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: Barbara Earnest, 16-17144	**)**	

ORDER AND REASONS

Before the Court is a Motion to Exclude Expert Testimony of Dr. Laura Plunkett (Doc. 6155) filed by Defendants Sanofi-Aventis U.S. LLC and Sanofi U.S. Services, Inc. (collectively, "Sanofi" or "Defendants"). For the following reasons, the Motion is **DENIED IN PART** and **DEFERRED 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. 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 of Plaintiff Barbara Earnest ("Plaintiff") is set to begin September 16, 2019.[2]

[1] Docetaxel is the generic version of Taxotere.
[2] To the extent Defendants' Motion relates to Plaintiff Tanya Francis, the Motion is moot, given the Court's dismissal of her case. To the extent the Motion relates to Plaintiff Antoinette Durden, the Motion is denied and deferred for the same reasons provided herein.

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:
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> > (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;
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> > (b) the testimony is based on sufficient facts or data;
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> > (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]

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[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]

LAW AND ANALYSIS

Dr. Laura Plunkett, one of Plaintiff's experts, is a pharmacologist and toxicologist. In the instant Motion, Defendants seek to limit her testimony. Defendants argue that Dr. Plunkett should not be permitted to offer two opinions: (1) that Taxotere is associated with a "greater risk" of permanent alopecia compared to "some other" chemotherapy drugs, including Taxol; and (2) that Taxotere is "more toxic" than Taxol. Defendants further argue that Dr. Plunkett should be prohibited from providing opinions on four topics she did not address in her expert report. These topics are causation, regulatory opinions, Taxotere's efficacy, and promotional activities related to Sanofi and

[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.*

Taxotere. In response, Plaintiff concedes that Dr. Plunkett will not be offering opinions pertaining to these four topics. Accordingly, Defendants' argument on this is moot, and the Court will not address it.

Defendants first attack Dr. Plunkett's opinion that Taxotere is associated with a greater risk of permanent alopecia. Defendants argue that this opinion is unreliable. They explain that Dr. Plunkett reviewed more information on Taxotere than on any other drugs she considered in making this comparison. Specifically, for Taxotere, Dr. Plunkett reviewed clinical trial reports, internal safety data, and company documents from Sanofi. She did not, however, have access to this kind of information regarding other drugs. For Taxol, for example, she reviewed six letters pertaining to Taxol that she located on the FDA website. She also reviewed two clinical studies on Taxol, neither of which recorded data about alopecia. Defendants take issue with Dr. Plunkett's failure to rely on targeted studies and aver that her reliance on general medical literature does not suffice. Lastly, Defendants suggest that Dr. Plunkett is unqualified, writing that "[o]ne whose background, training, and experience is lacking on a specific subject cannot make oneself an expert on the subject by 'reading up' on it."[16]

The Court finds that Dr. Plunkett's "greater risk" opinion is based on sufficient information. Dr. Plunkett states in her report that in forming her opinions in this case, she considered the types of sources she commonly references in her work as a pharmacologist, toxicologist, and risk assessor.[17] She reviewed, among other materials, "scientific literature relating to the pharmacology and toxicology of taxane drug products, including Taxotere (docetaxel) and Taxol (paclitaxel).[18] For example, she considered findings from

[16] Doc. 6155 at 12.
[17] Doc. 6155-8 (Plunkett Report) at 4.
[18] *Id.*

Dr. S.M. Sedlack, who reported that alopecia associated with docetaxel therapy as an adjuvant, or enhancement, to doxorubicin/cyclophosphamide chemotherapy was irreversible in some patients.[19] He reported that 6.3 percent of women administered doxorubicin plus Taxotere developed irreversible alopecia, compared to 0 percent of women administered doxorubicin plus Taxol.[20] Dr. Plunkett also considered the results of Sanofi's clinical studies, TAX 316 and GEICAM 9805. The studies showed a higher rate of persistent alopecia among patients administered a Taxotere regimen as opposed to a non-Taxotere regimen.[21] Dr. Plunkett also considered the frequency of reports in medical literature linking Taxotere to permanent alopecia as compared with the lower frequency of reports linking Taxol to permanent alopecia.[22]

The Court further rejects Defendants' assertion that Dr. Plunkett is an unqualified expert who simply "read up" on the subject matter at issue. Defendants emphasize that Dr. Plunkett has never given an expert opinion on alopecia or breast cancer, but they ignore the fact that Dr. Plunkett has years of relevant experience as a pharmacologist and toxicologist. Defendants also fail to convince the Court that Dr. Plunkett merely "read up" on the subject matter at issue in this case. With her knowledge and experience, Dr. Plunkett employed reliable methodologies to draw her conclusions regarding this case. As she explains in her report, she performed a "human health risk assessment," which she writes "is a standard tool used by pharmacologists and toxicologists when they are trying to understand the benefits and risks

[19] Doc. 7465 at 9.
[20] *Id.*
[21] *Id.*
[22] *Id.* at 10.

associated with a drug."[23] She also conducted a "weight of the evidence" assessment, in which she examined the Taxotere and Taxol product labeling and other materials.[24]

Defendants further aver that Dr. Plunkett's "greater risk" opinion would be unhelpful to the jury, given that Dr. Plunkett does not quantify the "greater risk" she discusses. This imprecision, however, does not render her opinion inadmissible. The Supreme Court has explained that "it would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty."[25] As other courts have recognized, "[l]ack of certainty is not, for a qualified expert, the same thing as guesswork."[26]

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.[27] 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.

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[23] Doc. 6155-8 at 5.
[24] *Id.* at 4–5.
[25] *Daubert*, 509 U.S. at 590.
[26] Milward v. Acuity Specialty Prods. Grp., Inc., 639 F.3d 11, 22 (1st Cir. 2011) (quoting Primiano v. Cook, 598 F.3d 558, 565 (9th Cir.2010)). *See* Horan v. Dilbet, Inc., No. 12-2273, 2015 WL 5054856, at *16 (D.N.J. Aug. 26, 2015) ("[T]he experts' opinions are drawn from what little scientific data and research may be available . . . . That Plaintiffs' experts remain unable to quantify the amount of the increase does not render their opinions so speculative as to be inadmissible." (internal quotations omitted)).
[27] *See* Trout v. Milton S. Hershey Med. Ctr., 576 F. Supp. 2d 673, 679 (M.D. Pa. 2008) ("If introduced, Dr. Brumback's cross-examination testimony would threaten to confuse and mislead the jury by causing them to apply general information about amputation and limb salvage to Trout's case without a sufficient medical basis for doing so. The testimony could lead jurors to draw medically unsound conclusions or to question unwarrantedly other expert testimony tied more closely to the material facts of the case.").

CONCLUSION

For the foregoing reasons, **IT IS ORDERED** that the Motion to Exclude Expert Testimony of Dr. Laura Plunkett (Doc. 6155) is **DENIED IN PART** and **DEFERRED IN PART**.

New Orleans, Louisiana this 23rd day of August, 2019.

JAY E TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE