UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) EYE INJURY PRODUCTS LIABILITY LITIGATION	)	**MDL No. 3023**
	)	**SECTION: "H" (5)**
This document relates to: Shannon Pruett v. Hospira, Inc., Case No. 2:22-cv-02804	)	

ORDER AND REASONS

Before the Court is the Motion for Summary Judgment filed by Defendants Hospira Worldwide, LLC f/k/a/ Hospira Worldwide Inc. and Hospira, Inc. (collectively, "Hospira") (Rec. Doc. 294). 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, that Plaintiffs were administered for the treatment of cancer.[1] Among these companies is Defendant Hospira. Plaintiffs allege that Taxotere or docetaxel caused them to sustain injuries to their lacrimal systems, including punctal, canalicular, and/or nasolacrimal

[1] Docetaxel is the generic version of Taxotere, although the Court uses the term "generic" loosely.

duct stenosis, which resulted in excessive tearing, otherwise known as epiphora.

Hospira manufactures an unbranded version of Taxotere, developed by Sanofi U.S. Services, Inc. and Sanofi-Aventis U.S. LLC and approved in 1996 by the United States Food and Drug Administration ("FDA") for the treatment of advanced or metastatic breast cancer.[2] In 2007, Hospira submitted a New Drug Application ("NDA") pursuant to § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act to sell its docetaxel product.[3] In March 2011, the FDA approved Hospira's docetaxel and its labeling.[4]

Plaintiff Shannon Pruett ("Plaintiff") was diagnosed with breast cancer on January 6, 2016.[5] Plaintiff began chemotherapy with Hospira's docetaxel on March 10, 2016, and underwent four rounds of chemotherapy concluding on May 12, 2016.[6] Plaintiff resides in Texas and underwent treatment for cancer in Texas.[7]

In August 2022, Plaintiff sued Hospira, alleging her chemotherapy treatment resulted in epiphora.[8] Plaintiff asserts five claims against Hospira in her complaint: (1) Strict Products Liability – Failure to Warn; (2) Negligence; (3) Negligent Misrepresentation; (4) Fraudulent Misrepresentation; and (5) Fraudulent Concealment.[9] On December 5, 2022, this Court granted Defendants' Motion to Dismiss Plaintiffs' Master Complaint

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[2] Rec. Doc. 294-1 at 1.
[3] *Id.*
[4] *Id.*
[5] *Id.* at 2.
[6] Rec. Doc. 310 at 1.
[7] Rec. Doc. 294-1 at 2.
[8] *Id.*
[9] *Id.* (citing Rec. Doc. 1 in member case no. 2:22-cv-02804).

as to three claims—Negligent Misrepresentation, Fraudulent Misrepresentation, and Fraudulent Concealment.[10]

On May 29, 2024, Hospira filed the instant Motion for Summary Judgment requesting dismissal of Plaintiff's remaining failure to warn and negligence claims, arguing that such claims are barred by Texas law, which provides "a complete statutory defense against liability for FDA-approved labels."[11]

LEGAL STANDARD

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law."[12] A genuine issue of fact exists only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party."[13]

In determining whether the movant is entitled to summary judgment, the Court views facts in the light most favorable to the non-movant and draws all reasonable inferences in his favor.[14] "If the moving party meets the initial burden of showing that there is no genuine issue of material fact, the burden shifts to the non-moving party to produce evidence or designate specific facts showing the existence of a genuine issue for trial."[15] Summary judgment is

[10] Rec. Doc. 80.
[11] Rec. Doc. 294-1 at 1.
[12] Sherman v. Hallbauer, 455 F.2d 1236, 1241 (5th Cir. 1972).
[13] Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).
[14] Coleman v. Houston Indep. Sch. Dist., 113 F.3d 528, 532 (5th Cir. 1997).
[15] Engstrom v. First Nat'l Bank of Eagle Lake, 47 F.3d 1459, 1462 (5th Cir. 1995).

appropriate if the non-movant "fails to make a showing sufficient to establish the existence of an element essential to that party's case."[16] "In response to a properly supported motion for summary judgment, the non-movant must identify specific evidence in the record and articulate the manner in which that evidence supports that party's claim, and such evidence must be sufficient to sustain a finding in favor of the non-movant on all issues as to which the non-movant would bear the burden of proof at trial."[17] "We do not . . . in the absence of any proof, assume that the nonmoving party could or would prove the necessary facts."[18] Additionally, "[t]he mere argued existence of a factual dispute will not defeat an otherwise properly supported motion."[19]

LAW AND ANALYSIS

All parties agree that Plaintiff's claims are subject to Texas law.[20] Hospira argues that pursuant to the Texas Civil Practice and Remedies Code, Hospira's FDA-approved docetaxel labeling is presumed adequate.[21] Hospira further argues that Plaintiff cannot establish that any of the five enumerated exceptions to this presumption apply.

Plaintiff does not dispute that pursuant to Texas law, Hospira is entitled to a presumption against liability. Rather, Plaintiff argues that her claims should proceed to trial "because dismissal of her claims allows Hospira to avoid

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[16] Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986).

[17] John v. Deep E. Tex. Reg. Narcotics Trafficking Task Force, 379 F.3d 293, 301 (5th Cir. 2004) (internal citations omitted).

[18] Badon v. R J R Nabisco, Inc., 224 F.3d 382, 394 (5th Cir. 2000) (quoting Little v. Liquid Air Corp., 37 F.3d 1069, 1075 (5th Cir. 1994)).

[19] Boudreaux v. Banctec, Inc., 366 F. Supp. 2d 425, 430 (E.D. La. 2005).

[20] Rec. Doc. 294-1 at 3; Rec. Doc. 310 at 4.

[21] Rec. Doc. 294-1 at 5.

liability for failing to warn her of the permanent injuries she now suffers after using its docetaxel."[22]

I. Whether the Presumption Against Liability Applies

Texas Civil Practice and Remedies Code section 82.007(a) provides in relevant part:

> (a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:
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> (1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act . . . .[23]

Thus, pursuant to section 82.007, "a drug manufacturer enjoys a rebuttable presumption that it is not liable to warn if the FDA has approved the 'warnings or information' accompanying the product alleged to have harmed the plaintiff."[24]

In determining whether this presumption applies, the initial inquiry is whether the asserted claim falls within the definition of a "products liability action."[25] If so, the "further inquiry is whether the claim in substance alleges

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[22] Rec. Doc. 310 at 1.

[23] TEX. CIV. PRAC. & REM. CODE § 82.007(a).

[24] Lofton v. McNeil Consumer & Specialty Pharms., 672 F.3d 372, 374 (5th Cir. 2012) (citing TEX. CIV. PRAC. & REM. CODE § 82.007(a)).

[25] Moncibaiz v. Pfizer, 532 F. Supp. 3d 452, 458 (S.D. Tex. 2021) (citing TEX. CIV. PRAC. & REM. CODE § 82.001(2)).

the injury was caused by a failure to warn."[26] "This requires scrutiny of the complaint and determination of whether the allegations actually describe failure to warn claims, despite characterizations and labels stated by the plaintiff."[27] "Any claim that in substance alleges an injury caused by failure to warn is subject to the statutory presumption and thus barred by the Texas Civil Practice and Remedies Code."[28]

a. *Whether this action is a "products liability action"*

Section 82.001(2) defines a "products liability action" as

> any action against a manufacturer or seller for recovery of damages arising out of personal injury, death, or property damage allegedly caused by a defective product whether the action is based in strict tort liability, strict products liability, negligence, misrepresentation, breach of express or implied warranty, or any other theory or combination of theories.[29]

Further, "Texas courts are clear that this definition is to be applied broadly."[30] Here, Plaintiff alleges that she sustained a personal injury from the use of a defective product and that such injury gives rise to claims for strict liability and failure to warn. Accordingly, this action constitutes a "products liability action" within the meaning of section 82.007(a)(1).[31]

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[26] *Id.*

[27] *Id.* (citing TEX. CIV. PRAC. & REM. CODE § 82.007(a)).

[28] *Id.*

[29] TEX. CIV. PRAC. & REM. CODE § 82.001(2).

[30] *Moncibaiz*, 532 F. Supp. 3d at 458 (citing Fresh Coat, Inc. v. K-2, Inc., 318 S.W.3d 893, 900 (Tex. 2010)).

[31] *See id.*

b. *Whether Plaintiff alleges an injury caused by failure to warn*

Plaintiff's Short Form Complaint asserts claims for failure to warn and negligence, and Plaintiff concedes that her "claims of negligence and strict liability are based on Hospira's failure to warn that she could have easily prevented the injuries she suffered."[32] Further, Plaintiff avers that while her "doctor counseled her tearing would be a potential side effect," "because Hospira did not inform her oncologist that the tearing could be an early sign of permanent but preventable damage to the lacrimal drainage system, her oncologist was unaware of the need to closely monitor this side effect."[33] Thus, according to Plaintiff, "when she did experience tearing during her chemotherapy treatment, she and her oncologist did not appreciate the need to seek timely treatment to prevent the progressive stenosis occurring in her lacrimal drainage system."[34] As such, it was not until 2020 that she saw a specialist, who diagnosed her with "complete and total blockage of the left nasolacrimal duct passage."[35]

Here, Plaintiff's claims in substance allege an injury caused by a failure to warn, and no party disputes that the FDA approved Hospira's docetaxel product and its warnings. Accordingly, the statutory presumption against liability applies.[36]

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[32] Rec. Doc. 310 at 2.
[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] *See, e.g.*, *Moncibaiz*, 532 F. Supp. 3d at 457–62; *see also* Gonzalez v. Bayer Healthcare Pharms., Inc., 930 F. Supp. 2d 808, 814 (S.D. Tex. 2013) ("Texas law groups all inadequate warnings causes together regardless of how they are pleaded.").

II. Whether Plaintiff May Rebut the Presumption Against Liability

Section 82.007(b) provides that a plaintiff may rebut the presumption by establishing, *inter alia*, that "[t]he defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the [FDA] required information that was material and relevant to the performance of the product and was causally related to the claimant's injury . . . ."[37]

Hospira, anticipating that Plaintiff will invoke the exception provided in section 82.007(b), argues that it nevertheless fails under *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*.[38] In *Lofton*, United States Court of Appeals for the Fifth Circuit considered whether plaintiffs alleging negligence and strict products liability claims against a manufacturer under Texas law could rebut the presumption against liability by invoking section 82.007(b)(1), known as the "fraud-on-the-FDA exception."[39] The Fifth Circuit, affirming the district court's ruling entering summary judgment for the defendants, held that section 82.007(b)(1) is preempted by federal law "unless the FDA itself has found fraud."[40]

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[37] TEX. CIV. PRAC. & REM. CODE § 82.007(b)(1). A plaintiff may also rebut the presumption by proving one of the following: (1) the defendant sold the product after the FDA ordered it removed from the market; (2) the defendant promoted the product for an unapproved use and the injury was caused by that use; or (3) the defendant bribed an FDA official, causing the FDA approved warnings to be inadequate. *Gonzalez*, 930 F. Supp. at 808 (citing TEX. CIV. PRAC. & REM. CODE § 82.007(b)(2)–(5)). Here, Plaintiff does not argue that these exceptions to the presumption against liability apply. *See* Rec. Doc. 310 at 7; Rec. Doc. 320 at 1–2.

[38] Rec. Doc. 294-1 at 6 (citing Lofton v. McNeil Consumer & Specialty Pharms., 672 F.3d 372, 379 (5th Cir. 2012)).

[39] *Lofton*, 672 F.3d at 380.

[40] *Id.* at 381.

In reaching this conclusion, the *Lofton* court analyzed a circuit split concerning preemption of a similar Michigan statute.[41] First, the court noted that while "[t]he Supreme Court has occasionally stated that a preemption inquiry 'start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress,"[42] it would not apply a "presumption against preemption."[43]

Next, the court held that section 82.007(b)(1) conflicted with federal law.[44] "[W]here the FDA has not found fraud, the threat of imposing state liability on [a] drug manufacturer for defrauding the FDA intrudes on the competency of the FDA and its relationship with regulated entities."[45] The court noted that in such circumstances, the Supreme Court has "found a

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[41] *Id.* at 377.

[42] *Id.* at 378 (brackets in original).

[43] *Id.* at 379.

[44] *Id.* at 377–80 (citing (citing Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001)). The *Lofton* court did not address whether section 82.007(b)(1) was severable from section 82.007(a) because, as the plaintiffs conceded, it was raised for the first time on appeal. *Id.* at 380–81.

[45] *Id.* at 380. Further,

> The Fifth Circuit explained that the Texas statute permits two kinds of interference in cases where the FDA, itself, has not yet found fraud. First, the statute "allows the state court to interject varying views on what disclosures are sufficient," which causes the FDA to lose control over its ability to "intelligently limit" the scope of disclosures necessary for its work based on scientific expertise. Second, the statute authorizes lawsuits that "may directly invade the agency's processes when close questions of 'withholding' or 'misrepresentation' arise." The Fifth Circuit made clear that "[t]hese dangers are inherent in [the United States Supreme Court's] concern to preserve the agency's discretion to police the conduct of regulated entities."

Offshore Serv. Vessels, L.L.C. v. Surf Subsea, Inc., No. 12–1311, 2012 WL 5183557, at *10 (E.D. La. Oct. 17, 2012) (quoting *Lofton*, 672 F.3d at 378) (Africk, J.).

violation of the Supremacy Clause."[46] Thus, "section 82.007(b)(1) is preempted unless the FDA itself has found fraud."[47]

Here, Plaintiff does not allege that the FDA has found that Hospira committed any fraud by withholding or misrepresenting relevant information related to docetaxel. Moreover, Plaintiff concedes that she cannot "come forth with evidence that the FDA itself has declared that Hospira committed fraud."[48] Thus, Plaintiff cannot rebut the presumption against liability by invoking the exception in section 82.007(b)(1).

Plaintiff contends that the United States Supreme Court has not ruled on the issue of whether section 82.007(b)(1) is preempted by federal law. Citing to caselaw emanating from outside of this circuit, Plaintiff devotes much of her Opposition to arguing that the *Lofton* holding was incorrect.[49] This Court, however, must follow the law of the Fifth Circuit. Plaintiff has not cited any cases suggesting that this Court is not bound by *Lofton*. Accordingly, Plaintiff cannot show that she can rebut the presumption against liability under Texas law. As such, her claims are foreclosed by Texas law and must be dismissed.

CONCLUSION

For the foregoing reasons, Hospira's Motion for Summary Judgment is **GRANTED**.

IT IS ORDERED that all of Plaintiffs' claims are **DISMISSED WITH PREJUDICE**.

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[46] *Lofton*, 672 F.3d at 380 (citing *Buckman*, 531 U.S. at 351).
[47] *Id.* (citing TEX. CIV. PRAC. & REM. CODE § 82.007(b)(1)).
[48] Rec. Doc. 310 at 3.
[49] *Id.* at 5 (citing Wyeth v. Levine, 555 U.S. 555 (2009)).

New Orleans, Louisiana this 15th day of August, 2024.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE