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 are Defendants' Motion to Exclude Testimony of Dr. Antonella Tosti (Doc. 11377) ("Motion to Exclude") and Defendants' Motion for Summary Judgment on Specific Causation (Doc. 11378) ("Motion for Summary Judgment"). The Court held oral argument on the Motions on December 14, 2020. For the following reasons, the Motions are **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]

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

Plaintiff Elizabeth Kahn, the second bellwether plaintiff, was diagnosed with breast cancer in 2008. As part of her treatment, she participated in a clinical trial and underwent three phases of chemotherapy, during which she received Taxotere, Avastin, Xeloda, Adriamycin, and Cytoxan. After chemotherapy, she took Tamoxifen, a hormone therapy, for nine years.

Kahn plans to call Dr. Antonella Tosti as an expert witness at trial to testify on specific causation. Dr. Tosti is a dermatologist who treats women suffering from hair loss disorders. In the Motion to Exclude, Sanofi argues that Dr. Tosti's testimony is unreliable. In the Motion for Summary Judgment, Sanofi raises similar arguments and avers that Plaintiff fails to carry her burden on specific causation, warranting summary judgment in Sanofi's favor. Plaintiff Kahn opposes Sanofi's Motions.

LEGAL STANDARDS

I. Evidentiary Standards

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;
> >
> > (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]

[3] FED. R. EVID. 702.

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]

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

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[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.
[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).

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]

II. Summary Judgment Standard

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law."[17] A genuine issue of fact exists only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party."[18]

In determining whether the movant is entitled to summary judgment, the Court views facts in the light most favorable to the non-movant and draws all reasonable inferences in his favor.[19] "If the moving party meets the initial burden of showing that there is no genuine issue of material fact, the burden shifts to the non-moving party to produce evidence or designate specific facts showing the existence of a genuine issue for trial."[20] Summary judgment is appropriate if the non-movant "fails to make a showing sufficient to establish the existence of an element essential to that party's case."[21] "In response to a properly supported motion for summary judgment, the non-movant must identify specific evidence in the record and articulate the manner in which that

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[15] *Id.*
[16] FED. R. EVID. 703.
[17] Sherman v. Hallbauer, 455 F.2d 1236, 1241 (5th Cir. 1972).
[18] Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).
[19] Coleman v. Houston Indep. Sch. Dist., 113 F.3d 528, 532 (5th Cir. 1997).
[20] Engstrom v. First Nat'l Bank of Eagle Lake, 47 F.3d 1459, 1462 (5th Cir. 1995).
[21] Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986).

evidence supports that party's claim, and such evidence must be sufficient to sustain a finding in favor of the non-movant on all issues as to which the non-movant would bear the burden of proof at trial."[22]

LAW AND ANALYSIS

In the Motion to Exclude, Sanofi raises two challenges to Dr. Tosti's testimony. Sanofi argues (1) that Dr. Tosti does not use a reliable methodology to rule out androgenetic alopecia as the cause of Kahn's hair loss; and (2) that even if Dr. Tosti could rule out androgenetic alopecia, she does not use a reliable methodology to rule out other chemotherapies as the cause of Kahn's hair loss. In the Motion for Summary Judgment, Sanofi argues that Dr. Tosti's failure to rule out other possible causes of Kahn's alleged injury warrants judgment in Sanofi's favor. The Court will address each argument in turn.

I. Methodology Regarding Androgenetic Alopecia

In her report, Dr. Tosti explains that during her examination of Plaintiff Kahn, she took two scalp biopsies.[23] She testified that biopsies are "a kind of gold standard" because they offer "more possibilities to get the diagnosis."[24] Plaintiff's expert pathologist, Dr. Curtis Thompson, then examined the biopsies and produced a dermatopathology report, which Dr. Tosti considered.[25] He found that "Biopsy A" showed androgenetic alopecia and that "Biopsy B" showed permanent chemotherapy-induced alopecia ("PCIA").[26] At his deposition, however, Dr. Thompson testified that he could not rule out

[22] John v. Deep E. Tex. Reg. Narcotics Trafficking Task Force, 379 F.3d 293, 301 (5th Cir. 2004) (internal citations omitted).
[23] Doc. 11377-6 at 20.
[24] Doc. 11377-8 at 4.
[25] *See* Doc. 11377-6 at 20.
[26] The parties make clear that the terms "androgenetic alopecia" and "female pattern hair loss" refer to the same condition. *See* Doc. 11377-1 at 5 n.11; Doc. 11495 at 8.

androgenetic alopecia on Biopsy B. Similarly, Dr. Tosti testified that androgenetic alopecia and PCIA are often "indistinguishable" under a microscope and require a "clinicopathological correlation."[27]

Sanofi takes issue with the fact that Dr. Tosti claims to agree with Dr. Thompson yet at the same time indicates that the biopsy findings are irrelevant given the difficulty in distinguishing between the presentation of PCIA and androgenetic alopecia. Sanofi argues that either Dr. Thompson read the pathology correctly and Kahn has androgenetic alopecia, or he read the pathology incorrectly and she does not. Sanofi avers that Kahn "cannot simply set aside Dr. Thompson's conclusions in rendering her differential diagnosis."[28] In addition, Sanofi avers that Tamoxifen, which Kahn took, can cause androgenetic alopecia yet Dr. Tosti did not reliably rule out this possibility. In response, Plaintiff argues that Dr. Tosti did rule out androgenetic alopecia based on Kahn's clinical history—specifically, the chronology of her hair loss.

The Court rejects Sanofi's argument. In his pathology report, Dr. Thompson found that Biopsy B showed PCIA.[29] His conclusion, in fact, read as follows: "Given the features diagnostic of permanent chemotherapy-induced alopecia in Part B, the increased number of telogen bodies seen in Part A most likely also represents permanent chemotherapy-induced alopecia."[30] In her report, Dr. Tosti agrees with this, writing that "Dr. Thompson confirms the diagnosis of 'Permanent Chemotherapy-Induced Alopecia.'"[31] Dr. Tosti, then, does not "simply set aside" Dr. Thompson's conclusions as Sanofi claims. Instead, she appears to give the biopsies their due consideration.

[27] Doc. 11377-8 at 8.
[28] Doc. 11377-1 at 7.
[29] Doc. 11377-11 at 3.
[30] *Id.*
[31] Doc. 11377-6 at 33.

In addition to this, Dr. Tosti considers Kahn's hair density, the timeline of her hair loss, and the fact that she experienced thinning of her eyebrows and eyelashes.[32] Dr. Tosti explains that these factors allow her to rule out androgenetic alopecia as the cause of Kahn's hair loss:

> Androgenetic alopecia involves the miniaturization of hairs, but, total follicular number is almost normal. Even if hair density might slightly decrease with ageing only 5.7% of women with FPHL [female pattern hair loss] after the age of 70 showed a reduction in follicle number (and this was not severe: approximately 18%).
>
> Ms. Kahn had normal hair density before chemotherapy. She lost her hair during chemotherapy, and it never regrew to normal density. She developed a severe alopecia in less than 1 year, whereas androgenetic alopecia takes place over the course of years.
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> Thinning of eyebrows and eyelashes is not a feature of androgenetic alopecia.
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> Endocrine therapy can cause androgenetic alopecia. Ms. Kahn was on Tamoxifen from April 2009 through April 2018. Ms. Kahn started taking Tamoxifen 6 months after finishing chemotherapy. At that time, she had incomplete hair regrowth. She has now finished Tamoxifen therapy and did not experience any hair regrowth. Ms. Kahn reports that her hair today is the same as it was just before starting Tamoxifen. The chronology of her alopecia is not consistent with this diagnosis as patients with alopecia due to endocrine therapy have normal hair regrowth after chemotherapy and then develop progressive hair thinning several months after starting endocrine therapy. Ms. Kahn instead had incomplete hair regrowth with severe alopecia before

[32] In discussing Kahn's clinical history, Dr. Tosti notes that "[Kahn] lost her hair during chemotherapy and that she had incomplete hair regrowth after that with severe permanent alopecia involving not only the scalp hair but also eyebrows and eyelashes." *Id.* at 20.

> starting endocrine therapy. As stated above, PCIA can be misdiagnosed as androgenetic alopecia at clinical examination and at pathology, even though in PCIA there is often a reduction in the follicle number in addition to miniaturization.[33]

Having reviewed Dr. Tosti's report, the Court finds that Dr. Tosti considered androgenetic alopecia in her differential diagnosis and reliably ruled out this possibility.[34] The Court sees no reason to limit this testimony.

In the Motion for Summary Judgment, Sanofi points to case law holding that while a plaintiff may prove the cause of her injury through circumstantial evidence, she must present expert evidence excluding every other reasonable hypothesis with a fair amount of certainty. Sanofi emphasizes that Dr. Thompson believed Biopsy A showed androgenetic alopecia, and Sanofi seizes on the following testimony from Dr. Tosti:

> Q: And at the same time, you would agree that you can't entirely rule out androgenetic alopecia [i.e., female-pattern hair loss] for Ms. Kahn in some degree, correct?
>
> A: I think this is—well, it's very unlikely, but I cannot.[35]

This testimony does not negate the analysis Dr. Tosti provided in her report. In her report, Dr. Tosti soundly rules out androgenetic alopecia based on the timing of Kahn's hair loss and the thinning of her eyebrows and eyelashes, which are not features of androgenetic alopecia. In the deposition excerpt

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[33] *Id.* at 32–33.

[34] Sanofi notes that Kahn's hairdresser testified that Kahn's hair *did* regrow after chemotherapy and has become progressively thinner over the last nine years. Doc. 11377-1 at 9. Sanofi argues that Dr. Tosti ignored these facts. *Id.* Her failure to address this testimony in her report, however, does not render her differential diagnosis unreliable. Dr. Tosti offered support for her version of the facts, noting that Kahn herself reported that her hair today is the same as it was before taking Tamoxifen. To the extent there is conflicting evidence, Sanofi can challenge Dr. Tosti (and Plaintiff Kahn) on this at trial.

[35] Doc. 11378-1 at 5.

above, Dr. Tosti is perhaps stating that, although unlikely, Kahn may have some androgenetic alopecia *in addition* to her PCIA. Taken as a whole, Dr. Tosti's opinions offer a sufficient basis upon which the jury can find that Kahn suffers from PCIA, with or without androgenetic alopecia.[36]

II. Methodology Regarding Other Chemotherapies

Next, Sanofi argues that Dr. Tosti has failed to set forth a reliable methodology for attributing Kahn's alleged PCIA to Taxotere rather than any of the other chemotherapy drugs that she took. According to Sanofi, Dr. Tosti fails to tie her reasoning to the facts and circumstances of Kahn's case and instead assumes that Taxotere was the cause of her hair loss based on what Dr. Tosti has seen in her practice and in the literature. In response, Plaintiff does not dispute that Dr. Tosti relies on her experience and on the literature. Plaintiff avers that Dr. Tosti clearly explained her basis for attributing Kahn's hair loss to Taxotere rather than Adriamycin or Cytoxan; she explained that Adriamycin and Cytoxan are uncommonly associated with permanent alopecia, whereas the evidence shows an increased risk of PCIA with Taxotere.

Sanofi cites the case of *Comardelle v. Pennsylvania General Insurance Co.*, 76 F. Supp. 3d 628 (E.D. La. 2015) for the proposition that a "blanket specific causation opinion [that] is not based on or tied to the specific facts and circumstances of" the plaintiff is an unreliable "one-size-fits-all approach."[37] In *Comardelle*, the plaintiffs intended to call Dr. Samuel P. Hammar to opine that a certain product was a substantial contributing factor to the development of

[36] Sanofi argues that "even if the [Plaintiffs' Steering Committee] were to argue that Ms. Kahn is suffering from hair loss caused by Tamoxifen and PCIA caused by Taxotere, it has advanced no mechanism that would allow the court or the jury to ascertain which portion of Ms. Kahn's injury allegedly is Sanofi's responsibility and which is not." Doc. 11378-1 at 6. Sanofi, however, fails to cite any law providing that Plaintiff is required to advance such a mechanism at this juncture.

[37] *Id.* at 634.

the decedent's mesothelioma.[38] The court, however, found that Dr. Hammar had adopted the "every exposure" theory—the idea that "any exposure to asbestos fibers *whatsoever* constitutes an underlying cause of injury to the individual exposed."[39] The court explained as follows:

> In his expert report, Dr. Hammar opines that "all asbestos fibers inhaled by an individual that reach the target organ have the potential to contribute to the development of lung cancer, mesothelioma, and other asbestos-related diseases." At his deposition, he went further and opined that "all of the exposures that that individual had who developed mesothelioma, all of those would have contributed to cause his mesothelioma." Accordingly, Dr. Hammar opines based on this "every exposure" theory that "if [the decedent] was exposed to asbestos . . . those exposures [would] have been a substantial contributing cause of his disease."[40]

Calling it a one-size-fits-all approach as Sanofi notes, the court stated that Dr. Hammar's opinion "elides any differences or nuances of duration, concentration, exposure, and the properties of the fibers to which [the decedent] may have been exposed."[41]

Dr. Tosti is not offering a one-size-fits-all opinion as Sanofi avers. Dr. Tosti is not assuming that because Plaintiff Kahn has permanent hair loss, Taxotere must have caused it. Dr. Tosti conducted a differential diagnosis, and in doing so, she considered and ruled out the possibility that Kahn had permanent hair loss due to Tamoxifen, as previously discussed. Similarly, Dr. Tosti considered and ruled out several other conditions, including scarring alopecia, telogen effluvium, alopecia areata, and anagen effluvium.[42]

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[38] *Id.* at 630.
[39] *Id.* at 632.
[40] *Id.* (citations omitted).
[41] *Id.* at 634.
[42] Doc. 11377-6 at 26–30.

After ruling out these conditions and diagnosing Kahn with PCIA, Dr. Tosti then resorted to her experience and the literature to isolate Taxotere from the other chemotherapy drugs that Kahn took during treatment. She noted that there are no case reports of PCIA from Xeloda or Avastin.[43] She explained that Adriamycin and Cytoxan have been on the market since 1974 and 1959, yet the first cases of PCIA were described in 2001, when Taxotere was introduced in combination chemotherapy regimens.[44] In addition to this, Dr. Tosti relied on the work of Plaintiff's other experts to isolate Taxotere from other chemotherapy drugs.[45] Unlike the expert in *Comardelle*, Dr. Tosti considers the facts of Kahn's case and the properties of the chemotherapies to which Kahn was exposed. The Court, therefore, will not exclude Dr. Tosti's testimony. Instead, Sanofi can raise challenges to her opinions before the jury.

In the Motion for Summary Judgment, Sanofi argues that Dr. Tosti's testimony ruling out Adriamycin and Cytoxan is equivocal and cannot carry Plaintiff's burden of proof on specific causation. Sanofi highlights this testimony from Dr. Tosti's deposition:

> Q: So you do believe that the other chemotherapies outside of Taxotere that Ms. Kahn took played a role. You just think the Taxotere role is bigger?
>
> A: I think the Taxotere role is substantial, is the key factor, but I believe the others probably also play a role because of patients taking only Taxotere don't have the problem, so – it's more complicated. I don't know.[46]

Sanofi relies on the Fifth Circuit case of *Wheat v. Pfizer*, 31 F.3d 340 (5th Cir. 1994). In *Wheat*, the Fifth Circuit affirmed summary judgment for a drug

[43] *Id.* at 20 n.60.
[44] *Id.* at 15.
[45] *See id.* at 17.
[46] Doc. 11378-1 at 7.

manufacturer when the plaintiffs, survivors who alleged that the drug at issue caused the decedent's hepatitis, failed to rule out other possible causes.[47] The court wrote that the plaintiffs "did not offer sufficient evidence from which a reasonable jury could have concluded that [the defendant's drug] was the most probable cause."[48]

The evidence in this case is distinguishable from the evidence in *Wheat*. In *Wheat*, several treating physicians testified that they believed the decedent had a form of viral hepatitis unrelated to medication.[49] The defendant's expert shared this view.[50] The evidence showed, too, that the decedent had been in contact with a family member who had hepatitis.[51] The plaintiffs, however, "offered no evidence" excluding the possibility that the decedent contracted a form of viral hepatitis rather than a hepatitis from medication.[52]

In the instant case, Plaintiff Kahn *has* offered evidence excluding the possibility that she suffered from permanent hair loss unrelated to her chemotherapy. As previously noted, Dr. Tosti ruled out several conditions in her report before diagnosing Kahn with PCIA. Dr. Tosti also considered the chemotherapy drugs that Kahn took, and she ruled out Xeloda and Avastin. She similarly gave due consideration to Adriamycin and Cytoxan, and while she may not have ruled them out with the same certainty as she did the other possible causes, she nevertheless ruled them out and pointed to Taxotere as the cause of Kahn's PCIA:

> The use of Taxotere in Ms. Kahn's regimen was, to a reasonable degree of scientific certainty, the factor that substantially contributed to causing her PCIA. . . . [N]one of the of the other chemotherapies

[47] *Id.* at 342–43.
[48] *Id.* at 343.
[49] *Id.*
[50] *Id.*
[51] *Id.*
[52] *Id.*

> used in the treatment of breast cancer carry such a high risk of causing PCIA as Taxotere/docetaxel. Taxotere/docetaxel has the most reports of PCIA reported in the literature compared to any other drug Ms. Kahn received. My review of the scientific literature and the conclusions of the expert reports of Dr. Madigan and Dr. Feigal shows that there is not a signal of PCIA with her chemotherapy drugs other than Taxotere/docetaxel. There is only a strong causal association between Taxotere/docetaxel and PCIA. Taxotere's use in the regimen was the substantial contributing factor to Ms. Kahn's PCIA.[53]

If accepted by the jury, Dr. Tosti's opinions are enough to carry Plaintiff's burden on specific causation.[54] The Court, therefore, denies Sanofi's Motion for Summary Judgment.

CONCLUSION

For the foregoing reasons, Defendants' Motion to Exclude Testimony of Dr. Antonella Tosti (Doc. 11377) and Defendants' Motion for Summary Judgment on Specific Causation (Doc. 11378) are **DENIED.**

New Orleans, Louisiana, this 7th day of April, 2021.

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[53] Doc. 11377-6 at 34.

[54] In the *Earnest* trial, the jury charges provided as follows:

> Proximate cause does not mean the sole cause. The Defendants' conduct can be a proximate cause if it was at least one of the direct, concurring causes of the alleged injury. However, Plaintiff must show that Defendants' conduct was a substantial contributing factor in bringing about the result. In other words, it is not necessary for Plaintiff to negate all other contributing factors or causes of Mrs. Earnest's injuries, provided they show that Defendants' failure to provide an adequate warning in the Taxotere label substantially contributed to her injuries.

Doc. 8283-1 at 11.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE