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 Defendants' Motion to Exclude Expert Testimony of Dr. Laura Plunkett (Doc. 10918). 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 May 24, 2021.[2]

In the instant Motion, Sanofi moves to exclude the testimony of Dr. Laura Plunkett. Dr. Plunkett is pharmacologist and toxicologist. Plaintiff

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

Elizabeth Kahn, the second bellwether plaintiff, plans to call Dr. Plunkett as a witness at trial. Plaintiff Kahn opposes Sanofi'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

Sanofi raises four challenges to Dr. Plunkett's testimony. Sanofi challenges (1) her opinion that Taxotere is "more toxic than Taxol," (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.

opinions that, according to Sanofi, are "causation-based," (3) her opinion that permanent chemotherapy-induced alopecia ("PCIA") is distinguishable from drug-induced alopecia ("DIA"); and (4) her opinions based on the "weight-of-the-evidence" methodology. This Court will consider each argument in turn.

I. Testimony that Taxotere Is "More Toxic" than Taxol

Sanofi argues that Dr. Plunkett's "more toxic" opinion is irrelevant and misleading. Sanofi emphasizes that for the first bellwether trial, the *Earnest* trial, this Court excluded Dr. Plunkett's "more toxic" opinion, and Sanofi avers that her opinion has not changed since that trial. In response, Plaintiff does not address the fact that this Court previously excluded Dr. Plunkett's "more toxic" opinion, and Plaintiff does not articulate why a different ruling is warranted here. Instead, she focuses on showing that this opinion is reliable.

In the *Earnest* trial, the Court issued the following ruling:

> The second opinion Defendants attack is that Taxotere is "more toxic" than Taxol. Defendants argue that this opinion is irrelevant and would be unhelpful to the jury. They aver that the opinion does not "fit" the facts of this case, which is about permanent hair loss. The Court agrees. If the jury were to hear this opinion, it may assume without a sufficient basis for doing so that if Taxotere is more toxic than Taxol, Taxotere is more likely to cause permanent hair loss. The Court cautions, however, that if Defendants present evidence about Taxotere's level of toxicity, the Court will reassess whether Dr. Plunkett's "more toxic" opinion is appropriate for the jury to hear.[17]

The Court sees no reason to deviate from this ruling for Plaintiff Kahn's trial. When asked at her deposition if her "more toxic" opinion has changed since the Earnest trial, Dr. Plunkett testified that "there's no new evidence that I would

[17] Doc. 8097 at 6.

point to."[18] At another deposition, she stated that "I don't believe I changed that part of my report much."[19] Therefore, the Court will again preclude Dr. Plunkett from testifying that Taxotere is more toxic than Taxol.

II. "Causation-Based" Testimony

Sanofi next takes issue with the following two opinions from Dr. Plunkett: (1) that Taxotere carries an "independent risk" of permanent alopecia; and (2) that when used in combination with other drugs, Taxotere is a "substantial contributing factor" to permanent alopecia. Sanofi argues that these are causation opinions and that Dr. Plunkett did not conduct the appropriate test to support any causation opinions. In response, Plaintiff avers that Dr. Plunkett is not offering causation opinions and need not have conducted the test that Sanofi identifies.

After reviewing Dr. Plunkett's report, the Court will not permit Dr. Plunkett to opine that Taxotere *carries* an independent risk of permanent alopecia. Dr. Plunkett did not conduct an analysis to assess general causation, so she may not suggest to the jury that Taxotere can cause permanent alopecia. To the Court, stating that Taxotere carries an independent risk of permanent alopecia is indistinguishable from stating that Taxotere alone can cause alopecia. Dr. Plunkett, therefore, must take care to state only that Taxotere has been *associated* with an independent risk of permanent hair loss.

For similar reasons, the Court will not permit Dr. Plunkett to opine that when used in combination with other drugs, Taxotere is a "substantial contributing factor" to permanent alopecia. This opinion would "invade the

[18] Doc. 10918-2 at 34.
[19] Doc. 10918-6 at 9.

province of the jury."[20] The jury will be tasked with determining proximate causation, and in the *Earnest* trial, the jury was instructed, per Louisiana law, to consider whether "Defendants' conduct was a 'substantial contributing factor' in bringing about the [alleged injury]."[21] If Dr. Plunkett were to tell the jury that Taxotere was a "substantial contributing factor" that led to permanent alopecia in patients who took combination regimens, the jury may see this as a direct answer to the question of proximate causation. For these reasons, Dr. Plunkett may not testify that in combination regimens, Taxotere is a "substantial contributing factor" to permanent alopecia.

III. Testimony Regarding PCIA and DIA

Next, Sanofi challenges Dr. Plunkett's testimony that permanent chemotherapy-induced alopecia ("PCIA") is distinguishable from drug-induced alopecia ("DIA") because DIA is not permanent. Sanofi avers that Dr. Plunkett is not qualified to offer this opinion and that because the opinion is vague, it will be unhelpful to the jury. In response, Plaintiff explains that Dr. Plunkett has reviewed the literature and disputes that her opinions are vague.

The Court finds that Dr. Plunkett is qualified to offer this opinion. As a toxicologist, she has the requisite expertise to review and opine on what the literature provides about PCIA and DIA. Insofar as Sanofi asserts that Dr. Plunkett's opinions are vague and unhelpful, the Court disagrees. Her report clearly articulates her opinion: "Because [PCIA] is a toxicity that results in lack of hair regrowth, permanent, irreversible hair loss is a different condition from chemotherapy-induced, or drug-induced, alopecia."[22] Additionally, she

[20] *See* In re FEMA Trailer Formaldehyde Prods. Liab. Litig., MDL No. 07-1873, 2009 WL 2169224, at *3 (E.D. La. July 15, 2009) (precluding expert from offering testimony on adequacy of warning because this was factual issue for the jury to decide).
[21] Doc. 8283-1 at 11.
[22] Doc. 10918-3 at 15.

reiterated this at her deposition: "I see drug-induced alopecia as hair loss; whereas, the issue of the persistent alopecia, irreversibility, is a different injury; it's the inability to regrow. So to me, as a toxicologist, they are two different things."[23] Since the alleged injury in this case is permanent alopecia, not temporary alopecia, Dr. Plunkett's opinion may assist the jury in drawing a distinction between the types of injuries.

IV. Testimony Based on "Weight-of-the-Evidence" Methodology

Lastly, Sanofi broadly asks the Court to exclude all of Dr. Plunkett's opinions because, according to Sanofi, they are all based on a faulty application of the "weight-of-the-evidence" methodology. Sanofi argues that Dr. Plunkett failed to explain how she gathered and assessed evidence, how she weighed the evidence, and why her weighing method was scientifically reliable. In response, Plaintiffs point to portions of Dr. Plunkett's report and deposition testimony and aver that Dr. Plunkett did in fact "show her work."

The Court finds that Dr. Plunkett's methodology passes muster. In her report, she explained what information she reviewed.[24] She made clear that she weighed the evidence and found certain sources especially informative, like case reports "where the physician in the paper actually may have a combination of drugs, but indeed, has attributed causation to docetaxel in some of those."[25] Also, she testified that clinical data is "a really important piece of the puzzle that allows you to say something about comparative risk."[26] Contrary to what Sanofi says, Dr. Plunkett has "shown her work." Sanofi cites cases describing "great analytic gaps" in expert reports, but Sanofi has

[23] Doc. 11085-3 at 13.
[24] Doc. 10918-3 at 4.
[25] Doc. 11085-3 at 5.
[26] *Id.* at 17.

identified no such gap in this case.[27] To the extent that Sanofi takes issue with Dr. Plunkett's selection of sources or her weighing of the evidence, Sanofi can explore this before the jury on cross-examination.

CONCLUSION

For the foregoing reasons, Defendants' Motion to Exclude Expert Testimony of Dr. Laura Plunkett (Doc. 10918) is **GRANTED IN PART** and **DENIED IN PART**. Dr. Plunkett's testimony will be limited as described in this opinion.

New Orleans, Louisiana, this 13th day of January, 2021.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE

[27] In *Byrd v. Janssen Pharm.*, Inc., 333 F. Supp. 3d 111, (N.D.N.Y. 2018), the court noted that Dr. Plunkett "specifically identified only three pieces of scientific literature as the bases for her opinion." *Id.* at 128. The court found that there were weaknesses readily apparent in each of these sources. *See id.* at 128–29. Each source described an underlying study, and each source expressly acknowledged that the underlying study did not involve a control group. *Id.* In *In re Mirena Ius Levonorgestrel-Related Prods. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213, 259–60 (S.D.N.Y. 2018), the court found that Dr. Plunkett had relied on a study that had been repudiated by its own author. The court found Dr. Plunkett's "uncritical and unwarranted reliance" on the study suggested a "conclusion-driven" analysis. Sanofi has not identified any analogous flaws in Dr. Plunkett's work in this case.