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. Ellen Feigal (Doc. 10931). 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. Ellen Feigal. Dr. Feigal is an oncologist who has decades of experience with clinical

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

trials, pharmacological product development, and pharmacovigilance. Plaintiff Elizabeth Kahn, the second bellwether plaintiff, plans to call Dr. Feigal 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:
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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;
> >
> > (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,

[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.").

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 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]

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[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).
[15] *Id.*
[16] FED. R. EVID. 703.

LAW AND ANALYSIS

Sanofi raises three challenges to Dr. Feigal's testimony. Specifically, Sanofi asks the Court to (1) preclude Dr. Feigal's case-specific opinions; (2) preclude Dr. Feigal from opining on whether the dissemination of risk information regarding Taxotere and permanent alopecia was adequate; and (3) preclude Dr. Feigal from offering a general causation opinion.

I. Case-Specific Opinions

Sanofi asks the Court to preclude Dr. Feigal from offering case-specific opinions. According to Sanofi, Dr. Feigal should not be allowed to opine on what a reasonable physician would have done if he or she had known of a risk of permanent alopecia associated with Taxotere. Sanofi emphasizes that Plaintiff Kahn's treating physicians will be available to offer such testimony; they can testify about whether they would have warned Kahn of such a risk. In response, Plaintiff avers that Dr. Feigal will not offer any case-specific opinions. At the same time, though, Plaintiff states that Dr. Feigal intends to testify "as to what a reasonable physician would do with information regarding the causative relationship between permanent alopecia and Taxotere."[17]

Plaintiff appears to ignore this Court's prior ruling. In the first bellwether trial, Plaintiff Barbara Earnest wished to have Dr. Feigal testify about how a reasonable physician should have navigated the decision-making process with his or her patient. Addressing this argument, the Court issued this ruling: "Because Plaintiff's treating physician, Dr. James Carinder, is available to testify, Dr. Feigal will not be allowed to opine on the facts of Earnest's case. Dr. Carinder can testify about how he would have responded to an adequate warning from Defendants."[18]

[17] Doc. 11083 at 4.
[18] Doc. 8094 at 18.

For the *Kahn* trial, Dr. Feigal will not be allowed to testify about what a reasonable physician would have done with a warning about permanent alopecia. This is thinly veiled case-specific testimony, and it would carry little relevance. To determine causation, the jury will need to decide whether "a proper warning would have changed the decision of the treating physician."[19] The question is not whether a proper warning would have changed the decision of a third-party physician. Because Drs. Larned and Kardinal will be available to testify directly on this question, Dr. Feigal's testimony is not needed.

As in *Earnest*, however, Dr. Feigal may testify about the standard of care for physicians for informing patients through the decision-making process. This testimony should be the kind of material Dr. Feigal would cover in the college courses she taught on the topic of informed consent. Also, Dr. Feigal may testify about the alternative treatments that exist for Taxotere patients.

II. Opinions on the Dissemination of Risk Information

Next, Sanofi argues that Dr. Feigal should be precluded from opining on whether the dissemination of risk information regarding permanent alopecia and Taxotere was adequate. Sanofi avers that Dr. Feigal offers opinions that imply that Sanofi provided inadequate warnings about permanent alopecia. In response, Plaintiff avers, again, that testimony "as to what a reasonable physician could do with information regarding the causative relationship between permanent alopecia and Taxotere" is relevant.[20] Plaintiff states that

[19] Willett v. Baxter Intern., Inc., 929 F.2d 1094, 1098–99 (5th Cir. 1991). *See also* Doc. 8201 at 3 ("To find proximate causation, the jury will have to find that Dr. Carinder's prescribing decision would have changed if he had known of Taxotere's risk of permanent alopecia."); Doc. 8206 at 4 ("As previously ruled, the jury must decide whether the prescribing decision would have changed; this depends on the oncologist's conversations with Plaintiff and what risks Plaintiff was willing to accept."); Doc. 9300 at 4 ("Considering the evidence, the Court finds that there are fact issues for the jury to decide regarding how the conversation between Plaintiff and her doctor would have gone if they had known of Taxotere's risk.").

[20] Doc. 11083 at 6.

Dr. Feigal "simply offers" this opinion: "Had physicians been informed of the risk of permanent chemotherapy-induced alopecia, reasonable physicians would and could have included a discussion of the risk of PCIA in their benefit-risk interaction with patients about treatment options for their early stage breast cancer, to allow for more informed decisions."[21]

For reasons previously stated, Dr. Feigal may not opine on what reasonable physicians would have done had they been informed of a risk of permanent alopecia. Also, as Sanofi argues, such testimony necessarily implies that physicians were not given adequate warnings. Plaintiff seems to agree that Dr. Feigal should not opine on the adequacy of the Taxotere label, but she fails to realize that these opinions do in fact relate to the adequacy of the Taxotere label. As in *Earnest*, Dr. Feigal may offer general opinions about how pharmaceutical companies disseminate risk information, but she may not opine on whether reasonable physicians would have discussed the specific risk of permanent chemotherapy-induced alopecia ("PCIA") with their patients.

III. General Causation Opinion

Lastly, Sanofi takes issue with Dr. Feigal's general causation opinion. Sanofi argues that Dr. Feigal has made slight modifications to her *Earnest* report, rendering her general causation opinion unreliable. Specifically, Sanofi emphasizes that Dr. Feigal has admitted that the drugs Adriamycin and Cytoxan may cause permanent alopecia. Sanofi notes that in the Taxotere clinical trials, all participants took a regimen that included these drugs. Consistent with her admission that it is impossible to count cases of permanent alopecia caused by Taxotere alone, her report now counts Taxotere/docetaxel "regimens" as opposed to Taxotere/docetaxel "cases." In response, Plaintiff argues that this linguistic change is of no moment.

[21] *Id.*

The Court agrees with Plaintiff. In her *Earnest* report, Dr. Feigal acknowledged there have been reports of permanent alopecia associated with other drugs.[22] Nonetheless, she set out a reliable methodology, namely a Bradford Hill analysis, to support her opinion that Taxotere is the cause of permanent alopecia even in combination regimens. She has done the same for Plaintiff Kahn's trial. The linguistic change that Sanofi highlights appears to be only an attempt to clarify her opinion. It does not change the substance of it or detract from its reliability.

CONCLUSION

For the foregoing reasons, Defendants' Motion to Exclude Expert Testimony of Dr. Ellen Feigal (Doc. 10931) is **GRANTED IN PART** and **DENIED IN PART**. Dr. Feigal's testimony will be limited as described in this opinion.

New Orleans, Louisiana, this 12th day of January, 2021.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE

[22] Doc. 6149-6 at 37 (discussing TAX 316) ("At the end of the 10-year follow up period, PCIA was seen in 3.9% (n=29) of patients on the Taxotere-containing regimen (TAC) and in 2.2% (n=16) on the control (FAC)."); *id.* at 38 (discussing GEICAM 9805) ("3 of the 49 patients on TAC had ongoing PCIA, with 1 of 35 patients on FAC"); *id.* at 45–46 (discussing Kang study) ("Patients received Taxotere/docetaxel-based regimens or anthracycline and cyclophosphamide-based regimens without Taxotere/docetaxel. . . . Patients with Taxotere/docetaxel-based regimens had about 8 times higher odds of PCIA 3 years after completion of chemotherapy.").