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BLOG

Fifth Circuit Affirms Two Summary-Judgment Orders Dismissing Plaintiffs' Failure-to-Warn Cases

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Last month, the U.S. Court of Appeals for the Fifth Circuit affirmed two summary-judgment decisions in *In re Taxotere (Docetaxel) Products Liability Litigation*, a coordinated multidistrict litigation (MDL) that is centralized in the Eastern District of Louisiana. Plaintiffs in the MDL allege that the distributors of the drug Taxotere (a chemotherapy drug used for the treatment of breast cancer) failed to warn of potentially permanent chemotherapy-induced hair loss. The label for Taxotere was changed in December 2015 to include a warning that "cases of permanent hair loss have been reported."[1]

Decision One: Plaintiffs' Failure-to-Warn Claims Are Time-Barred under Louisiana's One-Year Prescription Period and Doctrine of *Contra non valentem*

In *In re Taxotere (Docetaxel) Products Liability Litigation*, 995 F.3d 384 (5th Cir. 2021), three plaintiffs appealed the dismissal of their claims based on the statute of limitations. The plaintiffs, who were treated with Taxotere from 2008 to 2010, did not file their complaints until late 2016.[2] In determining the timeliness of the plaintiffs' complaints, the Fifth Circuit analyzed two questions.

First, the court analyzed whether the plaintiffs' claims were untimely on their face. The Fifth Circuit accepted the plaintiffs' definition of permanent, chemotherapy-induced alopecia, which they defined as "an absence of or incomplete hair regrowth six months beyond the completion of chemotherapy." Using this definition, the Court held that the prescription period began to run on the date of the plaintiffs' injuries—i.e., six months after the completion of chemotherapy.[3] Therefore, the Fifth Circuit agreed with the district court that the plaintiffs' claims were facially prescribed.[4]

Next, the Fifth Circuit analyzed whether the doctrine of *contra non valentem* tolled the prescription period. *Contra non valentem* is an equitable-tolling doctrine that tolls the prescription period "where the cause of action is not known or reasonably knowable by the plaintiff, even though this ignorance is not induced by the defendant."[5]

The Fifth Circuit interpreted Louisiana's law "to require that once hair loss persisted after six months, *contra non valentem* tolled the prescription period until the point when a prospective plaintiff through the exercise of reasonable diligence should have considered Taxotere as a potential root cause of her injury."[6] The Fifth Circuit noted that while the plaintiffs attributed their initial hair loss to chemotherapy, none of the plaintiffs asked their doctors about the cause of their permanent hair loss and did not otherwise conduct any inquiries for the cause.[7]

Because the plaintiffs dispute what any reasonable inquiry would have revealed, the Fifth Circuit looked to the evidence cited in the plaintiffs' complaint—since the plaintiffs "are charged with whatever information that is"—and found the following types of evidence relevant: an online women's group, an article in a Canadian newspaper, an online article published by CBS News, a scientific study, and articles published in medical journals, all noting persistent hair loss in women after allegedly taking Taxotere.[8] Because of this evidence, the Fifth Circuit held that "a reasonable inquiry would have uncovered at least some information that linked Taxotere to persistent alopecia" by at least 2015.[9] Therefore, because the plaintiffs "did not act reasonably in light of their injuries" and "their causes of action were reasonably knowable in excess of one year prior to their filing suit," the Fifth Circuit affirmed the district court's dismissal of their claims.[10]

Decision Two: Plaintiff Cannot Establish That the Alleged Failure to Warn Was the Actual and Proximate Cause of Her Injuries

In *In re Taxotere (Docetaxel) Products Liability Litigation*, 994 F.3d 704 (5th Cir. 2021), the plaintiff appealed the district court's grant of summary judgment to the defendants on her failure-to-warn claim against the manufacturers of Taxotere for allegedly failing to provide an adequate warning of potentially permanent hair loss.[11] During the course of her breast cancer treatment, plaintiff's oncologist recommended and prescribed chemotherapy treatment that included Taxotere.[12] At the time of treatment, the warning label for Taxotere did not include any mention of the risk for potentially permanent hair loss, but the plaintiff's oncologist discussed with her the possibility that her hair would fall out and might grow back differently.[13]

To prevail on a failure-to-warn claim in Louisiana, a plaintiff must prove "(1) a manufacturer's failure to adequately warn the prescribing physician of a risk associated with the product that the physician did not otherwise know about, and (2) that the failure to warn was the cause in fact and the proximate, or legal, cause of the plaintiff's injury."[14] Because Louisiana recognizes the learned-intermediary doctrine,[15] in order to prove causation, a plaintiff "must show that a proper warning would have changed the decision of the prescribing physician, *i.e.*, that but for the inadequate warning, the prescribing physician would not have used or prescribed the product."[16]

In determining whether a warning would have changed the prescribing decision of the plaintiff's oncologist, the Fifth Circuit focused on three facts. First, the oncologist testified that the additional warning of potentially permanent hair loss "has not materially altered his risk-benefit assessment of Taxotere" and that "alopecia is, and has been, a common and widely known side effect of" Taxotere.[17] Second, the oncologist testified that a Taxotere warning label of potentially permanent hair loss "would not have changed his decision" to use Taxotere to treat the plaintiff because any alternatives to Taxotere would not have been appropriate because of the plaintiff's age, preexisting cardiac conditions, and high risk of cancer reoccurrence.[18] Third, the Fifth Circuit noted that the plaintiff and her oncologist had discussed the risk of temporary hair loss and abnormal hair regrowth, and the plaintiff consented to the Taxotere treatment.[19] Nor is there any evidence that the plaintiff investigated or asked about alternative treatments that might avoid hair loss.[20]

Therefore, the Fifth Circuit held that "[b]ecause [the plaintiff] has failed to introduce sufficient evidence to enable a reasonable jury to find that [the defendants'] alleged failure to warn of the risk [of] permanent—as opposed to temporary—alopecia in connection with the use of Taxotere was the actual and proximate cause of her injuries," it affirmed the district court's grant of summary judgment in favor of the defendants.[21]

These Fifth Circuit decisions provide important guidance for companies defending products-liability cases at the summary-judgment stage and show the types of evidence that defendants can use in support of their statute-of-limitations and proximate-causation arguments.

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[1] *In re Taxotere (Docetaxel) Products Liability Litigation*, 995 F.3d 384, 387 (5th Cir. 2021).

[2] *Id.* at 387-88.

[3] *Id.* at 389-90.

[4] *Id.* at 389-90.

[5] *Id.* at 390 (quoting *Morgan v. Entergy New Orleans, Inc.*, 234 So. 3d 113, 116, 120 (La. Ct. App. 2017)). Actual knowledge is not required for Louisiana's discovery rule, only constructive notice. *Id.* at 390. Therefore, the prescription period will run "from the time there is notice enough to call for inquiry about a claim, not from the time when the inquiry reveals facts or evidence sufficient to prove the claim." *Id.* at 390 (quoting *Terrel v. Perkins*, 704 So. 2d 35, 39 (La. Ct. App. 1997)).

[6] *Id.* at 392-93 (citations omitted).

[7] *Id.* at 393

[8] *Id.* at 393-94.

[9] *Id.* at 394.

[10] *Id.* at 394-95 (quotations omitted).

[11] *Id.* at 706.

[12] *Id.* at 706.

[13] *Id.* at 706.

[14] *Id.* at 708.

[15] The learned-intermediary doctrine in Louisiana requires that the "drug manufacturer has a duty to warn the prescribing physician, rather than the patient, of potential risks associated with the use of the drug." *Id.* at 708 (citing *Mikell v. Hoffman-LaRoche, Inc.*, 649 So. 2d 75, 79-80 (La. App. 1 Cir. 1994)).

[16] *Id.* at 708 (quoting *Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1099 (5th Cir. 1991)).

[17] *Id.* at 709.

[18] *Id.* at 709-10.

[19] *Id.* at 710.

[20] *Id.* at 710. The plaintiff had argued that patient choice, and how patient choice might have affected the physician's prescribing decision, should be the focus of the Fifth Circuit's analysis. *Id.* at 708-09. But the Fifth Circuit dismissed her argument because, on the record, "there is little evidence that [the plaintiff] might have steered the conversation in such a way that [the oncologist] would have changed his prescribing decision." *Id.* at 710.

[21] *Id.* at 710-11. On May 3, 2021, the plaintiff filed a petition for en banc rehearing to ask the full Fifth Circuit to review the dismissal of her failure-to-warn claim. *In re Taxotere (Docetaxel) Products Liability Litigation*, No. 20-30405 (5th Cir. May 3, 2021).

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