**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF LOUISIANA**

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| **IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION** | ) | **MDL No. 16-2740** |
| | ) | **SECTION: "H" (5)** |
| **This document relates to:** Wanda Stewart, 17-10817 | ) | |

## ORDER AND REASONS

Before the Court is a Motion for Summary Judgment (Doc. 11473). The Court held oral argument on the Motion on March 19, 2021. 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 is Defendant Sandoz Inc. ("Sandoz"). 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 August 23, 2021.[2]

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

In October 2019, the Court selected Plaintiff Wanda Stewart to proceed with discovery in preparation for the third bellwether trial.[3] Plaintiff Stewart was diagnosed with an aggressive breast cancer in May 2014 at the age of 45.[4] Her oncologist, Dr. Christopher McCanless, discovered a large tumor on her right breast, and a biopsy revealed that the cancer had infiltrated her lymph nodes.[5] To shrink the tumor, Plaintiff began chemotherapy treatments in June 2014.[6] Upon her doctor's recommendation, she received a regimen that contained docetaxel.[7] Following chemotherapy, she had a double mastectomy, opting for this over a unilateral mastectomy to avoid the risk of developing cancer in her other breast.[8] Ultimately, her treatments were successful in stopping her cancer, and she has been cancer-free since September 2014.[9]

In the instant Motion, Sandoz seeks summary judgment, arguing that under the learned intermediary doctrine, Plaintiff Stewart cannot establish the essential element of causation in her case.[10] Plaintiff 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

[3] The Court selected two other Plaintiffs as well—Dora Sanford and Alice Hughes. *See* Doc. 8430 (Case Management Order No. 21). The Court has since dismissed Dora Sanford's case. *See* Doc. 10807.
[4] *See* Doc. 11473-3 at 5; Doc. 11473-4 at 3.
[5] *See* Doc. 11473-15 at 50; Doc. 11473-5 at 15.
[6] See Doc. 11473-5 at 15; Doc. 11473-3 at 5.
[7] *See* Doc. 11473-5 at 74.
[8] *Id.* at 51.
[9] *See id.* at 12, 54.
[10] Sandoz raises two arguments that the Court will not address: (1) that it is entitled to summary judgment on all claims that do not sound under inadequate warning under the Louisiana Products Liability Act; and (2) that Plaintiff cannot establish specific causation through expert testimony. The Court will not address the first argument because Plaintiff, in her response, clarifies that the only claim she brings is her inadequate warning claim, and the Court will not address the second argument because the Court will grant summary judgment pursuant to the learned intermediary doctrine.

law."[11] A genuine issue of fact exists only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party."[12] 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.[13]

## LAW AND ANALYSIS

### I. The Parties' Arguments

Sandoz 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. Sandoz points to deposition testimony from Dr. McCanless, saying that he never read the Sandoz docetaxel label because he was familiar with the Taxotere label and "didn't know there would be a difference between the two."[14] Sandoz further argues that even if Dr. McCanless had read the label and the label contained information on the risk of permanent hair loss, Dr. McCanless would not have changed his decision to prescribe docetaxel because there were no alternatives that he believed were adequate to treat Plaintiff's aggressive cancer. Citing this Court's prior opinions, Sandoz acknowledges that patient choice does factor into the prescribing decision, but Sandoz avers that Plaintiff trusted Dr. McCanless and would not have inquired about alternatives.

In response, Plaintiff argues that this case presents a genuine issue of fact for the jury to resolve. She avers that Dr. McCanless would have learned of an update to the Sandoz label through a service called UpToDate, and

[11] FED. R. CIV. P. 56.
[12] Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).
[13] Crawford v. Formosa Plastics Corp., 234 F.3d 899, 902 (5th Cir. 2000).
[14] Doc. 11473-2 at 23.

Plaintiff emphasizes that at the time of her treatment, Dr. McCanless was unaware of the risk of permanent alopecia associated with docetaxel. She points to testimony from Dr. McCanless stating that if the label had contained wording as to permanent hair loss, "that would be something that [he would] counsel his patients to," and he does not recall doing so with Stewart.[15] Plaintiff notes that the National Comprehensive Cancer Network ("NCCN") guidelines listed nine alternative chemotherapy regimens that were available to treat Plaintiff's cancer, and she avers that if she had been presented with other effective chemotherapy options that did not carry a risk of permanent hair loss, she "probably would have went with the other option."[16]

## II. The Court's Analysis

Under Louisiana law, failure to warn claims involving prescription drugs are subject to the learned intermediary doctrine.[17] Under the doctrine, the manufacturer of a prescription drug "has no duty to warn the patient, but need only warn the patient's physician."[18] In other words, a manufacturer's duty runs only to the physician—the learned intermediary.[19]

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 must show that this failure to warn the physician was

[15] Doc. 11758 at 8; Doc. 11473-15 at 32.
[16] *Id.* at 10.
[17] 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).
[18] Willett v. Baxter Intern., Inc., 929 F.2d 1094, 1098 (5th Cir. 1991).
[19] *Grenier*, 99 F. Supp. 2d at 766.

> both a cause in fact and the proximate cause of the plaintiff's injury.[20]

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."[21]

As the Court has discussed in prior rulings, the chemotherapy decision-making process is unique. The Court must consider not only whether an oncologist would have warned his or her patient of the risk of permanent alopecia but also how patient choice then would have steered the conversation and the ultimate prescribing decision. Here, Sandoz shown that under the learned intermediary framework, Plaintiff cannot establish causation.

**a. Dr. McCanless and the Sandoz Label**

As an initial matter, Plaintiff has failed to create an issue of fact on whether Dr. McCanless would have reviewed the Sandoz label or learned of any update to it regarding permanent hair loss. Without evidence to establish this, Plaintiff cannot establish that a different warning from Sandoz would have changed Dr. McCanless's prescribing decision.

Dr. McCanless testified that because he was familiar with the Taxotere label, he would not have reviewed the Sandoz label for docetaxel, a generic version of Taxotere.[22] He further testified as follows:

> Q: And I believe you testified to this earlier, I could be mistaken, but you haven't seen the label for the docetaxel that's manufactured by Sandoz?

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[20] Stahl v. Novartis Pharmaceuticals Corp., 283 F.3d 254, 265–66 (5th Cir. 2002) (internal citation omitted).
[21] *Willett*, 929 F.2d at 1099. *See also* Pellegrin v. C.R. Bard, 2018 WL 3046570, at *4 (E.D. La. June 20, 2018).
[22] Doc. 11473-15 at 15.

A: The --

Q: The drug label.

A: You mean the drug pamphlet?

Q: Correct, with the warnings and all that.

A: I mean, I'm sure I've looked at it at one point. I haven't recently reviewed it.[23]

Indeed, even though Sandoz changed its label in 2016 to warn of a possibility of permanent hair loss,[24] Dr. McCanless testified at his deposition in 2019 that he had not seen this warning.[25]

When a physician does not recall ever reading the label at issue, the learned intermediary doctrine requires summary judgment for the manufacturer.[26] In *Pustejovsky v. Pliva, Inc.*, the plaintiff, like Stewart, sued a drug manufacturer for failure to warn.[27] The Fifth Circuit held that the plaintiff failed to produce sufficient evidence showing that the manufacturer's inadequate warning was the "producing cause" of the plaintiff's injuries, as required by the learned intermediary doctrine.[28] Significantly, the plaintiff's prescribing physician testified that she did not recall ever reading the package insert for the generic drug at issue.[29] The court wrote that "[the physician's] lack of memory, of course, does not preclude the possibility that she had read these materials, but neither can it sustain [the plaintiff's] burden."[30]

The same is true here. This Court finds that Plaintiff Stewart cannot sustain her burden on this question. Plaintiff emphasizes testimony from Dr.

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[23] *Id.* at 31.
[24] *See* Doc. 11473-3 at 10; Doc. 4407 at 12.
[25] *See* Doc. 11473-15 at 31.
[26] *See* Pustejovsky v. Pliva, Inc., 623 F.3d 271, 277 (5th Cir. 2010).
[27] *Id.* at 274.
[28] *See id.* at 276–77.
[29] *Id.* at 273, 277.
[30] *Id.* at 277.

McCanless saying, "I'm sure I've looked at [the Sandoz docetaxel] label at one point."[31] Under *Pustejovsky*, though, this is not enough. Plaintiff further suggests that because Dr. McCanless uses a service called UpToDate, he would have learned of a label update for permanent alopecia through this service.[32] Yet, again, under *Pustejovsky*, this is not enough. The *Pustejovsky* plaintiff argued that her prescribing physician might have learned of an adequate warning through conversations with other physicians.[33] The Fifth Circuit rejected this argument, writing: "Certainly, these scenarios are possible. Ultimately, however, without any summary-judgment evidence to support them, they remain nothing more than possibilities."[34] Plaintiff Stewart similarly has presented no evidence that Dr. McCanless would have learned of a Sandoz label change through UpToDate. At best, this is nothing more than a possibility. At worst, the record suggests that Dr. McCanless would *not* have learned of such an update. At his deposition in 2019, Dr. McCanless still had seen nothing about the 2016 update to the Sandoz label.[35] Ultimately, then, Plaintiff has failed to carry this part of her burden.[36]

**b. Dr. McCanless's Prescribing Decision**

Even if the Court assumes that Dr. McCanless would have learned of a Sandoz label change, either through the docetaxel label or another source, Plaintiff nonetheless cannot defeat Sandoz's Motion. Plaintiff argues that she is entitled to a "heeding presumption" recognized in Louisiana—a presumption

[31] Doc. 11758 at 13. Doc. 11473-15 at 31.
[32] Doc. 11758 at 13.
[33] *Pustejovsky*, 623 F.3d at 277.
[34] *Id.*
[35] *See* Doc. 11473-15 at 31.
[36] *See* Dykes v. Johnson & Johnson, Civil Action No. 09–5909, 2011 WL 2003407, at *5 (E.D. La. May 20, 2011) ("Dr. Williams never read the warning, and thus the warning played no role in the events leading to plaintiff's injury. . . . [E]ven if the Court were to assume, *arguendo*, that the warning was inadequate, plaintiff would be unable to show that a proper warning would have changed her doctor's decision—she never read it.").

that "had there been adequate warnings, 'the user would have read and heeded [the] admonitions.'"[37] Plaintiff acknowledges, though, this presumption can be rebutted with evidence showing that an adequate warning would have been futile under the circumstances.[38] Indeed, that is the case here. Setting aside whether the warning would have been futile because it did not reach Dr. McCanless, the evidence shows that even if Dr. McCanless had learned of a risk of permanent alopecia associated with the drug, he still would have ultimately prescribed a docetaxel-containing regimen to Plaintiff Stewart.

Deposition testimony makes clear that in deciding upon Plaintiff's treatment, Dr. McCanless was considering "the aggressiveness of her cancer."[39] He "needed treatment quickly" because it was critical that he reduce Plaintiff's tumor size prior to her surgery and prevent metastatic disease.[40] The regimen he chose gave her the "best chance" of success with these goals.[41] While Plaintiff does reference nine options listed in the NCCN guidelines, she fails to offer any evidence showing that Dr. McCanless considered any of these to be viable options for Stewart's aggressive cancer. Instead, Dr. McCanless testified that while there were other commonly used regimens available, those were longer regimens and, in his mind, not suitable for Plaintiff Stewart.[42] Significantly, he testified that even if the label had warned of permanent hair loss, this would not have affected his decision.[43] Instead, he "still would look at the response rates and the outcome pattern."[44]

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[37] Wagoner v. Exxon Mobil Corp., 813 F. Supp. 2d 771, 797 (E.D. La. 2011) (quoting Bloxom v. Bloxom, 512 So.2d 839, 850 (La. 1987)).
[38] *See id.*
[39] *See* Doc. 11473-15 at 30.
[40] *Id.* at 9, 30. He further testified that it was important to get Plaintiff to surgery sooner than later. *Id.* at 32.
[41] *Id.* at 9.
[42] *See id.* at 30.
[43] *See id.* at 32.
[44] *Id.*

In her opposition, Plaintiff avers that Dr. McCanless would have counseled her on the risk of permanent hair loss. Dr. McCanless, however, testified that to this day he counsels patients on hair loss the same way he did in 2014.[45] He tells them that "with Taxotere it will usually come back."[46] Even assuming Dr. McCanless would have counseled Plaintiff differently, he still would have presented the docetaxel regimen as Plaintiff's "best chance."[47]

Plaintiff further emphasizes that if Stewart had voiced an opinion on whether or not to use docetaxel based on a risk of permanent hair loss, Dr. McCanless would have respected this opinion. However, the record makes clear that Stewart ultimately would not have rejected Dr. McCanless's recommendation to take a docetaxel-containing regimen. Stewart testified unequivocally that she would have taken any recommended treatment by Dr. McCanless if he said it would save or prolong her life.[48] She testified that Dr. McCanless presented the docetaxel-containing regimen to her as "the best option" based on the size of her tumor and her age.[49] She testified that she "didn't have any reason to say no" because she "didn't know there were any other options."[50] The Court notes, again, that according to Dr. McCanless, there were in fact no other options that were suitable for Stewart, given his determination that she needed treatment quickly.[51] Notably, Stewart further testified that she "didn't know to ask" about alternatives but "just went on his

[45] *Id.* at 29.
[46] *Id.* at 16.
[47] *See id.* at 9, 32. In responding to a question about whether he would have warned Stewart of a risk of permanent hair loss, he testified that "we don't really make decisions on which regimen to give for, you know, whether they have complete hair loss or just partial hair loss." *Id.* at 29.
[48] Doc. 11473-5 at 14.
[49] Doc. 11473-5 at 54.
[50] *Id.*
[51] Doc. 11473-15 at 30–32.

professional advice."[52] She repeatedly testified that "all of this was new" to her, and she testified that there was no source she would have considered to reject his advice.[53]

Lastly, her testimony shows that she would not have chosen a less effective chemotherapy for the sake of avoiding permanent hair loss. She said only that "if [Dr. McCanless] would have offered another option without the permanent hair loss and *with the same result*, I *probably* would have went with the other option."[54] She testified that "the most important thing" to her was to save her life.[55]

Considering this evidence, Sandoz has demonstrated that even with a different warning, Plaintiff Stewart and Dr. McCanless would have decided on a docetaxel-containing regimen to treat her cancer. Plaintiff has failed to rebut this and create a genuine dispute of material fact on causation. Plaintiff has pointed to no evidence suggesting that she would have looked for another oncologist. Instead, the evidence shows that she trusted Dr. McCanless and followed his advice, and she never thought to ask about other options.

## CONCLUSION

Accordingly, for the foregoing reasons, the Motion for Summary Judgment (Doc. 11473) is **GRANTED**. Plaintiff Wanda Stewart's case is **DISMISSED WITH PREJUDICE**;

**IT IS FURTHER ORDERED** that all other motions pending in Plaintiff's case are **DISMISSED AS MOOT**.

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[52] Doc. 11473-5 at 54 ("I didn't know to ask about any other drugs.").
[53] *Id.* at 45, 54.
[54] *Id.* at 54 (emphasis added).
[55] *Id.* at 14.

New Orleans, Louisiana, this 19th day of April, 2021.

JAME TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE