

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

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

ORDER AND REASONS

Before the Court is Plaintiff’s Motion to Exclude Testimony of Professor L.J. Wei (Doc. 10940). 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 trial is set for 2021.²

In the instant Motion, Plaintiff Elizabeth Kahn, the second bellwether plaintiff, moves to exclude the testimony of Professor Lee-Jen Wei. Dr. Wei is a biostatistician, and Sanofi intends to call him as an expert witness at trial. Sanofi opposes Plaintiff’s Motion.

¹ Docetaxel is the generic version of Taxotere.

² The second trial was continued due to the COVID-19 pandemic.

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

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).

⁸ *Wellogix*, 716 F.3d at 881.

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 raises three challenges to Dr. Wei's testimony. Specifically, she argues (1) that Dr. Wei should not be allowed to opine on whether other drugs can cause permanent alopecia as he has not studied other drugs; (2) that his opinions on the TAX 316 clinical trial are unreliable; and (3) that he should not

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.

be allowed to rely on the opinions of others since he did not validate their work. The Court will address each argument in turn.

I. Testimony Regarding Other Drugs

Plaintiff moves to exclude testimony from Dr. Wei about whether other drugs can cause permanent chemotherapy-induced alopecia (“PCIA”). Plaintiff emphasizes that Dr. Wei has not addressed whether a statistically significant association exists between permanent alopecia and any other drug. In response, Sanofi concedes that Dr. Wei will not opine on possible alternative causes of Plaintiff Kahn’s hair loss. Since Sanofi concedes that Dr. Wei did no work in this area and will not offer testimony on this, the Court need not address this argument.

II. Testimony Regarding TAX 316

Next, Plaintiff criticizes Dr. Wei’s opinions on the TAX 316 clinical trial.¹⁷ Plaintiff avers that Dr. Wei did not consider the study protocols and that he examined data for only 45 of the 1,491 patients who participated in TAX 316. In response, Sanofi avers that Dr. Wei did consider the study protocols and that Dr. Wei focused on the same 45 patients that were the focus of Plaintiff’s expert, Dr. David Madigan.

Having reviewed Dr. Wei’s report, the Court finds that his TAX 316 opinions are based on sufficient data. In his report, Dr. Wei references and even quotes the study protocols.¹⁸ Also, he acknowledges that TAX 316 involved 1,491 patients.¹⁹ He explains that only 1,480 of these patients received treatment, with 744 receiving a Taxotere regimen and 736 receiving

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

¹⁸ Doc. 11103-1 at 11 (“The protocols for each study discuss the need to follow ‘ongoing clinical adverse experiences possibly or probably related to study drug at the time of End of Chemotherapy.’”).

¹⁹ *Id.* at 13.

a non-Taxotere regimen.²⁰ He explains that the final data from the study reports that 45 of the patients suffered “ongoing” alopecia—29 in the Taxotere arm of the study and 16 in the non-Taxotere arm.²¹ Since Plaintiff’s expert, Dr. David Madigan, found a statistically significant difference between these figures, Dr. Wei focuses on these figures in forming his rebuttal opinion.²² This narrow focus does not render his opinion unreliable.

III. Testimony Based on the Work of Others

Lastly, Plaintiff argues that Dr. Wei relied on the work of others without validating it. Plaintiff avers that Dr. Wei owns a company called Blue Null, which employs several statisticians, and that Dr. Wei “used potentially five other statisticians to perform calculations for his report.”²³ In response, Sanofi acknowledges that Dr. Wei relied on the work of Dr. James Wu and that Dr. Wei analyzed Dr. Wu’s work before accepting it.

Under Federal Rule of Evidence 703, an expert may offer opinions based on otherwise inadmissible facts or data 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.²⁴ At his deposition, Dr. Wei explained that he does not work alone.²⁵ He explained that when working with lawyers, “the contract is not with me.”²⁶ The contract is with his group, Blue Null, and he “is just part of it.”²⁷ He further testified that in his practice, he works with his team and does not “fly solo.”²⁸

²⁰ *Id.*

²¹ *Id.*

²² *See id.* at 23.

²³ Doc. 10940-1 at 11.

²⁴ FED. R. EVID. 703.

²⁵ Doc. 10940-3 at 16–17.

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

Despite this testimony, Dr. Wei's report makes no mention of Blue Null or any statisticians that work for Blue Null. This is improper. However, at his deposition, Dr. Wei made clear that in his practice, he typically relies on the work of his colleagues at Blue Null. He testified that he relied on certain work by Dr. James Wu in connection with this MDL and that he validated Dr. Wu's work.²⁹ His reliance on his colleagues for purposes of this litigation, therefore, is reasonable under FRE 703. The Court further sees no prejudice to Plaintiff, given that Dr. Wei disclosed at his deposition in December of 2019 that Blue Null works as a team. The Court, then, will not limit Dr. Wei's testimony due to the fact that he collaborated with his team.

CONCLUSION

For the foregoing reasons, Plaintiff's Motion to Exclude Testimony of Professor L.J. Wei (Doc. 10940) is **DENIED**.

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



JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE

²⁹ *Id.* at 35–36.