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 Plaintiff's Motion to Exclude Certain Opinions of Ellen T. Chang, Sc.D. (Doc. 10934). The Court held oral argument on the Motion on October 7, 2020. For the following reasons, the Motion is **GRANTED IN PART** and **DENIED IN PART.**

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 trial is set for 2021.[2]

In the instant Motion, Plaintiff Elizabeth Kahn, the second bellwether plaintiff, moves to exclude certain testimony of Dr. Ellen T. Chang. Dr. Chang

[1] Docetaxel is the generic version of Taxotere.
[2] The second trial was continued due to the COVID-19 pandemic.

is an epidemiologist specializing in cancer, and Sanofi intends to call her as a witness at trial. Sanofi opposes Plaintiff's Motion.

LEGAL STANDARD

The admissibility of expert testimony is governed by Federal Rule of Evidence 702, which provides as follows:

> 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.[3]

The current version of Rule 702 reflects the Supreme Court's decisions in *Daubert v. Merrell Dow Pharms., Inc.*[4] and *Kumho Tire Co. v. Carmichael*.[5] The threshold inquiry in determining whether an individual may offer expert testimony under Rule 702 is whether the individual has the requisite qualifications.[6] After defining the permissible scope of the expert's testimony, a court next assesses whether the opinions are reliable and relevant.[7] As the

[3] FED. R. EVID. 702.
[4] 509 U.S. 579 (1993).
[5] 526 U.S. 137 (1999).
[6] Wagoner v. Exxon Mobil Corp., 813 F. Supp. 2d 771, 799 (E.D. La. 2011). *See also* Wilson v. Woods, 163 F.3d 935, 937 (5th Cir. 1999) ("A district court should refuse to allow an expert witness to testify if it finds that the witness is not qualified to testify in a particular field or on a given subject.").
[7] *See* United States v. Valencia, 600 F.3d 389, 424 (5th Cir. 2010). *See also* Wellogix, Inc. v. Accenture, L.L.P., 716 F.3d 867, 881–82 (5th Cir. 2013).

"gatekeeper" of expert testimony, the trial court enjoys broad discretion in determining admissibility.[8]

First, to assess reliability, a court considers whether the reasoning or methodology underlying the expert's testimony is valid.[9] The party offering the testimony bears the burden of establishing its reliability by a preponderance of the evidence.[10] Courts should exclude testimony based merely on subjective belief or unsupported speculation.[11] Courts must, however, give proper deference to the traditional adversary system and the role of the jury within that system.[12] "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."[13] After assessing reliability, a court evaluates relevance.[14] In doing so, a court must determine whether the expert's reasoning or methodology "fits" the facts of the case and will thereby assist the trier of fact in understanding the evidence.[15]

Federal Rule of Evidence 703 further provides that an expert may offer opinions based on otherwise inadmissible facts or data but only if (1) they are of the kind reasonably relied upon by experts in the particular field; and (2) the testimony's probative value substantially outweighs its prejudicial effect.[16]

LAW AND ANALYSIS

Plaintiff asks the Court to exclude three areas of Dr. Chang's testimony: (1) her testimony regarding the results of the TAX 316 clinical study; (2) her

[8] *Wellogix*, 716 F.3d at 881.
[9] *See Daubert*, 509 U.S. at 592–93.
[10] *See* Moore v. Ashland Chem. Inc., 151 F.3d 269, 276 (5th Cir. 1998).
[11] *See Daubert*, 509 U.S. at 590.
[12] *See id.* at 596.
[13] *Id.*
[14] Burst v. Shell Oil Co., 120 F. Supp. 3d 547, 551 (E.D. La. June 9, 2015).
[15] *Id.*
[16] FED. R. EVID. 703.

testimony regarding whether other medications can cause permanent chemotherapy-induced alopecia; and (3) her testimony regarding the "forms and risk factors" of alopecia. The Court will address each argument in turn.

I. Testimony Regarding TAX 316

Dr. Chang opines that the results of the TAX 316 clinical trial do not support a causal finding between Taxotere and permanent alopecia.[17] She found that the study did not specifically assess permanent or irreversible alopecia and that most patients classified as having "ongoing" alopecia did not have irreversible or even long-lasting alopecia. Plaintiff argues that Dr. Chang's analysis of the trial data is inadmissible. Specifically, Plaintiff argues that Dr. Chang's analysis is unreliable because Sanofi provided her only limited data relating to TAX 316. In response, Sanofi avers that Dr. Chang analyzed data relating to all 1,480 participants in the TAX 316 trial.

As this Court has explained, the purpose of the TAX 316 clinical trial was to test the efficacy of Taxotere in the treatment of adjuvant breast cancer. The participants were followed for 10 years after their treatment. During this period, researchers tracked 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." Sanofi notes, however, that the study classified a patient as having "ongoing alopecia" if she had alopecia at the time that researchers stopped monitoring her. For example, if a patient had alopecia at the time she prematurely withdrew from the TAX 316 trial, she was classified as having "ongoing alopecia." Sanofi avers, therefore, that "ongoing alopecia" does not equate to "persistent alopecia."

[17] For background on TAX 316, see this Court's Order and Reasons dated October 21, 2020 (Doc. 11332).

For these reasons, then, Sanofi asked its experts to parse through the 29 reports of "ongoing alopecia." After doing so, Dr. Chang found that 9 patients—6 from the Taxotere arm of the study and 3 from the non-Taxotere arm—possibly had persistent or irreversible alopecia. While this work was performed in the context of this litigation, it is not inherently unreliable as Plaintiff argues. Indeed, Dr. Chang did not focus only on the 29 Taxotere patients reported as having "ongoing alopecia," but she evaluated patients outside of this group as well. The Court, therefore, finds her testimony sufficiently reliable. To the extent that her work differs from what was reported to the FDA, Plaintiff can explore this before the jury on cross-examination.

II. Testimony Regarding Whether Other Medications Can Cause Permanent Chemotherapy-Induced Alopecia

Dr. Chang opines that numerous medications have been reported to cause alopecia. She states that "[b]ecause cancer patients often use concomitant medications other than chemotherapy, these drugs could act as potential confounders of observed associations between anticancer chemotherapy use and irreversible or permanent alopecia."[18] Plaintiff argues that the Court should preclude Dr. Chang from "inferring general causation" as to any non-Taxotere drug and permanent alopecia.[19] Plaintiff argues that Dr. Chang did not conduct a full literature search to support any such opinion. In response, Sanofi notes that Dr. Chang reviewed 228 articles and abstracts and cites 13 of these to support her opinion that permanent alopecia has been associated with non-Taxotere chemotherapy regimens.

To the extent that Plaintiff argues that Sanofi must prove general causation with respect to non-Taxotere drugs, the Court rejects this argument

[18] Doc. 10934-2 at 29.
[19] Doc. 10934-1 at 9.

for the reasons provided in its Order and Reasons on Plaintiff's Motion to Exclude Testimony of Dr. John Glaspy, M.D.[20] Further, the Court finds that Dr. Chang has conducted a sufficient search of the literature to support her opinions. The Court, however, will not allow Dr. Chang to testify about specific medications that Plaintiff Kahn did not take. Such testimony would be irrelevant in this case. Dr. Chang must limit her testimony to the medications or types of medications that Plaintiff Kahn has taken.

III. Testimony Regarding "Forms and Risk Factors" of Alopecia

Lastly, Plaintiff argues that Dr. Chang is not qualified to testify regarding the "forms and risk factors" of alopecia. Plaintiff emphasizes that Dr. Chang is not a medical doctor and that she has never studied alopecia outside the context of this litigation. Plaintiff further argues that Dr. Chang did not conduct a thorough literature search, rendering her testimony in this area unreliable. In response, Sanofi avers that as an epidemiologist, Dr. Chang need not be a medical doctor to offer expert testimony on alopecia.

Considering the nature of epidemiology, courts have rejected arguments like Plaintiff's argument here.[21] Analyzing studies to assess a relationship between a drug and a disease is "precisely [an epidemiologist's] area of expertise."[22] As Plaintiff acknowledges, Dr. Chang is an epidemiologist, and in her work, she observes data to measure disease occurrences and patterns. That is what she has done in this case.

---

[20] Doc. 11780.

[21] Deutsch v. Novartis Pharmaceuticals Corp., 768 F. Supp. 2d 420, 455 (E.D.N.Y. 2011) ("[The epidemiologist] does not need to be an oncologist or a dental surgeon or any other type of medical doctor to analyze the data and studies for a relationship between a pharmaceutical drug and a disease. As a pharmacoepidemiologist, designing, executing, analyzing, and evaluating studies on this very subject is precisely [the epidemiologist's] area of expertise."); In re Mirena IUD Prods. Liab. Litig., 169 F. Supp. 3d 396, 484 (S.D.N.Y. 2016) ("[A]n epidemiologist does not need to be an expert in a particular field to analyze the data or studies showing a relationship between a drug and a disease.").

[22] *See Deutsch*, 768 F. Supp. 2d at 455.

To the extent Plaintiff challenges Dr. Chang's literature review, the Court rejects this argument as well. Plaintiff suggests that Dr. Chang draws sweeping conclusions based on limited data in the literature. To the contrary, however, Dr. Chang's report cites hundreds of sources, and her alopecia opinions cite several sources, not just two sources, as Plaintiff avers.[23] Also, Dr. Chang's deposition testimony makes clear that she familiarized herself with the literature and appropriately relied upon it. Plaintiff takes issue with Dr. Chang's statement that androgenetic alopecia is the most common type of alopecia. Dr. Chang testified, however, that it is commonly stated in the literature that androgenetic alopecia is the most common type of alopecia.[24] While she admitted that she does not have a dermatologist's perspective on the most common type of alopecia, she explained that she consulted the literature to answer this "epidemiology question."[25] The Court, then, finds that Dr. Chang has based her testimony on sufficient data, and the Court will permit her to testify on the forms and risk factors of alopecia.

CONCLUSION

For the foregoing reasons, Plaintiff's Motion to Exclude Certain Opinions of Ellen T. Chang, Sc.D. (Doc. 10934) is **GRANTED IN PART** and **DENIED IN PART**. Dr. Chang's testimony will be limited as described in this opinion.

New Orleans, Louisiana, this 1st day of February, 2021.

[23] *See* Doc. 10934-2 at 26–28.
[24] Doc. 10934-5 at 22.
[25] *See id.* at 23.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE