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: Clare Guilbault, 16-17061	)	

ORDER AND REASONS

Before the Court is a Motion for Summary Judgment Based on the Learned Intermediary Doctrine (Doc. 12538). On November 24, 2021, the Court granted the Motion with written reasons to follow (Doc. 13462). For the following reasons, the Motion is **GRANTED**.

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 Hospira, Inc. and Hospira Worldwide, LLC, formerly doing business as Hospira Worldwide, Inc. (collectively, "Hospira" or "Defendants"). Plaintiffs allege that the drug caused permanent alopecia, or 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 was held in November 2021.[2]

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

In May 2020, the Court selected Plaintiff Clare Guilbault to proceed with discovery in preparation for the fifth bellwether trial.[3] Plaintiff Guilbault was diagnosed with breast cancer in 2013 at the age of 61.[4] Her oncologist, Dr. Chris Theodossiou, prescribed her "the standard preoperative [chemotherapy] regimen," which contained Adriamycin, Cytoxan, and docetaxel.[5] After completing chemotherapy, Guilbault underwent a lumpectomy.[6] Guilbault has now filed this lawsuit against Hospira, claiming that she suffers permanent hair loss as a result of taking docetaxel.

In the instant Motion, Hospira moves for summary judgment against Plaintiff Guilbault, arguing that under the learned intermediary doctrine, she cannot establish the essential element of causation in her case. Plaintiff Guilbault opposes the Motion.

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."[7] A genuine issue of fact exists only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party."[8] When considering a summary judgment motion, the Court must view the entire record in the light most favorable to the non-moving party and indulge all reasonable inferences in that party's favor.[9]

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[3] The Court selected three other Plaintiffs as well—Debbie Hubbard, Audrey Plaisance, and Lula Gavin. *See* Doc. 10461 (Case Management Order No. 26).
[4] Doc. 12538-3 at 3.
[5] Doc. 12538-4 at 3.
[6] *See* Doc. 12538-3 at 5.
[7] FED. R. CIV. P. 56.
[8] Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).
[9] Crawford v. Formosa Plastics Corp., 234 F.3d 899, 902 (5th Cir. 2000).

LAW AND ANALYSIS

Hospira argues that Plaintiff has failed to carry her burden of showing that a different warning in the docetaxel label would have changed her doctor's prescribing decision. Hospira emphasizes testimony from Dr. Theodossiou saying he did not recall reading the Hospira label or relying on any information in the Hospira label before prescribing docetaxel to Guilbault. Hospira also emphasizes that when Dr. Theodossiou prescribed docetaxel to Plaintiff, he did not prescribe Hospira's docetaxel specifically and did not know which manufacturer's docetaxel Plaintiff would receive. In response, Plaintiff argues that Hospira is speculating and that at his deposition, Dr. Theodossiou was never clearly asked whether he had read the Hospira label.

Having reviewed the evidence, this Court finds that there is no genuine dispute of fact on causation. Under Louisiana law, failure to warn claims involving prescription drugs are subject to the learned intermediary doctrine.[10] Under the doctrine, the manufacturer of a prescription drug "has no duty to warn the patient, but need only warn the patient's physician."[11] In other words, a manufacturer's duty runs only to the physician—the learned intermediary.[12]

The Fifth Circuit has held that there is a two-prong test governing inadequate warning claims under the Louisiana Products Liability Act ("LPLA") when the learned intermediary doctrine is applicable:

> First, the plaintiff must show that the defendant failed to warn (or inadequately warned) the physician of a risk associated with the product that was not otherwise known to the physician. Second, the plaintiff

[10] Grenier v. Med. Eng'g Corp., 99 F. Supp. 2d 759, 765 (W.D. La. 2000) (applying Louisiana law), *aff'd*, 243 F.3d 200 (5th Cir. 2001).
[11] Willett v. Baxter Intern., Inc., 929 F.2d 1094, 1098 (5th Cir. 1991).
[12] *Grenier*, 99 F. Supp. 2d at 766.

> must show that this failure to warn the physician was both a cause in fact and the proximate cause of the plaintiff's injury.[13]

Regarding the second prong, the law is well established that, to prove causation, "the plaintiff must show that a proper warning would have changed the decision of the treating physician, i.e. that but for the inadequate warning, the treating physician would not have used or prescribed the product."[14]

The Fifth Circuit recently issued a ruling relating to a case in this MDL—*June Phillips v. Sanofi U.S. Services, et al.*[15] Applying the learned intermediary doctrine in the chemotherapy context, the court noted that while "[t]he decision to use a drug in a particular circumstance rests with [both] the doctor and the patient,"[16] a causation analysis must focus on "the prescribing physician's decision to prescribe the drug."[17] The court then considered whether a warning regarding permanent alopecia would have altered the physician's risk-benefit assessment of Taxotere.[18]

Here, the record is lacking in evidence showing that a warning in the Hospira label would have affected Dr. Theodossiou's prescribing decision. As this Court has noted, when a physician does not recall ever reading the label

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[13] Stahl v. Novartis Pharms. Corp., 283 F.3d 254, 265–66 (5th Cir. 2002) (internal citation omitted).

[14] *Willett*, 929 F.2d at 1099; *see also* Pellegrin v. C.R. Bard, No. 17-12473, 2018 WL 3046570, at *4 (E.D. La. June 20, 2018).

[15] In re Taxotere (Docetaxel) Prods. Liab. Litig. (June Phillips v. Sanofi U.S. Services, et al.), 994 F.3d 704 (5th Cir. 2021).

[16] *Id.* at 708 (quoting Calhoun v. Hoffman-La Roche, Inc., 768 So. 2d 57, 59 n.1 (La. App. 1 Cir.), *writ denied*, 765 So. 2d 1041 (La. 2000)).

[17] *Id.* The Court acknowledges the clarification from the Fifth Circuit in footnote four of its opinion, providing that the question is not "whether and how the doctor would have advised the patient of the risk of permanent alopecia associated with Taxotere, whether the patient would have inquired about other options, what the doctor would have recommended, and what decision the plaintiff would have ultimately made." *Id.* at 709 n.4.

[18] *See id.*

at issue, the learned intermediary doctrine requires summary judgment for the manufacturer.[19] Dr. Theodossiou testified as follows:

> Q: Did you review the Hospira Docetaxel label before prescribing Docetaxel for Ms. Guilbault?
>
> A: I don't recall.
>
> [. . .]
>
> Q: So you don't recall whether you relied upon any information in the Hospira label before prescribing Docetaxel to Ms. Guilbault?
>
> A: No, sir, I do not recall.[20]

As the Fifth Circuit recognized in *Pustejovsky v. Pliva, Inc.*, "[a physician's] lack of memory, of course, does not preclude the possibility that [he] read these materials, but neither can it sustain [the plaintiff's] burden."[21] The same is true here. Plaintiff cannot sustain her burden on this question.

Plaintiff seemingly suggests that because Dr. Theodossiou also considers information acquired from peer-reviewed literature, attendance at educational seminars, and discussions with colleagues when determining what drug to prescribe, he would have learned of an update to the Hospira label in one of

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[19] Doc. 12494 at 6 (citing Pustejovsky v. Pliva, Inc., 623 F.3d 271, 277 (5th Cir. 2010)). Although *Pustejovsky* applied the Texas learned intermediary doctrine, the Court finds the case instructive here. *See* Dykes v. Johnson & Johnson, No. 09-5909, 2011 WL 2003407, at *5 (E.D. La. May 20, 2011) (relying on *Pustejovsky* in applying the Louisiana learned intermediary doctrine).

Plaintiff argues that *Pustejovsky* is distinguishable because Texas, unlike Louisiana, does not recognize a "read and heed" presumption in cases involving prescription medical products—in other words, there is no presumption under Texas law that an intermediary would have read and heeded an adequate warning. *See* Ackermann v. Wyeth Pharms., 526 F.3d 203, 212 (5th Cir. 2008). However, even under Louisiana law, the heeding presumption cannot save a plaintiff's case when there is no evidence that the manufacturer's warning played any role in the events leading to a plaintiff's injury. *See* Hall v. Sinn, Inc., 102 F. App'x 846, 849 (5th Cir. 2004).

[20] Doc. 12538-4 at 10.

[21] *Pustejovsky*, 623 F.3d at 277.

these ways and altered his prescribing decision.[22] However, the Fifth Circuit rejected this argument in *Pustejovsky*.[23] There, the plaintiff speculated about other ways the prescribing physician might have become aware of an update to the drug's label, such as conversations with other physicians or discussions at continuing education seminars. The court recognized that these scenarios were certainly possible but found that "without any summary-judgment type evidence to support them, they remain nothing more than possibilities."[24] Again, the same is true here.[25]

Accordingly, without more evidence, the Court must assume that even if the Hospira label had warned of permanent alopecia, Dr. Theodossiou would not have seen this warning or altered his decision because of it. Ultimately, then, there is no issue of fact regarding whether Hospira's allegedly inadequate warning was the cause of Plaintiff's injuries.[26]

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[22] *Id.*
[23] *Id.*
[24] *Id.*
[25] In *Pustejovsky*, the Fifth Circuit specifically noted the evidence that was lacking, stating:

> Although Dr. Collini did testify that she attended continuing-education seminars where [the drug] was discussed as a treatment option, there is no evidence of the content of these lectures, and Dr. Collini did not recall whether side effects were ever discussed at any seminar she had attended. Neither did she recall discussing [the drug's] side effects with any of her colleagues.

Id. The evidence is even slimmer here. It is not enough that Dr. Theodossiou read peer-reviewed literature, attended educational seminars, and had discussions with his colleagues in general; rather, there must be some evidence that he acquired information about the side effects of docetaxel through these acts, and there is not.
[26] Doc. 12494 at 6–7.

CONCLUSION

For the foregoing reasons, Hospira's Motion for Summary Judgment Based on the Learned Intermediary Doctrine (Doc. 12538) is **GRANTED**. Plaintiff Clare Guilbault's case is **DISMISSED WITH PREJUDICE**.

New Orleans, Louisiana this 11th day of January, 2022.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE