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 Linda Bosserman, M.D. (Doc. 10929). 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 2021.[2]

Plaintiff Elizabeth Kahn, the second bellwether plaintiff, plans to call Dr. Linda Bosserman as a witness at trial. Dr. Bosserman is a clinical

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

oncologist who specializes in breast cancer. In the instant Motion, Sanofi moves to exclude her testimony. 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;
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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

[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 three challenges to Dr. Bosserman's testimony. Specifically, Sanofi asks the Court to (1) preclude Dr. Bosserman's case-specific

[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; (2) limit Dr. Bosserman's testimony regarding online predictive tools; and (3) preclude Dr. Bosserman from testifying about what was known or knowable by Sanofi or Plaintiff's treating physicians in 2008 regarding permanent hair loss. The Court will address each argument in turn.

I. Case-Specific Opinions

Sanofi asks the Court to preclude Dr. Bosserman from offering case-specific opinions. According to Sanofi, Dr. Bosserman should not be allowed to opine on what Plaintiff Kahn's treating physicians would have done if they 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. Bosserman will not offer any case-specific opinions. Plaintiff claims that she will offer only general opinions on informed consent and alternative treatments to Taxotere.

In her report, Dr. Bosserman writes that she will offer this opinion:

> The accurate communication of information concerning the risk of [permanent chemotherapy-induced alopecia] with the use of Taxotere, from Sanofi to Dr. Kardinal, the treating physicians of Ms. Kahn, via the product label, marketing pieces, correspondence and through the sales representatives that visited the doctors' offices, would more likely than not, have been included in the discussion and process of informed consent in a real and substantial way for any standard or clinical trial docetaxel based regimen. It would have allowed for a more honest, accurate and complete informed consent process and discussions between the physician, the oncology nurse, the clinical trial investigators and Ms. Kahn, and would have allowed for a decision to be made on more truthful and accurate information.[17]

[17] Doc. 10929-9 at 56.

This contains case-specific testimony. Dr. Bosserman is opining that if Sanofi had warned Dr. Kardinal of a risk of permanent alopecia, Dr. Kardinal would have included this in his discussion with Plaintiff Kahn. Also, Dr. Bosserman is indirectly stating that the conversations Kahn had with her medical providers lacked honesty, accuracy, and truthfulness.

To determine causation, the jury will need to decide whether "a proper warning would have changed the decision of the treating physician."[18] This Court, therefore, has ruled that testimony from a treating physician, not a third-party physician, is appropriate to assist the jury.[19] Consistent with this, in the first bellwether trial, the *Earnest* trial, the Court ruled as follows:

> Because Plaintiff's treating physician, Dr. James Carinder, is available to testify, Dr. Bosserman 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. Dr. Bosserman, therefore, can testify about the guidelines from the National Comprehensive Cancer Network and what they require, and she can testify about the standard of care for physicians for informing patients through the decision-making process; she cannot, however, testify about the application of these principles to Earnest's case.[20]

Similarly, Plaintiff Kahn's treating physicians will be available to testify at her trial. They can testify about how they would have responded to a warning from Sanofi, and they can share any opinions they have about the honesty, accuracy,

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[18] 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.").

[19] *See* Doc. 8094 at 18.

[20] Doc. 7807 at 5.

and truthfulness of the conversations they had with Plaintiff Kahn. The Court will not allow Dr. Bosserman to testify on this.[21]

In her report, Dr. Bosserman also notes that Plaintiff Khan had preferences for "different acute, chronic and permanent toxicities like [permanent chemotherapy-induced alopecia] which would have a major impact on her quality of life."[22] This is inadmissible case-specific testimony. Plaintiff Kahn herself will be available to testify about her preferences and any concerns she had about her quality of life. Her treating physicians, too, will be available to testify about what preferences and concerns Kahn shared with them. Dr. Bosserman's testimony on this, therefore, will not be helpful to the jury.

The Court, however, will allow Dr. Bosserman to offer general testimony about any non-Taxotere treatment options that were available in 2008 when Plaintiff Kahn received her treatment. The Court will also allow Dr. Bosserman to provide general testimony about how drug companies disseminate risk information, such as her testimony that pharmaceutical companies provide information to physicians through various sources and that it is essential for physicians that the educational and promotion content from pharmaceutical companies prominently include safety discussions.

II. Testimony Regarding Online Predictive Tools

Next, as in the *Earnest* trial, Sanofi argues that in forming her opinions, Dr. Bosserman improperly relied on certain "online predictive tools" that estimate the benefits of different chemotherapy treatments. Indeed, in her report, Dr. Bosserman discusses "Adjuvant! Online" and "Predict."[23] Sanofi argues that the Court should preclude Dr. Bosserman from testifying about

[21] The Court makes no determination as to the admissibility of such testimony in a case where the treating physician is unavailable.
[22] Doc. 10929-9 at 57.
[23] *Id.* at 32.

these tools in connection with Plaintiff Kahn's case. Sanofi emphasizes that there is no evidence showing that Kahn's treating physicians used Adjuvant! Online, and Sanofi notes that Predict was not available until 2010. In response, Plaintiff argues that Dr. Bosserman should be allowed to educate the jury on the use of these tools generally, even though some were not available in 2008. Quoting Dr. Bosserman, Plaintiff notes that oncologists use the tools today to "confirm[] information concerning individualized predictions."[24]

The parties have given the Court no reason to deviate from its ruling in the *Earnest* trial. In *Earnest*, the Court ruled as follows:

> Defendants aver that in forming certain opinions, Dr. Bosserman relied on "online predictive tools" that estimate the benefits of different chemotherapy treatments. Defendants argue that certain versions of these tools—specifically, "PredictUK 2.0" and "ONCOassist"—are irrelevant as they were not available at the time Plaintiff underwent chemotherapy and could not have played a role in the decision for Plaintiff Earnest.
>
> In her report, Dr. Bosserman generally discusses the benefit of using online tools in the creation of a treatment plan. Such general testimony is permissible, although for reasons discussed herein, Dr. Bosserman will not be permitted to testify about the use of these tools in connection with Earnest's case. On cross-examination, Defendants will have the opportunity to clarify that PredictUK 2.0 and ONCOassist were not available in 2011, and Defendants can illuminate any limitations associated with using online predictive tools.[25]

Similarly, for Plaintiff Kahn's trial, Dr. Bosserman can generally discuss these tools, and she may opine that oncologists use them today to confirm their

[24] *Id.* at 32.
[25] Doc. 7807 at 5.

predictions. On cross-examination, Sanofi can emphasize that there is no evidence showing that Kahn's treating physicians used these tools.

III. Testimony About What Was Known or Knowable in 2008 Regarding Permanent Hair Loss

Lastly, Sanofi takes issue with Dr. Bosserman's testimony regarding Sanofi's knowledge of the risk of permanent alopecia. In her report, Dr. Bosserman writes that "[a]t the time Ms. Kahn entered the [clinical] trial, Sanofi was in fact aware of the risk of [permanent chemotherapy-induced alopecia] yet did not warn physicians or patients. As a result, this information was not in the [informed consent] form."[26] Similarly, Dr. Bosserman writes that "[n]either Dr. Kardinal, nor his oncology nurse, Shevonda Thomas, nor the writers of the national NSABP B-40 informed consent form, were informed about the risk of PCIA from Sanofi's adjuvant clinical trials . . . ."[27] In summarizing her opinions, she concludes with this:

> Sanofi failed to timely and accurately warn physicians of the risk of PCIA associated with the use of Taxotere, alone or in regimens, for use in the adjuvant setting in early stage breast cancer. Only Sanofi had this data from their proprietary, privately held clinical trial results that thousands of women and their clinicians participated in with the expectation of full disclosure of safety and efficacy results.[28]

Sanofi argues that Dr. Bosserman has no support for these statements. In response, Plaintiff argues that these statements are part of Dr. Bosserman's general opinion that "[i]n order for shared decision making to be meaningful it is essential that all risks that are significant to patients be discussed."[29]

[26] Doc. 10929-9 at 53.
[27] *Id.* at 52.
[28] *Id.* at 57.
[29] *Id.* at 26.

Plaintiff further avers that Dr. Bosserman is relying on Dr. Ellen Feigal, one of Plaintiff's other experts, to support these points.

The Court will not allow Dr. Bosserman to offer these opinions. She may not opine on what knowledge Sanofi had, what knowledge the writers of the informed consent document had, or what information Kahn's medical providers had. Dr. Kardinal will be available to testify about whether he was informed of a risk of permanent alopecia. More significantly, after reviewing her report, the Court finds that Dr. Bosserman provides no analysis that would support her opinions about the knowledge that Sanofi or the writers of the informed consent document had. To the extent she relies on opinions from Dr. Feigal, Dr. Bosserman did not validate these opinions in any way in her report. This is the kind of "unblinking reliance" on another expert's opinion that violates Federal Rule of Evidence 703.[30] As previously noted, however, the Court will allow Dr. Bosserman to provide general testimony about how drug companies disseminate risk information.

[30] *See* In re TMI Litig., 193 F.3d 613, 715–16 (3d Cir. 1999) (excluding expert's opinion because "unblinking reliance" on another's opinion demonstrates that the expert's opinion was flawed under *Daubert*); Burst v. Shell Oil Co., Civil Action No. 14–109, 2015 WL 3620111, at *5 (E.D. La. May 9, 2015) ("[T]o the extent Dr. Harrison relies on Dr. Infante's report and the studies cited therein, his opinion is inadmissible because it reflects no original analysis or any evaluation of Dr. Infante's methodology or the studies upon which he relies."); Mooring v. Capital Fund, LLC v. Phoenix Cent., Inc., No. 06-cv-0006, 2009 WL 4263359, at *5 (W.D. Okla. Feb. 12, 2009) ("It is true that an expert may rely on facts and opinions not otherwise admissible if they are information of a type reasonably relied on by experts in that particular field. Fed. R. Evid. 703. That may include reliance on the opinions of other experts so long as it does not involve the wholesale adoption of another expert's opinions without attempting to assess the validity of the opinions relied on."); Cooper v. Meritor, Inc., No. 4:16-CV-52-DMB-JMV, 2019 WL 545271, at *3 (N.D. Miss. Feb. 11, 2019) ("As this Court explained in its order addressing the Brinkman report, an expert may not parrot another expert's opinion when the subject relates to an issue in the case and is not a cut-and-dried procedure. . . . The issues discussed by Nicar—the existence, exposure and source of contamination on the plaintiffs' properties in the Subdivision—are both related to issues in this case and, as the massive number of pages of briefing on the subjects suggest, are not cut and dried. Accordingly, to the extent Nicar's report parrots the opinions of other experts, his repetition of such opinions will be excluded.").

CONCLUSION

For the foregoing reasons, Defendants' Motion to Exclude Expert Testimony of Linda Bosserman, M.D. (Doc. 10929) is **GRANTED IN PART** and **DENIED IN PART**. Dr. Bosserman's testimony will be limited as described in this opinion.

New Orleans, Louisiana, this 1st day of February, 2021.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE