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 David B. Ross (Doc. 12576). The Court held oral argument on the Motion on July 9, 2021. 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 August 23, 2021.[2]

Plaintiff Elizabeth Kahn, the second bellwether plaintiff, originally planned to call Dr. David Kessler as her regulatory expert at trial. Plaintiff has since learned, however, that Dr. Kessler is unavailable, and she has now

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

designated Dr. David Ross as her regulatory expert. Dr. Ross worked as a medical officer for the FDA from 1996 to 2006, and since then, he has worked as the Director of HIV, Hepatitis, and Related Conditions Programs for the United States Department of Veterans Affairs.[3] In the instant Motion, Sanofi seeks to exclude Dr. Ross's testimony. Plaintiff 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.[4]

The current version of Rule 702 reflects the Supreme Court's decisions in *Daubert v. Merrell Dow Pharms., Inc.*[5] and *Kumho Tire Co. v. Carmichael*.[6] The threshold inquiry in determining whether an individual may offer expert testimony under Rule 702 is whether the individual has the requisite qualifications.[7] After defining the permissible scope of the expert's testimony,

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[3] Doc. 12576-2 at 3–4, 9.
[4] FED. R. EVID. 702.
[5] 509 U.S. 579 (1993).
[6] 526 U.S. 137 (1999).
[7] 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

a court next assesses whether the opinions are reliable and relevant.[8] As the "gatekeeper" of expert testimony, the trial court enjoys broad discretion in determining admissibility.[9]

First, to assess reliability, a court considers whether the reasoning or methodology underlying the expert's testimony is valid.[10] The party offering the testimony bears the burden of establishing its reliability by a preponderance of the evidence.[11] Courts should exclude testimony based merely on subjective belief or unsupported speculation.[12] Courts must, however, give proper deference to the traditional adversary system and the role of the jury within that system.[13] "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."[14] After assessing reliability, a court evaluates relevance.[15] 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.[16]

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.[17]

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witness to testify if it finds that the witness is not qualified to testify in a particular field or on a given subject.").

[8] *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).

[9] *Wellogix*, 716 F.3d at 881.

[10] *See Daubert*, 509 U.S. at 592–93.

[11] *See* Moore v. Ashland Chem. Inc., 151 F.3d 269, 276 (5th Cir. 1998).

[12] *See Daubert*, 509 U.S. at 590.

[13] *See id.* at 596.

[14] *Id.*

[15] Burst v. Shell Oil Co., 120 F. Supp. 3d 547, 551 (E.D. La. June 9, 2015).

[16] *Id.*

[17] FED. R. EVID. 703.

LAW AND ANALYSIS

Sanofi argues that Dr. Ross failed to use a reliable methodology in forming his opinions. Specifically, Sanofi argues (1) that Dr. Ross cannot identify the facts and data that support his opinions; and (2) that Dr. Ross failed to follow FDA best practices in forming his opinions. The Court will address each argument in turn.

I. Support for His Opinions

Sanofi argues that Dr. Ross was unable to specifically identify the facts and data he used to form his opinions. Sanofi notes that when asked whether he reviewed the depositions cited in his reliance list, Dr. Ross "vaguely responded that he 'reviewed depositions and exhibits that were relevant to the opinions [he] was asked to . . . weigh in on or the topics that [he] was asked to provide opinions on.'"[18] When asked to identify "the precise methodology" that he used to determine if a document was relevant, he gave "a series of lengthy non-answers," according to Sanofi.[19] In response, Plaintiff avers that Dr. Ross adequately explains his methodology in his report.

The Court rejects Sanofi's argument. In his report, Dr. Ross specifically identifies the depositions he reviewed and those he did not review. In a footnote on the first page of his report, he admits that he did not review any case-specific depositions. [20] Elsewhere in his report, he specifically references the depositions of certain Sanofi employees, making clear that he reviewed those depositions.[21] He plainly states, too, that he reviewed the deposition of Sanofi's

[18] Doc. 12576-1 at 4.
[19] *Id.* at 4–5.
[20] Doc. 12576-2 at 2 ("I understand that my testimony will be offered in the case of Elizabeth Kahn, however I am offering regulatory opinions and have not reviewed Ms. Kahn's medical records, or any case-specific depositions.").
[21] *Id.* at 41 (quoting deposition of Emanuel Palatinsky); *id.* at 43 (referencing exhibits to deposition of Isabelle Richard-Cassin); *id.* at 44 (quoting deposition of Amy Freeman).

regulatory expert, Dr. Janet Arrowsmith, and he makes specific references to her deposition testimony.[22] Also, rather than providing "non-answers," as Sanofi asserts, Dr. Ross does describe his methodology when asked at his deposition. He stated: "My review was, basically, I would say the methodology that I would have used at the FDA."[23] He states that he considered the regulatory standard and the relevant data.[24]

Sanofi emphasizes, too, that Dr. Ross was unwilling to confirm whether he read a certain study, the Nabholtz study, which he cited in his report. Based on this, Sanofi assumes that Dr. Ross did not read the study. The Court, however, does not make the same assumption. At his deposition, Dr. Ross indicated that he knew what the contents of the study were, and he testified that he remembered it being an important piece of evidence.[25] He only seemed hesitant to confirm under oath that he had read it since he "[did not] have that document in front of [him]" at the time.[26] The Court, therefore, will not exclude Dr. Ross's opinions because of this but will instead leave the issue for Sanofi to explore before the jury on cross-examination.

II. FDA Best Practices

Next, Sanofi argues that Dr. Ross relies on an incomplete analysis by Plaintiff's expert statistician, Dr. David Madigan. According to Sanofi, a safety-signal analysis must involve signal identification followed by signal evaluation. In other words, per Sanofi, once individual case reports are identified in a database search, a reviewer should then evaluate each report to ensure that it does in fact relate to the adverse event at issue. Neither Dr. Madigan nor Dr. Ross, however, conducted such an evaluation of the reports

[22] *Id.* at 47–49.
[23] Doc. 12576-3 at 5.
[24] *Id.*
[25] *Id.* at 20.
[26] *Id.*

that Dr. Madigan identified in his search. In response, Plaintiff emphasizes that this Court has rejected a similar challenge to Dr. Madigan's testimony, and Plaintiff further avers that Dr. Madigan's work is only one of several sources Dr. Ross used to form his opinions.

Rule 703 of the Federal Rules of Evidence allows an expert to reasonably rely on the work of another expert, and the Court finds that Dr. Ross's reliance on Dr. Madigan's analysis appears reasonable. As Plaintiff notes, Dr. Ross relies upon Dr. Madigan's "Proportional Rate of Reporting" ("PRR") analysis among many other sources. Dr. Ross's report, then, does not show a "total reliance on Dr. Madigan's [analysis]" as Sanofi asserts.[27] Also, Dr. Ross explains that in his field of work, such reliance is common:

> Reliance upon a statistician in this regard is precisely what I did while performing and supervising the review of NDAs [New Drug Applications] [and] sNDAs [supplemental New Drug Applications] as a medical officer at FDA. I did not personally calculate PRRs or perform other analytics, and would rely upon calculations performed by others in performing medical officer reviews.[28]

Considering this testimony, the Court finds that Dr. Ross gave appropriate consideration to Dr. Madigan's work. To the extent that Sanofi argues that Dr. Madigan's search results lack relevance, Sanofi can explore this on cross-examination.

CONCLUSION

For the foregoing reasons, Defendants' Motion to Exclude Expert Testimony of David B. Ross (Doc. 12576) is **DENIED**.

[27] Doc. 12576-1 at 8.
[28] Doc. 12576-2 at 34.

New Orleans, Louisiana, this 14th day of July, 2021.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE