# United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
**FILED**
April 19, 2021
Lyle W. Cayce
Clerk

No. 20-30405

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION

---

JUNE PHILLIPS,

*Plaintiff—Appellant*,

*versus*

SANOFI U.S. SERVICES, INCORPORATED, *formerly known as* SANOFI-AVENTIS U.S., INCORPORATED; SANOFI-AVENTIS, U.S., L.L.C.,

*Defendants—Appellees*.

---

Appeal from the United States District Court
for the Eastern District of Louisiana
USDC No. 2:16-CV-15397

---

Before KING, SMITH, and HAYNES, *Circuit Judges*.

PER CURIAM:

Plaintiff-appellant June Phillips asks us to reverse the district court's grant of summary judgment on her failure-to-warn claim asserted against the manufacturers of Taxotere, a chemotherapy medication. Specifically, Phillips argues that Taxotere's manufacturers failed to provide an adequate

warning of potentially permanent hair loss, which caused her injuries. But, on this record, it is beyond any genuine dispute that a warning of the risk of permanent hair loss—as opposed to temporary hair loss—would not have affected the prescribing physician's decision to prescribe Taxotere. Therefore, under Louisiana law, Phillips cannot establish causation, and her failure-to-warn claim against Taxotere's manufacturers fails as a matter of law. We AFFIRM.

## I.

### *A. Factual Background*

In August 2013, plaintiff-appellant June Phillips, at the age of seventy-five, developed an aggressive form of breast cancer that spread through her body. Years before, Phillips had been diagnosed with dyslipidemia, diffuse arterial sclerotic plaquing, and paroxysmal atrial tachycardia, all cardiac conditions pre-existing her breast cancer diagnosis.

To help treat her breast cancer, Phillips underwent a surgery on October 9, 2013. During that surgery, Phillips's doctors discovered that her cancer had metastasized, or spread, to her lymph nodes. And when tests were run on her tissue, her doctors established that her cancer was HER2+, PR+, and ER+. Put simply, Phillips's cancer was aggressive, and presented a high risk—about a fifty-percent chance—of recurrence.

As a follow-up to her surgery, Phillips was referred to an oncologist, Dr. Scott Sonnier. On October 28, 2013, Dr. Sonnier reviewed her lab results and communicated to Phillips that her cancer had spread and that it was aggressive and likely to recur. Dr. Sonnier told Phillips that chemotherapy following surgery was the main treatment used to eliminate cancer and would improve her chances of "disease-free survival or living without recurrence." Specifically, Dr. Sonnier recommended, and ultimately prescribed, "adjuvant TCH in addition to adjuvant hormonal therapy and post

lumpectomy radiation therapy." TCH is a Taxotere-based chemotherapy treatment that aims to reduce the risk of cancer recurrence.

At that time, the warning for Taxotere—a main component of TCH—did not include any mention of a risk of permanent alopecia, or potentially permanent hair loss. But Dr. Sonnier nevertheless discussed TCH's potential side effect of temporary alopecia, and indicated that Phillips's hair would likely fall out but might grow back with a different texture, color, and thickness. Phillips did not ask Dr. Sonnier about alternative treatments in light of this risk, and she consented to the treatment in November 2013.

*B. Procedural Background*

Defendants-appellees Sanofi U.S. Services, Inc., and Sanofi-Aventis U.S., L.L.C., (collectively, Sanofi) manufacture, sell, distribute, or hold regulatory approval for certain prescription chemotherapy medications, specifically Taxotere, commonly used to treat breast cancer patients. As we mentioned, Taxotere was a main component of the TCH treatment Phillips received following her surgery.

Phillips's appeal arises out of multidistrict litigation pending in the Eastern District of Louisiana ("the MDL"). The MDL—which encompasses Phillips's case[1]—was formed when, in October 2016, the Judicial Panel on Multidistrict Litigation centralized numerous actions involving allegations related to Sanofi's failure to warn patients that Taxotere

[1] To be clear, however, Phillips's case is not part of a class action lawsuit, or a single, representative proceeding. *Cf. In re Vioxx Prod. Liab. Litig.*, 650 F. Supp. 2d 549, 558 (E.D. La. 2009) ("[T]he underlying actions in an MDL remain individual in nature while a class action is a representative proceeding.").

might cause permanent hair loss. *In re Taxotere (Docetaxel) Prods. Liab. Litig.*, 220 F. Supp. 3d 1360, 1361 (J.P.M.L. 2016).[2]

Before the district court, the MDL plaintiffs have collectively filed a Second Amended Master Complaint. They allege that Sanofi knew that Taxotere causes permanent hair loss and failed to warn patients of that side effect. On May 31, 2017, Phillips filed her individual Short Form Complaint bringing eleven claims against Sanofi. She did not assert any claims against Dr. Sonnier.

The only claim at issue on appeal[3] here is Phillips's claim that Sanofi failed to warn of the risk of permanent alopecia associated with Taxotere in accordance with Louisiana law.

Sanofi filed a motion for summary judgment—in Phillips's case only—asserting that Phillips could not establish the requisite causation for her failure-to-warn claim to survive as a matter of law. The district court granted this motion. After conferral, all of Phillips's remaining claims were

[2] As of March 2021, more than 12,500 actions were pending in this MDL, including Phillips's case. U.S. Judicial Panel on Multidistrict Litigation, *MDL Statistics and Report: Distribution of Pending MDL Dockets by District* (Mar. 15, 2021), available at https://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-March-15-2021.pdf

[3] Here, summary judgment was filed in Phillips's individual case, as is sometimes done in the context of an MDL. *See* Douglas Smith, *The Myth of MDL Settlement*, 107 KY. L. J. 467, 478 n.62 (2019) (collecting examples of lower courts' rulings on individual summary judgment motions). The challenge before us does *not* arise in the context of an omnibus dispositive motion filed to resolve common questions in the MDL in whole or in part. *See, e.g.*, *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. and Prods. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 649 (4th Cir. 2018) (affirming grant of summary judgment in product liability actions involving statins); *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 800 (3d Cir. 2017) (affirming summary judgment on all claims).

dismissed, the district court entered final judgment in her case, and this appeal followed.

## II.

Our review of a district court's grant of summary judgment is de novo, and we view all facts, and the inferences to be drawn from them, in the light most favorable to the non-movant. *Kariuki v. Tarango*, 709 F.3d 495, 501 (5th Cir. 2013).

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "[T]he substantive law will identify which facts are material." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

"[A] dispute about a material fact is 'genuine' . . . if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.*; *see Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). The movant has the initial burden of demonstrating the absence of a material fact issue. *St. Paul Ins. Co. v. AFIA Worldwide Ins. Co.*, 937 F.2d 274, 279 n.6 (5th Cir. 1991). If it satisfies that burden, the non-movant must identify specific evidence in the summary judgment record demonstrating that there is a dispute of material fact concerning the essential elements of its case for which it will bear the burden of proof at trial. *See* FED. R. CIV. P. 56(a), (e); *Celotex*, 477 U.S. at 324.

## III.

The only claim that Sanofi moved to have resolved on summary judgment in this case was Phillips's failure-to-warn claim, and the district court's resolution of this claim, under Louisiana law, is the only issue before us here.

Pursuant to the Louisiana Products Liability Act, a plaintiff asserting a failure-to-warn claim 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. *Kampmann v. Mason*, 921 So. 2d 1093, 1094, 1096 (La. App. 5 Cir. 2006) (citing LA. STAT. ANN. § 9:2800.57 (West 2013)).

An adequate warning is one that "would lead an ordinary reasonable user . . . to contemplate the danger in" the use of the product. LA. STAT. ANN. § 9:2800.53(9) (West 2013). Under the "learned intermediary doctrine," however, a patient's physician acts as an informed intermediary between the drug company and the patient. *Brown v. Glaxo, Inc.*, 790 So. 2d 35, 38-39 (La. App. 1 Cir. 2000), *writs denied*, 785 So. 2d 827 and 785 So. 2d 832. Thus, a drug manufacturer has a duty to warn the prescribing physician, rather than the patient, of potential risks associated with the use of the drug. *Mikell v. Hoffman-LaRoche, Inc.*, 649 So.2d 75, 79-80 (La. App. 1 Cir. 1994).

To prove causation in this context, 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." *Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1099 (5th Cir. 1991); *accord Sharkey v. Sterling Drug, Inc.*, 600 So. 2d 701, 711 (La. App. 1 Cir. 1992), *writs denied*, 605 So.2d 1099 and 605 So.2d 1100.

Phillips argues that the focus of our inquiry should be "how patient choice . . . would have steered the conversation and the ultimate prescribing decision." And, certainly, under Louisiana law, "[t]he decision to use a drug in a particular circumstance rests with [both] the doctor and the patient."

*Calhoun v. Hoffman-La Roche, Inc.*, 768 So. 2d 57, 59 n.1 (La. App. 1 Cir. 2000), *writ denied*, 765 So. 2d 1041.

But, as we have established, a causation analysis in a failure-to-warn claim asserted against a drug's manufacturer (the only claim at issue here) is focused on the prescribing physician's decision to prescribe the drug. *Willett*, 929 F.2d at 1099; *accord Sharkey*, 600 So. 2d at 711. So, to the extent that patient choice is relevant, that relevance is cabined to helping us decide whether Phillips's evidence—including that of other available treatments and the importance she places on her appearance—is sufficient to introduce a genuine dispute of material fact as to whether Dr. Sonnier's prescribing decision would have been different had *he* known that Taxotere's associated risk of alopecia was potentially permanent rather than temporary.[4] It is not.

First, as a general matter, Dr. Sonnier testified that the additional warning regarding permanent alopecia has not materially altered his risk-benefit assessment of Taxotere. Further, Dr. Sonnier testified that alopecia is, and has been, a common and widely known side effect of "Taxotere and other chemotherapy drugs." The "specific type of alopecia" appears on this record to have had no effect on Dr. Sonnier's prescribing decision, and this supports the conclusion that Sanofi's alleged failure-to-warn could not have been the cause of Phillips's injury. *Cf. Cooper v. Sams*, 628 So. 2d 1181, 1190 (La. App. 3 Cir. 1993), *writs denied*, 632 So. 2d 766, 632 So. 2d 767 (affirming

[4] The district court has indicated in this case and others that "[b]ecause the chemotherapy decision-making process is unique" the question is "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." *See, e.g., In re Taxotere (Docetaxel) Prod. Liab. Litig.*, No. 16-15607, 2019 WL 2995897, at *7 (E.D. La. July 9, 2019). Under Louisiana state law, we find no support for this proposition and no occasion to deviate from binding caselaw to apply this standard.

a grant of summary judgment where a failure to warn "could not have caused [a patient's] injuries . . . because [*the prescribing physician*] already knew of . . . those dangers") (emphasis added).

Second, when it comes to Phillips in particular, Dr. Sonnier repeatedly testified that a Taxotere label warning of potentially permanent hair loss—as opposed to temporary hair loss—would not have changed his decision to use the Taxotere-based chemotherapy to treat Phillips's breast cancer. For example, he was asked directly: "If someone with Ms. Phillips's medical history came [to] you today with the same tumor type, same medical history, would you make the same recommendation for her treatment?" "Yes," he replied. This was so because of Phillips's age—seventy-five—and her pre-existing cardiac conditions, along with the fact that Phillips's cancer carried a high risk of recurrence.

When Dr. Sonnier prescribed TCH, he identified alternatives, specifically Anthracycline-based therapies. But these alternatives to the Taxotere-based TCH carried a risk of cardio toxicity and are not recommended for use in those over the age of sixty-five. In light of the fact that Phillips was seventy-five and had pre-existing heart conditions, Dr. Sonnier did not prescribe these alternatives. Dr. Sonnier testified that had Phillips asked to undergo an Anthracycline-based therapy instead of TCH, he "[didn't] think it would have been okay with [him]," and he "would not give it."

Certainly, as Phillips indicates, the record reflects that there were available treatment options beyond those carrying a risk of cardio toxicity. These treatments, however, were less efficacious and would "not have reduced her risk[] of recurrence to the same degree as TCH." Phillips has not identified any testimony from Dr. Sonnier that these were adequate to help treat her aggressive cancer, let alone that a warning of potentially

permanent hair loss—as opposed to temporary hair loss—would have led Dr. Sonnier to prescribe these instead of TCH. *Cf. Sharkey*, 600 So.2d at 711 (finding causation where a physician "testified unequivocally" that an adequate warning against the use of aspirin in children would have prevented him from advising his patient to give her child an aspirin).[5]

Third, it is clear that Dr. Sonnier and Phillips discussed the risk that Dr. Sonnier was aware of all along—that is, the risk of temporary alopecia and abnormal hair regrowth. Although Phillips now argues that her "appearance is unmistakably important to her," there is no indication that Phillips investigated or asked about alternatives that might avoid the abnormal hair growth or hair loss. Dr. Sonnier did not present TCH to her as one of many viable options; rather, after explaining why available alternatives were inadequate, he stated that "[TCH] is the therapy that we do." In turn, she "put her faith in [him]," and consented to treatment. In other words, important to her as her appearance may be, on this record, there is little evidence that Phillips might have steered the conversation in such a way that Dr. Sonnier would have changed his prescribing decision had he known that the risk of alopecia associated with Taxotere was potentially permanent rather than temporary.

The "judge's inquiry, [at the summary judgment stage] . . . unavoidably asks whether reasonable jurors could find by a preponderance of the evidence that the plaintiff is entitled to a verdict."

---

[5] To the extent Phillips now challenges Dr. Sonnier's judgment in prescribing TCH, a failure-to-warn claim against drug manufacturers (the only claim at issue here) is not the proper vehicle for that challenge. *See generally Cobb v. Syntex Lab'ys, Inc.*, 444 So. 2d 203 (La. App. 5 Cir. 1983) (describing the relationship between the duties of a physician and those of a drug manufacturer and holding that a patient could not recover from a drug manufacturer for an injury allegedly sustained from taking its drug where, *inter alia*, warnings were adequate).

*Anderson*, 477 U.S. at 252. At most, Phillips's points about the existence of non-Anthracycline alternative therapies and her testimony about how she might have steered the conversation amount to a "scintilla of evidence in support of [her] position." *Id.*

Hence, at this stage of the litigation, this evidence is "insufficient," *id.*, to create a genuine dispute of material fact as to whether a warning that Taxotere caused potentially permanent—as opposed to temporary—alopecia would have changed Dr. Sonnier's prescribing decision, *see Willett*, 929 F.2d at 1099 (affirming a grant of summary judgment where "[t]he plaintiff . . . failed to present any specific evidence that this additional risk would have changed [the prescribing physician's] decision"). To the contrary, on this record, it is beyond any genuine dispute that "an adequate warning . . . would have been futile under the circumstances." *Sharkey*, 600 So. 2d at 711.

## IV.

Because Phillips has failed to introduce sufficient evidence to enable a reasonable jury to find that Sanofi's alleged failure to warn of the risk permanent—as opposed to temporary—alopecia in connection with the use of Taxotere was the actual and proximate cause of her injuries, we AFFIRM the district court's grant of summary judgment.