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: Barbara Earnest, 16-17144	)	

ORDER AND REASONS

Before the Court are several Motions in Limine: Plaintiff's Motion in Limine to Exclude Evidence of Unrelated Medical Conditions, Familial Medical History of Cancer, and Unrelated Medication Usage (Doc. 7647); Plaintiff's Motion in Limine to Preclude Any Comment or Argument that Taxol Would Have Enhanced the Severity of Plaintiff's Neuropathy (Doc. 7649); Plaintiff's Motion in Limine to Exclude Improper Arguments or Suggestions Regarding FDA Approval (Doc. 7659); Defendants' Motion to Preclude Evidence or Argument Concerning Sanofi Promotional and/or Marketing Materials Not Possessed or Relied on by Plaintiff or her Prescribing Physician (Doc. 7657); Defendants' Motion to Preclude Evidence or Argument Regarding Sanofi Sales Representatives (Doc. 7657); Defendants' Motion in Limine to Preclude Evidence or Argument Concerning Correspondence Between DDMAC and Sanofi (Doc. 7658); Defendants' Motion in Limine to Preclude Evidence or Argument Regarding Foreign Labeling and Regulatory Actions (Doc. 7666); Defendants' Motion in Limine to Preclude Evidence and Argument Regarding Shirley Ledlie and Any "Taxotears" or Other Third Party Advocacy or Communications Group or Group Members (Doc. 7670); and Defendants' Motion in Limine to Preclude Evidence and Argument Regarding Company Conduct that Post-Dates Plaintiff's Chemotherapy Treatment (Doc. 7671).

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. 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 of Plaintiff Barbara Earnest ("Plaintiff") is set to begin September 16, 2019.

On September 5, 2019, the Court held oral argument on several Motions in Limine as listed in its order setting oral argument (Doc. 8140). The Court ruled on certain Motions during the argument, as reflected in the minute entry (Doc. 8198). The Court rules on the remaining Motions herein.

I. Motion in Limine to Exclude Evidence of Unrelated Medical Conditions, Familial Medical History of Cancer, and Unrelated Medication Usage (Doc. 7647)

This Motion is granted in part and denied in part. The Court will not allow Defendants' experts to offer speculative testimony about medical conditions for which Plaintiff has no diagnosis. Similarly, Defendants cannot offer testimony regarding medication that Plaintiff does not use. If Defendants have a proper foundation for testimony on medical conditions for which Plaintiff has a diagnosis or medications that Plaintiff uses, Defendants may introduce limited testimony of this nature if it is relevant to determining the cause of Plaintiff's alleged hair loss. The Court will further allow limited

[1] Docetaxel is the generic version of Taxotere.

testimony on Plaintiff's family history of cancer as this is relevant to Plaintiff's mindset in deciding on her treatment plan.

II. Motion in Limine to Preclude Any Comment or Argument that Taxol Would Have Enhanced the Severity of Plaintiff's Neuropathy (Doc. 7649)

This Motion is granted in part and denied in part. The Court will allow testimony regarding the risk of neuropathy associated with Taxol. 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. As this Court has ruled, Dr. Carinder's prescribing decision would have been influenced by his conversations with Earnest. The jury will have to consider how Dr. Carinder and Earnest would have weighed the risks and benefits of her treatment options. The risk of neuropathy associated with Taxol is relevant to this analysis. The Court will not allow testimony of Earnest's subsequent development of neuropathy post-chemotherapy. Further, Defendants may not offer speculative testimony to suggest that Plaintiff would have suffered more severe neuropathy if she had chosen Taxol over Taxotere.

III. Motion in Limine to Exclude Improper Arguments or Suggestions Regarding FDA Approval (Doc. 7659)

This Motion is granted in part, denied in part, and deferred in part. The Court will not allow Defendants to argue or suggest that Sanofi was precluded from changing its label. This would be misleading given that Sanofi did not attempt to make a change under the "Changes Being Effected" ("CBE") regulation. This would further mislead the jury into believing that the FDA,

and not Sanofi, bears primary responsibility for their labeling.[2] In *Wyeth v. Levine*, the Supreme Court recognized that "manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times."[3] Sanofi cannot lead the jury to believe otherwise, and Sanofi cannot mispresent the fact that under the CBE regulation, a manufacturer may make a labeling change without waiting for FDA approval.

Consistent with this, the Court will not allow Defendants to argue or suggest that Sanofi provided the FDA with all pertinent information on reports of permanent alopecia and yet the FDA did not take action. This would improperly suggest to the jury that the FDA bears responsibility for Sanofi's label.

Plaintiff's Motion further seeks to exclude any argument that FDA review and approval equates to Taxotere being "safe and effective." The Court defers ruling on this until trial.

Lastly, Plaintiff's Motion seeks to exclude any argument that the FDA's deletion of information in the 2010 label is representative of specific intent, knowledge, or belief by the FDA regarding the adequacy of the Taxotere label as it relates to permanent hair loss. The Court will not allow such argument as this would be effectively arguing that Sanofi's obligations under state law are the same as their obligations to the FDA.

[2] *See* In re Trasylol Prods. Liab. Litig., 2010 WL 4259332, at *7 (excluding expert opinion that FDA is ultimate authority on information included in drug label).
[3] Wyeth v. Levine, 555 U.S. 555, 579 (2009).

IV. Motion to Preclude Evidence or Argument Concerning Sanofi Promotional and/or Marketing Materials Not Possessed or Relied on by Plaintiff or her Prescribing Physician (Doc. 7657 at p. 8)

This Motion is denied. Evidence showing how Sanofi communicated with doctors or patients about hair loss is relevant to Sanofi's state of mind and what knowledge Sanofi had of Taxotere's risk of hair loss.

V. Motion to Preclude Evidence or Argument Regarding Sanofi Sales Representatives (Doc. 7657 at p. 13)

This Motion is denied. Dr. Carinder's relationship with Sanofi's sales representatives is relevant.

VI. Defendants' Motion in Limine to Preclude Evidence or Argument Concerning Correspondence Between DDMAC and Sanofi (Doc. 7658)

This Motion is granted. The letters at issue relate to the use of Taxotere for lung cancer and metastatic breast cancer, neither of which Plaintiff had.

VII. Motion in Limine to Preclude Evidence or Argument Regarding Foreign Labeling and Regulatory Actions (Doc. 7666)

This Motion is granted in part and denied in part. Plaintiff may elicit evidence showing what Sanofi said about hair loss to foreign regulatory bodies. The Court will not allow evidence, however, regarding what any foreign regulatory bodies required of Sanofi.

VIII. Motion in Limine to Preclude Evidence and Argument Regarding Shirley Ledlie and Any "Taxotears" or Other Third Party Advocacy or Communications Group or Group Members (Doc. 7670)

This Motion is granted. However, if Plaintiff believes that Defendants have elicited testimony that "opened the door" on this subject, Plaintiff should request a conference with the Court to allow the Court to decide if the probative value of testimony relating to "Taxotears" or similar groups outweighs its prejudicial effect.

IX. Motion in Limine to Preclude Evidence and Argument Regarding Company Conduct that Post-Dates Plaintiff's Chemotherapy Treatment (Doc. 7671)

This Motion is granted. Any evidence of labeling changes occurring after Plaintiff's treatment constitute subsequent remedial measures as contemplated by Federal Rule of Evidence 407.

CONCLUSION

For the foregoing reasons, **IT IS ORDERED** that:

- Plaintiff's Motion in Limine to Exclude Evidence of Unrelated Medical Conditions, Familial Medical History of Cancer, and Unrelated Medication Usage (Doc. 7647) is **GRANTED IN PART** and **DENIED IN PART**;
- Plaintiff's Motion in Limine to Preclude Any Comment or Argument that Taxol Would Have Enhanced the Severity of Plaintiff's Neuropathy (Doc. 7649) is **GRANTED IN PART** and **DENIED IN PART**;
- Plaintiff's Motion in Limine to Exclude Improper Arguments or Suggestions Regarding FDA Approval (Doc. 7659) is **GRANTED IN PART**, **DENIED IN PART**, and **DEFERRED IN PART**;

- Defendants' Motion to Preclude Evidence or Argument Concerning Sanofi Promotional and/or Marketing Materials Not Possessed or Relied on by Plaintiff or her Prescribing Physician (Doc. 7657) and Motion to Preclude Evidence or Argument Regarding Sanofi Sales Representatives (Doc. 7657) are **DENIED**. The other arguments in Doc. 7657 remain pending before the Court;
- Defendants' Motion in Limine to Preclude Evidence or Argument Concerning Correspondence Between DDMAC and Sanofi (Doc. 7658) is **GRANTED**;
- Defendants' Motion in Limine to Preclude Evidence or Argument Regarding Foreign Labeling and Regulatory Actions (Doc. 7666) is **GRANTED IN PART** and **DENIED IN PART**;
- Defendants' Motion in Limine to Preclude Evidence and Argument Regarding Shirley Ledlie and Any "Taxotears" or Other Third Party Advocacy or Communications Group or Group Members (Doc. 7670) is **GRANTED**; and
- Defendants' Motion in Limine to Preclude Evidence and Argument Regarding Company Conduct that Post-Dates Plaintiff's Chemotherapy Treatment (Doc. 7671) is **GRANTED**.

New Orleans, Louisiana this 10th day of September, 2019.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE