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: All cases	)	

ORDER AND REASONS

Before the Court is Plaintiffs' Motion for Partial Summary Judgment on Affirmative Defenses Under La. Rev. Stat. § 9:2800.59 (Doc. 9230). The Court held oral argument on the Motion on May 7, 2020. 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. 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.

In the instant Motion, Plaintiffs attack a certain affirmative defense available under Louisiana law to the Taxotere manufacturers, Defendants sanofi-aventis U.S., LLC and Sanofi U.S. Services, Inc. (collectively, "Sanofi"). Under Louisiana Revised Statute 9:2800.59(B), a manufacturer is relieved of liability where, at the time the product left its control, it did not know and

[1] Docetaxel is the generic version of Taxotere.

could not have known of the damage-causing characteristic at issue. Plaintiffs ask the Court to grant partial summary judgment in their favor and hold that as of January 26, 2007, Sanofi had or could have had knowledge of Taxotere's risk of permanent alopecia.

LEGAL STANDARD

Summary judgment is warranted where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."[2] A genuine issue of fact exists only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party."[3] Rule 56 of the Federal Rules of Civil Procedure "mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial."[4] "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted."[5]

LAW AND ANALYSIS

"To successfully maintain a failure-to-warn claim under the LPLA [Louisiana Products Liability Act], a plaintiff must demonstrate that the product in question has a potentially damage-causing characteristic and that the manufacturer failed to use reasonable care to provide an adequate warning

[2] FED. R. CIV. P. 56.
[3] Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).
[4] Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).
[5] *Anderson*, 477 U.S. at 249–50 (internal citations omitted).

about this characteristic."[6] Under Louisiana Revised Statute 9:2800.59(B), an affirmative defense to a failure to warn claim exists where "the manufacturer proves that, at the time the product left his control, he did not know and, in light of then-existing reasonably available scientific and technological knowledge, could not have known of the characteristic that caused the damage or the danger of such characteristic."[7]

According to Plaintiffs, the evidence establishes that on January 26, 2007, Sanofi had knowledge of Taxotere's risk of permanent alopecia. Plaintiffs aver that on this date, Sanofi approved changes to a certain informed consent document. The document at issue was created by a Canadian facility, the Cross Cancer Institute, for use in a clinical trial.[8] Originally, it listed both "hair loss" and "permanent hair loss" as "Reported Side Effects" of Taxotere.[9] When the author of the document sent a draft to Sanofi for review, Dr. Emanuel Palatinsky responded for Sanofi.[10] He wrote that "'hair loss' is repetitive (permanent [hair loss] is sufficient once)."[11] Notably, the document provided that the side effects listed "are the side effects we know about at present," noting that there may be other side effects "that we do not know about yet."[12] Plaintiffs emphasize that Sanofi approved the language in this document.

Plaintiffs suggest that the reason Sanofi approved "permanent hair loss" on this form was because Sanofi had been acquiring information about permanent hair loss for years. Between 2003 and 2004, Sanofi received reports

[6] Stahl v. Novartis Pharm. Corp., 283 F.3d 254, 264 (5th Cir. 2002). *See also* LA. REV. STAT. ANN. § 9:2800.57(A).
[7] LA. REV. STAT. ANN. § 9:2800.59(B).
[8] Doc. 9970-1 at 19–20. *See also* 9230-9 at 4.
[9] Doc. 9230-9 at 11.
[10] *See id.* at 1.
[11] *Id. See also* Doc. 9230-1 at 3.
[12] Doc. 9230-9 at 9.

of "at least 15 cases" of permanent hair loss from participants in certain clinical trials.[13] In addition to this, Plaintiffs highlight a 2001 publication by Dr. Jean-Marc Nabholtz, which reported "long-lasting (longer than 2 years) partial alopecia" in four out of 54 patients.[14] Lastly, in 2006, Dr. Scot Sedlacek made a presentation at a breast cancer symposium describing a link between Taxotere and permanent alopecia. Plaintiffs note that Sanofi discussed Dr. Sedlacek's findings with him around the time of his presentation. Ultimately, Plaintiffs aver that this evidence and Sanofi's decision to sanction "permanent hair loss" on the informed consent document leave no genuine dispute of fact regarding Sanofi's knowledge of the risk as of January 26, 2007.

The statutory provisions at issue here contemplate two steps. First, a plaintiff must prove that the product in question had "a potentially damage-causing characteristic."[15] This requires proving general causation. A plaintiff must also prove that "the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic."[16] Once this first step is established, the burden shifts to the defendant to prove its affirmative defense. There, the manufacturer must prove that "at the time the product left his control, he did not know and, in light of then-existing reasonably available scientific and technological knowledge, could not have known of the characteristic that caused the damage or the danger of such characteristic."[17]

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[13] *See* Doc. 9230-2 at ¶ 18.
[14] Doc. 9230-38 at 5–6.
[15] *Stahl*, 283 F.3d at 264. *See also* LA. REV. STAT. ANN. § 9:2800.57(A) ("A product is unreasonably dangerous because an adequate warning about the product has not been provided if, at the time the product left its manufacturer's control, the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.").
[16] LA. REV. STAT. ANN. § 9:2800.57(A)
[17] *Id.* § 9:2800.59(B).

This second step focuses on the sufficiency of the information available to the manufacturer. Sanofi appears to conflate these two steps.

Sanofi focuses much of its briefing on a "Clinical Overview" that the company issued in 2011. To prepare this report, the company's safety department conducted a comprehensive review of information relating to persistent alopecia and Taxotere. After assessing 1,620 cases of alopecia, Sanofi concluded that it was "impossible" to determine the cause of any given patient's persistent alopecia because of the multiple confounding factors present with each report.[18] Relying on this evidence, Sanofi fails to focus on the information that was available to it as of January 26, 2007. Similarly, Sanofi notes that in 2015, the FDA found that "it's impossible to determine whether the permanence of [patients'] alopecia was due to docetaxel."[19] These pieces of evidence are more relevant to the first step of the analysis, although they do assist the Court in assessing the information that was available to Sanofi in 2007.

Focusing on the second step, which is the heart of the affirmative defense at issue, the Court finds that Plaintiffs have not carried their summary judgment burden. Plaintiffs have failed to show that there is no issue of material fact regarding whether Sanofi knew or had reason to know in January 2007 that Taxotere carried a risk of permanent alopecia. On this issue, Plaintiffs present the informed consent of the Cross Cancer Institute, Dr. Sedlacek's findings, the 2001 publication of Dr. Nabholtz, and several case reports.

[18] *See* Doc. 9970-8 at 102–03.
[19] Doc. 9970-25.

1. The Informed Consent

Although the informed consent document was prepared for use in a Sanofi-sponsored study, the document was not drafted by Sanofi. As previously noted, the author of the document sent it to Sanofi only for review and approval. Further, this study was permanently suspended before any patients ever enrolled at this Canadian study site, and the form at issue was never actually used.[20] Perhaps more importantly, however, the study had involved other drugs; it was not focused on Taxotere. The informed consent document states as follows:

> **"WHAT DO WE HOPE TO LEARN?"**
>
> The purpose of this Phase II study is to evaluate the safety, with respect to the heart, of adding treatment with a drug called bevacizumab to two established chemotherapy regimens whose cardiac (heart) safety profile has already been described and to evaluate the effectiveness of adding a drug, bevacizumab, to those two established chemotherapy regimens for breast cancer. Both anticancer regimens will include one or more established chemotherapy drugs: docetaxel, doxorubicin, and cyclophosphamide (TAC), or docetaxel and carboplatin combined with a biologic drug, trastuzumab (TCH). Both anticancer regimens will include the experimental addition of a biologic drug, bevacizumab.[21]

The evidence shows, therefore, that the focus of the study was on bevacizumab and how it affects heart safety.

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[20] *See* Doc. 9970-12 (p. 3) ("Enrollment was permanently suspended and all sites were terminated in November 2008."); (pp. 5736–39) (listing study sites with patients enrolled and not including the Cross Cancer Institute).

[21] Doc. 9230-9 at 5.

As the Court noted, Dr. Palatinsky responded to the author of the study and provided feedback on "the content of the docetaxel section."[22] In a "Track Changes" comment in the document's margin, Dr. Palatinsky wrote, "Hair loss-duplicate entry."[23] In the body of his email, he highlighted this, writing that "'Hair loss' is repetitive (permanent h. l. is sufficient once)."[24] Indeed, looking at the document, the Court sees that "hair loss" and "permanent hair loss" were initially both listed as side effects for Taxotere. Dr. Palatinsky, therefore, was pointing out a matter of fact. Given this and the other limitations discussed, the Court simply cannot extrapolate from Dr. Palatinsky's informal comments to find that Sanofi had knowledge as contemplated by the statute.

2. Dr. Sedlacek's Findings

The results from Dr. Sedlacek's research show that "[a]ll 7 of these women with [persistent significant alopecia] had received AC X 4 (60/600 mg/m2) every 3 weeks followed by docetaxel (100 mg/m2) every three weeks."[25] Dr. Sedlacek acknowledged the limitations of his findings, concluding only that "when docetaxel is administered after 4 doses of AC, there is a small but significant possibility of poor hair regrowth."[26] This evidence tells the Court that these seven women also received Adriamycin and Cytoxan in addition to docetaxel. Notably, Plaintiffs' own experts have acknowledged that these drugs are associated with permanent hair loss.[27]

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[22] *Id.* at 1.
[23] *Id.* at 11.
[24] *Id.* at 1.
[25] Doc. 9230-3.
[26] *Id.*
[27] *See* Doc. 9970-33 at 8 (Dr. Laura Plunkett) ("Q: You identified permanent hair loss as a hazard of Adriamycin; correct? A: Same answer. There are some case reports for that as well. Not many, but there are some."); *id.* at 9 (Dr. Plunkett) ("Q: So with regard to, again, your work in this case, your search, your review, your analysis of the literature, you would agree with me that you identified permanent hair loss as a hazard of Cytoxan; correct? A: In terms of case repots, yes, there are some case reports."); *id.* at 12–13 (Dr. Antonella

3. The 2001 Publication of Dr. Nabholtz

Like Dr. Sedlacek's research, the findings in the 2001 publication of Dr. Nabholtz have limitations. The Nabholtz study "investigated the efficacy and toxicity of docetaxel with doxorubicin and cyclophosphamide (TAC) as first-line chemotherapy for anthracycline-naive patients with metastatic breast cancer."[28] Of the 54 patients studied, around one third (31 percent) of the patients had received previous adjuvant and/or neoadjuvant chemotherapy.[29] No patient had, however, been previously exposed to anthracyclines.[30] While the Nabholtz study did report long lasting (greater than two years) partial alopecia in four patients,[31] there appears to be no indication of whether those patients had previously been exposed to chemotherapy. Given these confounding factors—the fact that these four patients may have had prior chemotherapy and the fact that they were given both doxorubicin and cyclophosphamide—the Court cannot determine the strength of this evidence.

4. The Case Reports

Plaintiffs identify several specific case reports that Sanofi received from Dr. John Mackey between 2003 and 2004. These reports, however, present confounding factors. For example, Plaintiffs highlight Dr. Mackey's Patient No. 11158, averring that she suffered persistent hair loss after completing her Taxotere treatment. This patient's records, however, show that she was

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Tosti) ("Q: Is Adriamycin considered an anthracycline drug? A: Yes. Q: And there's case reports of persistent chemotherapy induced alopecia with anthracycline regimens; true? A: Yes."); *id.* at 13 (Dr. Tosti) ("Q: And you'd agree that Cytoxan causes hair loss; true? A: Yes. Q: And you'd also agree with me, Doctor, that there are reports in the literature which you have seen personally of persistent chemotherapy induced alopecia with Cytoxan? A: Very rare.").

[28] Doc. 9230-38 at 2.

[29] *Id.* at 4.

[30] *Id.*

[31] *Id.* at 6.

administered other drugs along with Taxotere—namely, Adriamycin and Cytoxan.[32] Similarly, the records for Patient No. 12994, another patient who reported persistent hair loss, show that she was given "doxorubicin and cyclophosphamide followed by Taxotere."[33] In addition to these confounding factors, certain patients suffered other health conditions associated with hair loss. The records for Patient No. 12607 show that she suffered from hypothyroidism,[34] and the records for Patient No. 11293 show that she suffered from chronic anemia.[35]

The evidence presented by Plaintiffs gives the Court pause. However, without more this Court cannot say that there is no genuine dispute as to whether Sanofi had or should have had knowledge of Taxotere's alleged risk of permanent alopecia as of January 26, 2007. This is a question for the jury.

Sanofi has presented evidence to suggest that it was intentionally over-inclusive with its hair loss warnings. Sanofi avers that it warned of "alopecia," which by its very nature is unpredictable. In her deposition, Dr. Frances Polizzano, the Senior Labeling Director for Taxotere, testified that "[a]lopecia is a term that sort of encompasses a range of -- ranging from anything from you have nothing to permanent. So it could be transient. It could be temporary. It could be persisting. It's the full spectrum of hair loss."[36] Sanofi also points to testimony from Dr. Palatinsky, who testified that "[t]hey were warned about persistent alopecia because the concept of persistent alopecia is inherent to alopecia. A physician reading the USPI and a patient reading [] the product

[32] Doc. 9230-28 at 1; Doc. 9230-29 at 1.
[33] Doc. 9230-10 at 3.
[34] Doc. 9230-13.
[35] Doc. 9230-17.
[36] Doc. 9970-47 at 4–5.

information leaflet will know that alopecia could be reversible or it might not be reversible."[37]

The evidence presented is subject to multiple interpretations. Because of this, the evidence is "such that a reasonable jury could return a verdict for the nonmoving party."[38] Accordingly, the Court finds that Plaintiffs are not entitled to summary judgment under Rule 56. Instead, Sanofi must be given the opportunity to present its affirmative defense to the jury.

CONCLUSION

For the foregoing reasons, Plaintiffs' Motion for Partial Summary Judgment on Affirmative Defenses Under La. Rev. Stat. § 9:2800.59 (Doc. 9230) is **DENIED**.

New Orleans, Louisiana this 1st day of July, 2020.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE

[37] Doc. 9970-13 at 13.
[38] *Anderson*, 477 U.S. at 249–50 (internal citations omitted).