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 Causation Testimony of Dr. Gerald Miltello (Doc. 10919). 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 is set for May 24, 2021.[2]

In the instant Motion, Plaintiff Elizabeth Kahn, the second bellwether plaintiff, moves to exclude testimony from Dr. Gerald Miletello. Dr. Miletello

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

is an oncologist with years of experience treating breast cancer and other cancers. In her Motion, Plaintiff argues that Dr. Miletello's opinions are unreliable and misleading. 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:
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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]

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]

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[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. Miletello's Causation Opinions

First, Plaintiff argues that Dr. Miletello should not be able to opine on whether other drugs or conditions cause permanent hair loss. Plaintiff avers that Dr. Miletello did not use 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 or specific causation and need not use the same methodologies as Plaintiff. For the reasons provided in its order on Plaintiff's Motion to Exclude Testimony of John Glaspy, M.D., the Court rejects Plaintiff's argument and will not limit Dr. Miletello's testimony on this basis.[17]

Plaintiff next argues that Dr. Miletello makes misleading statements with little support. Plaintiff specifically takes issue with Dr. Miletello's statement that certain chemotherapy drugs, the aging process, and certain endocrine-based therapies may be responsible for a woman's hair loss. Plaintiff argues that this statement is based only on case studies and anecdotal reports, and jurors may make an inferential leap based on this to conclude that these occurrences can cause hair loss. The Court, however, disagrees. Dr. Miletello's years of clinical experience make him qualified to offer such a statement, and the Court disagrees that such a statement would mislead the jury to make any obvious erroneous conclusions.

The Court, however, will limit Dr. Miletello's testimony. The Court has noticed that both Dr. Glaspy and Dr. Miletello intend to testify on the types and causes of alopecia they have seen in their clinical practices. Similarly, both doctors intend to testify on alternative explanations for Plaintiff's hair loss. At oral argument, counsel for Sanofi admitted that the two doctors have overlapping testimony, although counsel stated that Dr. Glaspy's opinions are

[17] *See* Doc. 11780.

more expansive. Considering this, the Court will preclude Dr. Miletello from offering any opinions that are duplicative of Dr. Glaspy's opinions.

II. Dr. Miletello's Other Opinions

Lastly, Plaintiff takes issue with several of Dr. Miletello's opinions regarding Taxotere. The first is his opinion that Taxotere offered Plaintiff "the best chance of survival" compared to all other chemotherapy drugs, including Taxol. Plaintiff avers that this contradicts what the FDA has said, which is that Taxotere and Taxol offer the same chance of survivability and efficacy. In response, Sanofi avers that Dr. Miletello will opine only that taxane-containing regimens have shown better efficacy than older non-taxane-containing regimens.

To the extent his testimony is not duplicative of others' testimony, the Court will permit Dr. Miletello to testify about the efficacy of taxane-containing regimens. This opinion is supported by the medical literature and his years of clinical practice. Further, Sanofi concedes that Dr. Miletello finds Taxotere and Taxol equally efficacious. Indeed, at his deposition, Dr. Miletello agreed that Taxotere or Taxol would have given Plaintiff the best chance of survival.[18] The Court, therefore, does not anticipate that Dr. Miletello will contradict himself as Plaintiff argues. To the extent that he does, Plaintiff can illuminate this on cross-examination.

The next opinion Plaintiff challenges is Dr. Miletello's opinion as to what he believes was the best regimen to treat Plaintiff's breast cancer. Dr. Miletello testified that he "would have preferred Taxotere over Taxol in her situation."[19] In response, Sanofi emphasizes that in his report, Dr. Miletello discusses the risks and benefits of each drug and that he supports his opinions with clinical

[18] *Id.* at 3.
[19] Doc. 10919-3 at 9.

experience and medical literature. Sanofi further argues that the risk-benefit analysis of Taxotere as compared to other chemotherapies is very relevant to the jury.

The Court will permit Dr. Miletello to testify about his personal prescribing preferences and the risk-benefit analysis he employs in making his prescribing decisions. The jury will have to consider how Plaintiff Kahn and her treating physician would have weighed the risks and benefits of her treatment options, and Sanofi must be permitted to offer testimony that bears on this analysis.

Finally, Plaintiff challenges Dr. Miletello's opinion on the adequacy of the Taxotere label. Plaintiff argues that Dr. Miletello is not a labeling expert and that under the learned intermediary doctrine, only Plaintiff's prescribing oncologist should be able to testify about how he interpreted the label. In response, Sanofi argues that Dr. Miletello's understanding of the Taxotere label language is part-and-parcel of his testimony about why he prescribes Taxotere to his own patients.

The Court will permit Dr. Miletello to testify about the Taxotere label from his perspective as an oncologist. He may not, however, testify about whether the label complied with the FDA regulations as this falls outside of his expertise.[20]

CONCLUSION

For the foregoing reasons, Plaintiff's Motion to Exclude Causation Testimony of Dr. Gerald Miletello (Doc. 10919) is **GRANTED IN PART** and

[20] *See* Watkins v. Cook Inc., No. 13–CV–20370, 2015 WL 1395773, at *10 (S.D.W.Va. Mar. 25, 2015) (allowing doctor to opine on label based on knowledge and experience with product, but not on FDA regulations); Deutsch v. Novartis Pharmaceuticals Corps., 768 F. Supp. 2d 420, 440 (E.D.N.Y. 2011) (finding doctors qualified to "opine as to the adequacy

DENIED IN PART. Dr. Miletello'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

of the labels from the perspective of oncologists and prescribing physicians" but not as to whether label complied with FDA regulations).