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 Testimony of John Glaspy, M.D. (Doc. 10924). The Court held oral argument on the Motion on October 6, 2020. 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 testimony from Dr. John Glaspy, Sanofi's expert

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

oncologist. Plaintiff argues that Dr. Glaspy is not qualified and that his opinions are unreliable. Sanofi opposes the 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]

---

[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.

LAW AND ANALYSIS

I. Dr. Glaspy's Qualifications

First, Plaintiff challenges that Dr. Glaspy is qualified to offer opinions on alopecia. In his report, Dr. Glaspy opines on the types and causes of alopecia. He notes, for example, that stress, surgery, and hormone imbalances are common causes of alopecia.[17] In addition, he concludes that Plaintiff Kahn's alopecia is not attributable to Taxotere. In her Motion, Plaintiff emphasizes that Dr. Glaspy never examined Kahn. Plaintiff further notes that Dr. Glaspy is not a dermatologist and does not provide dermatology services at any of the hospitals where he treats cancer patients.

In response, Sanofi argues that Dr. Glaspy has sufficient expertise to testify on the common types and causes of alopecia he observes and treats in his breast cancer patients. Sanofi emphasizes that Dr. Glaspy "frequently relies on his clinical experience and training to identify and treat his patients' hair loss."[18] Sanofi avers that Dr. Glaspy "has treated thousands of women with hair loss and thinning following hormonal therapies."[19]

The Court finds that Dr. Glaspy is sufficiently qualified to testify on the types and causes of alopecia that he sees and treats in his clinical practice. At his deposition, Dr. Glaspy agreed that as an oncologist, he does not regularly attempt to differentiate between types of alopecia, but he does "eyeball" his patients.[20] He testified that "[i]f there was three reversible things that could be causing [hair loss], I would fix all three. I wouldn't try and figure out which one it was."[21] Dr. Glaspy, then, has experience treating alopecia, and he is

[17] Doc. 10924-2 at 23.
[18] Doc. 11101 at 4.
[19] *Id.*
[20] Doc. 11173-1 at 12.
[21] *Id.* at 12–13.

basing his testimony on the facts and data he has gleaned from this experience. Regarding Plaintiff Kahn, he admits that he is not in the best position to assess her hair loss since he has not seen her personally.[22] He explains, however, that he has seen many pictures of her. [23] Given his clinical experience observing and treating alopecia, he may opine on Kahn based on her pictures. On cross-examination, Plaintiff can make sure the jury understands that Dr. Glaspy did not see Kahn personally or conduct a differential diagnosis.

Next, Plaintiff argues that Dr. Glaspy is not qualified to opine on the FDA, its regulations, and the drug development and approval process. Plaintiff avers that Dr. Glaspy has no experience in FDA regulation or the drug approval process. Plaintiff takes issue with Dr. Glaspy's statement that the underlying data from TAX 311, TAX 316, and GEICAM 9805 were submitted to the FDA. Plaintiff points to evidence contradicting that the data from TAX 311 was in fact submitted to the FDA. In response, Sanofi notes that Dr. Glaspy has been involved in clinical trials and has participated in the "new drug application" ("NDA") process for several drugs.

The Court finds that Dr. Glaspy is sufficiently qualified to testify on these FDA-related topics. In the first bellwether trial, Dr Glaspy testified that he has been the principal investigator on hundreds of clinical trials,[24] and as Sanofi notes, Dr. Glaspy has been involved in preparing NDAs for several drugs. Informed by his experience, Dr. Glaspy can testify about clinical trials and the NDA process. Also, as in the first trial, the Court will allow Dr. Glaspy to testify about the Taxotere label from his perspective as an oncologist.[25] In

[22] *Id.* at 13.
[23] *Id.*
[24] Doc. 11101-1 at 6.
[25] Doc. 11101-2. *See* Knight v. Boehringer Ingelheim Pharmaceuticals, Inc., 323 F. Supp. 3d 837, 851 (S.D. W. Va. 2018) (allowing doctor with ample clinical and research experience

addition to this, the Court will allow Dr. Glaspy to testify about the Taxotere clinical trials given Dr. Glaspy's involvement in the trials.[26] To the extent Plaintiff has identified conflicting evidence about whether the TAX 311 data was submitted to the FDA, Plaintiff can ask about this on cross-examination.

II. Dr. Glaspy's Causation Opinions

Plaintiff argues that Dr. Glaspy improperly relies on the results of TAX 316 as interpreted by Dr. Michael Kopreski. For background on Dr. Kopreski's interpretation of TAX 316, see this Court's Order and Reasons dated October 21, 2020 (Doc. 11332) ("Order on Kopreski"). In response, Sanofi argues that under Rule 703, Dr. Glaspy can reasonably rely on the work of others.

For the reasons provided in its Order on Kopreski, the Court rejects Plaintiff's assertion that Dr. Kopreski's work was litigation-driven and therefore unreliable and inadmissible. For the same reasons, the Court rejects the notion that Dr. Kopreski was not qualified to analyze the TAX 316 data. In addition, the Court rejects Plaintiff's argument that Dr. Glaspy made no attempt to independently validate Dr. Kopreski's work. To the contrary, Dr. Glaspy expressly testified as follows:

> It wasn't that I read what [Dr. Kopreski] said and then took it for what it meant. It's that, independent of what he was saying, I am able to understand what's going on here; that this isn't – these patients don't necessarily have what we've been calling "permanent alopecia."[27]

Dr. Glaspy, therefore, may consider and rely upon Dr. Kopreski's work. Given his experience with clinical trials, Dr. Glaspy can testify about TAX 316.

---

to testify regarding sufficiency of label to notify doctors and patients of risk while noting that same doctor could not testify on FDA regulations).

[26] Doc. 11101-1 (testifying that he became involved early on in the development of Taxotere and was involved in clinical trials of the drug).

[27] Doc. 11101-3 at 5.

Plaintiff further argues that Dr. Glaspy opines on other causes of persistent hair loss without using a reliable methodology to assess causation for these other possible causes. In response, Sanofi argues that unlike Plaintiff, Sanofi is not required to prove general causation and need not use the same methodologies as Plaintiff. Instead, Dr. Glaspy is challenging Plaintiff's experts' causation opinions through reasonable testimony regarding alternative explanations for her hair loss. According to Sanofi, Dr. Glaspy opines only that the currently available scientific evidence is insufficient to establish that Taxotere causes persistent hair loss, and consistent with this, he offers reasonable hypotheses about other drugs that are associated with persistent hair loss.

Plaintiff Kahn bears the burden of proving that Taxotere caused her injury, and she must prove both general and specific causation.[28] Defendants may then challenge her evidence with admissible evidence of other possible causes.[29] As noted by the Fifth Circuit, to establish causation under the

[28] Seaman v. Seacor Marine LLC, 564 F. Supp. 2d 598, 600 (E.D. La. 2008), *aff'd*, 326 F. App'x 721 (5th Cir. 2009) ("[T]he plaintiff must present admissible expert testimony to establish general causation as well as specific causation."); Knight v. Kirby Inland Marine Inc., 482 F.3d 347, 351–52 (5th Cir. 2007) (assessing trial court plaintiffs' general causation evidence); Burst v. Shell Oil Co., Civil Action No. 14-109, 2015 WL 3755953, at *1 (E.D. La. June 16, 2015) ("[P]laintiff must show general causation—that gasoline containing benzene can cause AML—and specific causation—that defendants' products caused Mr. Burst's AML."); *Wagoner*, 813 F. Supp. 2d at 800 ("To prevail in a toxic tort case, a plaintiff must show both general causation and specific causation."); Frischhertz v. SmithKline Beecham Corp., Civil Action No. 10-2125, 2012 WL 6697124, at *6 (E.D. La. Dec. 21, 2012) (granting summary judgment because "plaintiffs have no expert testimony establishing general or specific causation and cannot meet their burden of establishing either general or specific causation from the ingestion of Paxil for the alleged birth defects under the [Louisiana Products Liability Act]").

[29] Wheat v, Pfizer, Inc., 31 F.3d 340, 342–43 (5th Cir. 1994). In *Wheat*, the Fifth Circuit wrote that "Plaintiffs have shown that Feldene can cause hepatitis." *Id.* The court noted, however, that some treating physicians and the defendant's expert witness believed that the decedent's illness was a type of hepatitis unrelated to medication. *Id.* Affirming judgment for the defendant, the court found that the plaintiffs offered no evidence excluding the possibility that the decedent had this type of hepatitis. *Id.* "In short, Plaintiffs did not offer sufficient evidence from which a reasonable jury could have concluded that Feldene was the most probable cause of Mrs. Gordon's hepatitis." *Id.*

Louisiana Products Liability Act, a plaintiff using circumstantial evidence to prove causation must establish "with reasonable certainty that all other alternatives are impossible."[30] The burden is not on the defendant to prove that other causes are possible.[31] Plaintiff has not pointed to any law providing that a defendant must prove general causation before testifying about possible alternative causes of a plaintiff's injury, and this Court has found no such law. The Court, therefore, will not limit Dr. Glaspy's testimony because he did not use one of the methodologies associated with proving general causation. Provided that his testimony is sound and reliable, he may opine on other possible causes of persistent alopecia.

III. Dr. Glaspy's Report

Plaintiff further argues that Dr. Glaspy did not adequately disclose his opinions in his report. Plaintiff points to several statements in Dr. Glaspy's report and avers that Dr. Glaspy offers no explanation or support for the statements. In response, Sanofi argues that Plaintiff takes the statements out of context. The Court will address the statements one by one.

The first statement Plaintiff highlights is "I will discuss common sentiments breast cancer patients may have." Notably, in Dr. Glaspy's report, the sentence in its entirety reads as follows: "In addition, will discuss common sentiments breast cancer patients may have and express to me regarding treatment and survival."[32] After this, Dr. Glaspy explains the sentiments he sees in his patients, including that "survival is their greatest priority" and that some women choose certain prophylactic treatment seeking peace of mind.[33] Contrary to what Plaintiff argues, Dr. Glaspy offers more than a "preview

[30] Pipitone v. Biomatrix, Inc., 288 F.3d 239, 243 n.5 (5th Cir. 2002) (citing Joseph v. Bohn Ford, Inc., 483 So.2d 934, 940 (La. 1986); Todd v. State, 699 So.2d 35, 43 (La. 1997)).
[31] *See Wheat*, 31 F.3d at 342–43.
[32] Doc. 10924-2 at 8.
[33] *Id.*

statement" on this topic, and his report makes it clear that his support for this discussion comes from his years of experience treating cancer patients. This is in compliance with Federal Rule of Civil Procedure 26(a)(2)(B).

The second and third statements Plaintiff highlights are these: "I will discuss survival rates for breast cancer, including the impact that various chemotherapy regimens have had on improving overall survival rates," and "I will discuss the difference in survival rates between the older regimens and taxane-containing regimens." Plaintiff claims that Dr. Glaspy "does not explain beyond [these] preview statement[s]" and offers no support for them. However, Dr. Glaspy goes on to state that since 1995, "treatment options for and earlier detection of breast cancer have led to increased survival rates."[34] He notes that today, the 5-year and 10-year survival rates for invasive breast cancer are 90 percent and 83 percent.[35] He cites sources in support of these statements.

Dr. Glaspy further notes that "[a]s chemotherapy regimens evolve, the newest generation of chemotherapy regimens become the 'standard of care.' This is because they offer the best survival rates and offer the patient the optimal chance for survival."[36] He states that "most recently the addition of taxanes to chemotherapy regimens have improved survival rates compared to earlier chemotherapy regimens that did not include taxanes."[37] Dr. Glaspy specifically notes that the outdated chemotherapy regimens AC, FEC, FAC, CAF, CEF, CMF, and EC have lower survival rates that taxane-containing regimens.[38] Plaintiff is therefore incorrect to assert that Dr. Glaspy does not identify which regimens' survival rate he will discuss, and the Court finds that Dr. Glaspy's oncology experience is sufficient support for these statements.

---

[34] Doc. 10924-2 at 14.
[35] *Id.*
[36] *Id.*
[37] *Id.*
[38] *Id.* at 14–15.

The fourth statement that Plaintiff highlights is "I will discuss the development of Taxanes." Plaintiff then highlights several sub-topics in this category, including the history of the Cancer Chemotherapy National Service Center, the extraction process of Taxol from the Pacific Yew tree, and the progression from the Taxotere clinical trials through its approval in 1998 and its adjuvant use approval in 2004. Plaintiff also takes issue with Dr. Glaspy's statement that "Taxotere is a life-saving drug" and his statement that the World Health Organization considers Taxotere one of the "most efficacious, safe and cost-effective medicines for priority conditions."

While Dr. Glaspy could have been more precise in citing his sources for this section of his report, the Court finds that it nonetheless complies with Rule 26(a)(2)(B). Plaintiff claims that Dr. Glaspy offers only a "preview statement" saying he will discuss the development of Taxanes, but at the same time, Plaintiff acknowledges the points that Dr. Glaspy makes in this discussion. He explains the search for anti-cancer properties in thousands of compounds and plants. He explains that the Pacific Yew tree had anti-cancer properties, that the trees were of limited supply, and that researchers created a synthesized version of the molecule that was needed. As support for these statements, he cites *The Story of Taxol*, which Plaintiff acknowledges. Plaintiff writes that Dr. Glaspy offers "only one substantive source, 'THE TAXOL STORY.'" Noticeably, what Plaintiff does not say is that *The Story of Taxol* does not support Dr. Glaspy's statements. The Court suspects that it does.

In addition, the Court rejects Plaintiff's argument that Dr. Glaspy lacks support for his discussion of the development of Taxotere and the Taxotere clinical trials. Dr. Glaspy testified that he became involved in the development of Taxotere "early on" and that he was involved in the clinical trials of the

drug.[39] Similarly, the Court rejects Plaintiff's argument that Dr. Glaspy lacks support for his statement that "Taxotere is a life-saving drug." Given his years of clinical practice in oncology, Dr. Glaspy can reliably make such a statement. Lastly, regarding Dr. Glaspy's statement that the World Health Organization lists Taxotere as a superior drug, the Court finds that Dr. Glaspy has sufficient support for his statement. Indeed, the statement is easily verifiable, and to the extent that it is wrong, Plaintiff can show this on cross-examination.

The fifth statement that Plaintiff highlights is "I will discuss the tradeoffs with alternatives to Taxotere-containing regimens and the absence of any guarantees in the oncological setting." Again, Plaintiff calls this an unfulfilled "preview statement," but Plaintiff ignores the paragraphs preceding this statement, which discuss the downsides of non-Taxotere regimens. Dr. Glaspy also elaborates on his statement that there are no guarantees in oncology; he writes that "it is impossible to tell a patient which side effects that patient will have or avoid compared to another patient."[40] Given his years of clinical practice in oncology, Dr. Glaspy can reliably discuss this and the notion that there are no guarantees in the oncological setting.

The sixth statement that Plaintiff highlights is "I will discuss chemotherapy regimens used to treat HER2- breast cancer." The Court is puzzled by Plaintiff's assertion that this is an unfulfilled "preview statement." The nine paragraphs following it discuss the treatment of HER2- breast cancer. Given his years of clinical practice in oncology, Dr. Glaspy can reliably discuss the treatment of these cancers.

The seventh statement that Plaintiff highlights is "I will discuss the efficacy and side effects of older chemotherapy regimens, including FEC, FAC,

[39] Doc. 11101-1.
[40] Doc. 10924-2 at 22.

AC and CMF." This is not simply a "preview statement" but instead relates to several sections of Dr. Glaspy's report, including the paragraph following it:

> In my practice, I generally prescribe a non-taxane containing regimen if a patient has an absolute reason not to receive the taxane, including a serious allergic reaction, severe pre-existing neuropathy, multiple sclerosis, or serious concerns with steroid use. I prescribe CMF in patients only where the patient cannot receive a taxane or anthracycline, and the patient is willing to accept a lower efficacy rate.[41]

While Dr. Glaspy could have more clearly identified the side effects of these drugs, this paragraph indicates that allergic reactions and neuropathy are side effects of these older regimens. He further makes clear that these older drugs have lower efficacy rates. Elsewhere in his report, he writes that "I do not generally recommend that a woman with early-stage breast cancer take a non-taxane-containing chemotherapy regimen because her overall likelihood of survival would diminish."[42] Dr. Glaspy makes clear, too, that these statements are supported by his experience in his clinical practice.

The eighth and final statement that Plaintiff highlights is "I will discuss the side effects of chemotherapy drugs, how clinicians weigh side effects, and how and what side effects are communicated to the patient." Again, Plaintiff makes a boilerplate assertion that Dr. Glaspy offers no support for this and does not explain beyond this "preview statement." This is false. Immediately following this statement, Dr. Glaspy discusses the side effects of chemotherapy, and he states that he warns patients of common side effects and life-threatening side effects. Elsewhere in his report, he discusses the weighing of side effects. Dr. Glaspy makes clear, too, that these statements are supported by his experience in clinical practice.

---

[41] *Id.* at 20.
[42] *Id.* at 13.

CONCLUSION

For the foregoing reasons, Plaintiff's Motion to Exclude Testimony of John Glaspy, M.D. (Doc. 10924) is **DENIED**.

New Orleans, Louisiana, this 8th day of January, 2021.

JAY E TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE