, Patient No. 15808 was no longer followed after three months. She finished her Taxotere treatments in September 1998, was recorded as having ongoing alopecia in December 1998 when she was diagnosed with a breast cancer relapse, and then she was no longer followed in TAX 316.

[9] Doc. 10938-10.

For obvious reasons, then, Sanofi asked Dr. Kopreski to parse through the 29 reports of "ongoing alopecia" before responding to Plaintiff's request that Sanofi identify cases of "persisting alopecia" in patients from TAX 316.[10] The Court does not see this as an expert analysis. "[T]he fact that he drew particular opinions and projection for the purpose of this case does not make him an 'expert' within the meaning of Federal Rule of Evidence 702."[11]

"Courts have permitted witnesses to give lay opinion testimony about a business's policies, practices, or procedures, based on an after-the-fact review or analysis of documents or facts, if the witness's testimony derived from personal knowledge gained through participation in the business's day-to-day affairs."[12] Dr. Kopreski conducted an analysis "derived from duties he held" at Sanofi.[13] As the head of the oncology pharmacovigilance department at Sanofi, Dr. Kopreski directly oversaw drug safety efforts for marketing and clinical trials of Sanofi's products, including Taxotere.[14] He reviewed safety documents for Taxotere, including Clinical Study Reports, Summaries of Clinical Safety, and Clinical Overviews, all of which required review and analysis of adverse events.[15] Among his regular duties, too, was reporting on information known or reasonably available to Sanofi. For example, in responding to the French Health Products Safety Agency in 2011, Dr. Kopreski and his team analyzed adverse event reports for cases of alopecia persisting one year after the completion of chemotherapy.[16] Upon Plaintiff's request, Dr. Kopreski similarly tried to take the results of TAX 316 and put them in the context of this MDL.

[10] The Court emphasizes that TAX 316 focused on the efficacy of Taxotere. The study tracked adverse event reports only as an ancillary issue.
[11] United States v. Valencia, 600 F.3d 389, 416 (5th Cir. 2015)).
[12] United States v. Kerley, 784 F.3d 327, 337 (6th Cir. 2015) (citing *Valencia*, 600 F.3d 389).
[13] *Valencia*, 600 F.3d at 416.
[14] Doc. 11149 at 3.
[15] *Id.* at 4.
[16] *Id.* at 10.

The Court notes that while Dr. Kopreski will be allowed to offer the opinions at issue, the Court is concerned about Plaintiff's ability to adequately cross-examine Dr. Kopreski about his analysis. Plaintiff must be able to conduct a robust cross-examination of him in a way that is conducive for the jury. Accordingly, the Court will address options with counsel prior to trial.

CONCLUSION

For the foregoing reasons, Motion to Exclude Testimony of Michael Kopreski (Doc. 10938) is **DENIED**.

New Orleans, Louisiana this 21st day of October, 2020.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE