United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
February 10, 2022
Lyle W. Cayce
Clerk

No. 20-30184

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION

BARBARA EARNEST,

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-MD-2740
USDC No. 2:16-CV-17144

Before HO, OLDHAM, and WILSON, *Circuit Judges*.

CORY T. WILSON, *Circuit Judge*:

Barbara Earnest sued drug makers Sanofi U.S. Services Inc. and Sanofi-Aventis U.S., L.L.C. (collectively, Sanofi) in the Eastern District of Louisiana. Earnest's suit is part of the multidistrict litigation (MDL) over several pharmaceutical companies' alleged failure to warn users of Taxotere (generically docetaxel), a chemotherapy drug, of the risk of permanent alopecia or hair loss. *See In re Taxotere (Docetaxel) Prod. Liab. Litig.*, 220 F. Supp. 3d 1360 (J.P.M.L. 2016). At trial, Sanofi elicited testimony from two medical doctors. One, Dr. John Glaspy, was accepted as an expert witness under Federal Rule of Evidence 702. The other, Dr. Michael Kopreski, was offered as Sanofi's designated corporate representative under Federal Rule of Civil Procedure 30(b)(6). As a general matter, both testified that little medical evidence linked Taxotere to permanent hair loss.

Earnest now challenges the admission of Dr. Kopreski's testimony, arguing it was actually expert testimony admitted in contravention of Rule 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). By extension, she argues that because Dr. Glaspy's testimony relied in relevant parts on Dr. Kopreski's testimony, it also should not have been admitted.

Sanofi's maneuvers in cloaking Dr. Kopreski's quasi-expert testimony as "lay witness" opinion testimony under Federal Rule of Evidence 701, and then using Dr. Glaspy to repeat it as expert analysis, effected a concerning end run around Rule 702. Because this strategy allowed Sanofi to shoehorn inadmissible opinion testimony into evidence—and then emphasize those "expert" conclusions in closing arguments to the jury—it significantly prejudiced Earnest's case. We REVERSE the district court's judgment and REMAND the claims appealed here for a new trial.

I.

We start with a brief overview of TAX316, the Taxotere clinical study on which the parties heavily relied for the issue of medical causation. Then,

we sketch the background of Earnest's case. After laying that groundwork, we consider the issues Earnest raises on appeal.

A.

A drug must obtain approval from the Food & Drug Administration before it is marketed and sold to the public. 21 U.S.C. § 355(a).[1] As with most new drugs, Taxotere was subjected to lengthy clinical testing divided into distinct trial phases. Phase I began in 1990 and determined the drug's proper dosage. Phase II started two years later. It assessed the safety of the drug using larger test groups. By 1996, after successful clinical testing, Taxotere gained FDA approval for treatment of patients with metastatic breast cancer.

After the initial FDA approval, Sanofi sought approval to use Taxotere as an adjuvant chemotherapy treatment. This would allow the use of Taxotere alongside other chemotherapy drugs to boost their efficacy. To that end, Sanofi sponsored a ten-year multi-center Phase III randomized clinical trial—the TAX316 study. TAX316 consisted of roughly 1,400 participants and ran from June 11, 1997, to January 25, 2010. Its primary objective was to determine the efficacy of Taxotere as an adjuvant chemotherapy treatment in breast cancer patients with positive axillary lymph nodes, like Earnest. The study had a secondary objective to compare the participants' overall survival rate, toxicity of the drug, and quality of life.

The clinical trial compared participants in two treatment arms. The first arm (or the "TAC" arm) treated 744 patients with Taxotere in

[1] *See Eckhardt v. Qualitest Pharms., Inc.*, 751 F.3d 674, 676 (5th Cir. 2014) ("Before a manufacturer can market a new drug, the FDA must approve 'that it is safe and effective and that the proposed label is accurate and adequate.'" (quoting *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011))).

combination with two other chemotherapy drugs, Adriamycin and Cytoxan.[2] The second arm (or the "FAC" arm) treated 736 patients with 5-fluorouracil, another chemotherapy drug, in combination with Adriamycin and Cytoxan.

The TAX316 study was designed to track the short-term and long-term effects of each combination therapy, starting from thirty days after the last administration of the study drugs. Interim analyses were conducted during the study. After reviewing the fifty-five-month interim data, the FDA approved the administration of Taxotere as an adjuvant chemotherapy medication in combination with Adriamycin and Cytoxan in August 2004. The FDA later agreed to the submission of TAX316's ten-year final study report.

Study investigators completed the final report in August 2010. It consisted of ten-year follow-up data from the 1480 patients treated with either TAC or FAC.[3] The study's results demonstrated similar findings to those from the interim study data: the TAC-regimen generated statistically better results, in terms of cancer deterrence and survival rate, than its FAC counterpart. The results indicated that Taxotere, given in combination with Adriamycin and Cytoxan, was "an appropriate adjuvant chemotherapy option for women."

Apart from these findings, the final study reported on sixty-nine adverse events of the drug regime, including alopecia, or hair loss. The adverse effects were categorized as "persisting into follow-up," "resolved,"

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[2] The generic name for Adriamycin is doxorubicin; Cytoxan's is cyclophosphadmide.

[3] Among the 1480 patients, eighty-two patients were reported as lost to follow-up, such that no new data were available for them.

and "ongoing." Of note, the study found that 4.2 percent of the population within the TAC arm, or twenty-nine of 744 participants, experienced "ongoing" hair loss.

B.

Earnest was diagnosed with early-stage breast cancer in February 2011. She underwent a lumpectomy to remove the cancerous tumor. That surgery was followed with several rounds of adjuvant chemotherapy.

At first, Earnest received four treatment cycles of dose-dense Adriamycin and Cytoxan, administered bi-weekly. Earnest lost her hair after the second treatment cycle. Later in 2011, Earnest's oncologist, Dr. James Carinder, treated her with Taxotere. In due course, the combination chemotherapy treatments proved successful, and Earnest was declared cancer free. Following chemotherapy, Dr. Carinder prescribed her Arimidex, a cancer reoccurrence preventive drug. Earnest was still taking Arimidex when she filed suit.

Although cancer free, Earnest's hair has never grown back. She alleges that her hair loss is permanent and that Sanofi knew that Taxotere caused permanent hair loss and yet failed to warn her of that side effect.

C.

Shortly before Earnest filed her original complaint in the Eastern District of Louisiana on December 12, 2016, the Judicial Panel on Multidistrict Litigation ordered the transfer of thirty-three pending Taxotere-related cases to that district court for management under MDL

procedures. *In re Taxotere (Docetaxel) Prod. Liab. Litig.*, 220 F. Supp. 3d at 1361; *see* 28 U.S.C. § 1407. Many more claims followed.[4]

In February 2017, the district court ordered the plaintiffs collectively to file a master complaint and individually to file particularized short form complaints. Pursuant to that order, Earnest filed an amended short form complaint on December 12, 2017, alleging "[d]isfiguring permanent [hair loss] beginning after treatment with Taxotere (docetaxel) and continuing to present." She asserted failure-to-warn and redhibition claims under Louisiana law.[5]

Discovery ensued. Pursuant to Federal Rule of Civil Procedure 30(b)(6), Sanofi produced Dr. Kopreski as its corporate designee for depositions. Earnest deposed Dr. Kopreski three times. One of those rounds of depositions focused on the TAX316 study. In response to Earnest's deposition notice regarding the study, Sanofi produced the identification numbers of the twenty-nine patients who were administered Taxotere in combination with Adriamycin and Cytoxan during the clinical trial and who

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[4] By January 2022, more than 12,000 individual cases were pending in this MDL. *See Pending MDLs By Actions Pending as of January 19, 2021*, https://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_Actions_Pending-January-19-2022.pdf.

[5] To prove a failure to warn under Louisiana law, "the claimant bears the burden of establishing that 'at the time the product left the manufacturer's control, the product possessed a characteristic that may cause damage and the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.'" *Hutto v. McNeil-PPC, Inc.*, 2011-606, p.12 (La. App. 3 Cir. 12/7/11); 79 So. 3d 1199, 1210–11 (quoting LA. STAT. ANN. § 9:2800.57).

"Redhibition is the avoidance of a sale on account of some vice or defect in the thing sold which renders it either absolutely useless, or its use so inconvenient and imperfect, that it must be supposed that the buyer would not have purchased it, had [she] known of the vice." *Hoffmann v. B & G, Inc.*, 2016-1001, p.5 (La. App. 1 Cir. 2/21/17); 215 So. 3d 273, 277.

were documented as experiencing "ongoing" alopecia at the end of the ten-year follow-up period. Sanofi additionally produced a spreadsheet that contained Dr. Kopreski's review of the TAX316 study. In the spreadsheet, Dr. Kopreski stated that only six of the twenty-nine patients sustained permanent hair loss, as defined by Earnest.

In February 2019, Earnest moved to exclude expert witnesses that Sanofi had designated including Dr. John Glaspy, a medical oncologist and professor of medicine at UCLA Jonsson Comprehensive Cancer Center. Earnest argued that the experts' proffered testimony improperly relied on Dr. Kopreski's review of the TAX316 study. Earnest argued that Dr. Kopreski had gone beyond testimony related to the corporate operations of Sanofi and had essentially offered expert medical testimony opining on the TAX316 study and its participants. Earnest further asserted that Dr. Kopreski's analysis was litigation-driven and therefore in the nature of improper expert opinion evidence. Earnest maintained that Dr. Kopreski's review was based on incomplete patient data because it encompassed only the twenty-nine patients identified in the final TAX316 clinical study report as experiencing "ongoing" hair loss, and his review relied solely on the fifty-five-month interim data as opposed to the final results. Specifically as to Dr. Glaspy, Earnest argued that he failed "independently [to] verif[y]" the data in Dr. Kopreski's review.

The district court denied Earnest's motion to exclude the expert testimony. Citing Federal Rule of Evidence 703 and case law, the court ruled that Dr. Glaspy was permitted to rely on Dr. Kopreski's review of the TAX316 study, "provided such reliance [was] reasonable."

The same month, Sanofi moved for summary judgment based on Louisiana's one-year statute of limitations. Sanofi asserted that Earnest was time-barred from asserting her failure-to-warn and redhibition claims.

Earnest responded in opposition. In July 2019, the district court granted Sanofi's summary judgment motion in part and dismissed Earnest's redhibition claim with prejudice.[6]

Earnest's failure-to-warn claim went to trial on September 16, 2019. In her case-in-chief, Earnest presented seventeen witnesses via video deposition and live testimony. That included testimony from eleven fact witnesses, one being Dr. Kopreski, and six expert witnesses. When Earnest rested on September 24, Sanofi moved for judgment as a matter of law, asserting preemption and Earnest's failure to prove her failure-to-warn claim.[7] The district court deferred ruling on Sanofi's motion.

Sanofi presented only two witnesses in its case-in-chief: Dr. Kopreski, as a Rule 30(b)(6) fact witness, and Dr. Glaspy, as an expert witness. Before Sanofi presented a segment of Dr. Kopreski's video deposition, Earnest renewed her objections to his testimony, but the court overruled her objections and allowed the testimony into evidence.

Dr. Kopreski testified regarding the procedure and theory behind clinical trials; specifically he spoke about the data adduced from TAX316's trial participants. Using that data, Dr. Kopreski generated a table of all study participants who experienced hair loss more than six months after concluding the drug regimen. After applying a methodology to exclude some of these participants, Dr. Kopreski testified that his analysis showed a vanishingly small number of TAC participants—six—who experienced permanent hair loss. In turn, Dr. Glaspy testified at length regarding his own experience as a

[6] Earnest does not challenge the dismissal of her redhibition claim on appeal. Therefore, this opinion does not address or apply to that claim.

[7] Both defendants moved for judgment as a matter of law; for the sake of simplicity, we refer to the motions, which were substantively the same, as a single motion in this discussion.

clinical oncologist and as a director of various clinical studies. Dr. Glaspy testified specifically about the TAX316 study and hair loss in participants. Relying wholly on Dr. Kopreski's analysis, Dr. Glaspy concluded that the study demonstrated that permanent hair loss was an outlier risk of the drug regimen.

At the close of evidence, Sanofi renewed its motion for judgment as a matter of law, which the district court again deferred. During its closing argument to the jury, Sanofi asserted that Earnest's "whole case fails" because Dr. Kopreski's testimony regarding TAX316 established that hair loss affected only a small number of patients. Sanofi's reliance on Dr. Kopreski's analysis was emphatic: "[I]f you want to know what really happened with TAX316, just like a book, you have to read the book to know how the story ends. And the only person in this case that did that was Dr. Kopreski."

Following deliberation, the jury rendered a unanimous verdict in favor of Sanofi, and the court entered judgment in accordance with that verdict. Earnest thereafter filed a motion for new trial pursuant to Federal Rule of Civil Procedure 59(a), asserting that the district court erroneously admitted improper opinion testimony from Dr. Kopreski and Dr. Glaspy. The district court concluded that Dr. Glaspy's reliance on Dr. Kopreski's analysis was reasonable under Rule 703 and denied Earnest's motion. The court reasoned that the testimony was proper because (1) Dr. Glaspy was heavily involved in the TAX316 study; (2) Dr. Glaspy was personally aware that "ongoing" and "permanent" were not synonymous within the meaning of the TAX316 data regarding side effects; (3) Earnest was permitted to cross-examine Dr. Glaspy on why such reliance was warranted; and (4) the jury was shown all the evidence, such that it could decide for itself whether to rely on Dr. Glaspy's expert testimony.

This appeal followed.

II.

We review the district court's evidentiary rulings for abuse of discretion. *Hewlett-Packard Co. v. Quanta Storage, Inc.*, 961 F.3d 731, 736 (5th Cir. 2020). "A district court abuses its discretion when its ruling is based on an erroneous view of the law or a clearly erroneous assessment of the evidence." *Heinsohn v. Carabin & Shaw, P.C.*, 832 F.3d 224, 233 (5th Cir. 2016) (quoting *Nunez v. Allstate Ins. Co.*, 604 F.3d 840, 844 (5th Cir. 2010)). "The harmless error doctrine applies to the review of evidentiary rulings, so even if a district court has abused its discretion, [this court] will not reverse unless the error affected 'the substantial rights of the parties.'" *Id.*

We afford the district court "broad discretion" in its rulings regarding the admission of expert testimony. *Sandifer v. Hoyt Archery, Inc.*, 907 F.3d 802, 807 (5th Cir. 2018). We reverse such a ruling only if it is "manifestly erroneous." *Guy v. Crown Equip. Corp.*, 394 F.3d 320, 325 (5th Cir. 2004) (emphasis omitted) (citing *Gen. Elec. Co. v. Joiner*, 552 U.S. 136, 141–42 (1997)). "We reverse the trial court only in unusual and exceptional cases." *Sandifer*, 907 F.3d at 807 (cleaned up).

Likewise, we review the denial of a motion for new trial for abuse of discretion. *Williams v. Manitowoc Cranes, L.L.C.*, 898 F.3d 607, 614 (5th Cir. 2018) (citation omitted). We reverse the district court only if "there is an absolute absence of evidence to support the jury's verdict." *Id.* (citation omitted).

III.

Earnest raises two interrelated issues on appeal: the district court's evidentiary rulings during trial and the court's denial of her post-judgment motion for a new trial. Both challenges rest on Earnest's assertion that the

district court erred by admitting testimony grounded on Dr. Kopreski's post hoc review of the TAX316 clinical study.

A.

Earnest first contends that the district court improperly admitted what she terms Dr. Kopreski's "re-analysis" of the TAX316 data. She asserts that, as a lay witness, Dr. Kopreski could not offer expert opinions and his testimony was neither relevant nor reliable under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).[8] Sanofi counters that Dr. Kopreski's testimony was admissible for two reasons. First, Sanofi contends that, as the district court concluded, Dr. Kopreski's testimony was properly admissible "opinion testimony by a lay witness" under Federal Rule of Evidence 701. Alternatively, Sanofi asserts that Earnest opened the door to Dr. Kopreski's testimony, noting that Earnest first introduced Dr. Kopreski's testimony in her own case-in-chief.

Weighing the parties' contentions, we are persuaded that the district court erred by admitting Dr. Kopreski's testimony under Rule 701, and the error was not harmless because Earnest's substantial rights were prejudiced by admission of the testimony. Sanofi's stratagem of skating the line between Rules 701 and 702 with Dr. Kopreski's testimony—borne out by the record and essentially confirmed at oral argument—reflects a calculated and troubling end-run around Rule 702 and *Daubert*. These evidentiary gates exist to keep out error that may impermissibly affect the jury, *see Carlson v.*

[8] The substantive aspects of this case are governed by Louisiana law, but the Federal Rules of Evidence control the admission of evidence. *Roman v. Western Mfg., Inc.*, 691 F.3d 686, 692 (5th Cir. 2012); *see also Wackman v. Rubsamen*, 602 F.3d 391, 400 n.2 (5th Cir. 2010) (citations omitted).

Bioremedi Therapeutic Sys., Inc., 822 F.3d 194, 202 (5th Cir. 2016), and the district court should not have left the gate ajar here.

Rule 701 governs the admissibility of opinion testimony by a lay witness:

> If a witness is not testifying as an expert, the testimony in the form of an opinion is limited to one that is:
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> (a) rationally based on the witness's perception;
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> (b) helpful to clearly understanding the witness's testimony or to determining a fact in issue; and
>
> (c) not based on scientific, technical, or other specialized knowledge within the scope of Rule 702.

FED. R. EVID. 701. A lay opinion is thus admissible if it is "based on personal perception, . . . one that a normal person would form from those perceptions, and . . . helpful to the jury." *Miss. Chem. Corp. v. Dresser-Rand Co.*, 287 F.3d 359, 373 (5th Cir. 2002) (citations omitted). "In particular, the witness must have personalized knowledge of the facts underlying the opinion and the opinion must have a rational connection to those facts." *Id.* "If these two requirements are met[,] 'a layman can under certain circumstances express an opinion even on matters appropriate for expert testimony.'" *Id.* (quoting *Soden v. Freightliner Corp.*, 714 F.2d 498, 511 (5th Cir. 1983)).

The thrust of Earnest's argument on this issue is that Dr. Kopreski's testimony was riddled with unqualified and unreliable expert opinions. In support of her contention, she relies on *Montgomery County v. Microvote Corp.*, 320 F.3d 440 (3d Cir. 2003), and *Crowley v. Chait*, 322 F. Supp. 2d 530 (D.N.J. 2004). In *Microvote Corp.*, the district court excluded the testimony of Microvote's expert witness as unreliable because the witness conceded that he did not review actual election use data in evaluating electronic voting

equipment that had malfunctioned. 320 F.3d at 448–49. Instead, the expert relied on a document prepared by Microvote's former sales director who "guesstimate[d]" about the amount of time the equipment was down. *Id.* The district court also found that the sales director had not based his guess on primary data. *Id.* at 449. Applying Rule 702 and *Daubert*, the Third Circuit affirmed the district court. *Id.*

In *Crowley*, the receiver of an insolvent insurance company sued the company's senior management for breach of fiduciary duty and also sued PricewaterhouseCoopers (PwC) for alleged negligence in connection with audits of the insurance company's parent company. 322 F. Supp. 2d at 534. PwC moved to exclude one of the receiver's experts, contending that the expert prepared his reports solely based on highly selective deposition testimony chosen by the receiver and the receiver's attorney, who disregarded contradictory testimony. *Id.* at 545–46. The district court found that the expert's conclusions were unreliable because they were reached through a "highly filtered version of the events." *Id.* at 547.

Sanofi counters that neither *Microvote* nor *Crowley* should inform our analysis here. Instead, Sanofi offers *United States v. Valencia*, 600 F.3d 389 (5th Cir. 2010) (per curiam), as instructive. In *Valencia*, the defendant argued that one of the Government's witnesses, Glenn Labhart, was in reality an expert witness who consequently implicated Rule 702's reliability requirements. 600 F.3d at 413. Rejecting that argument, the district court ruled that Labhart was a lay witness because his testimony, while analytical, "related to his former job duties." *Id.* at 416. On review, this court agreed that "Labhart was a lay witness, not an expert witness." *Id.* "Because Labhart's knowledge and analysis were derived from duties he held at [his company], his opinions were admissible as testimony based upon personal knowledge and experience gained while employed . . . ." *Id.*; *accord* FED. R. EVID. 701 advisory committee's note to 2000 amend. ("[Officer] opinion

testimony is admitted not because of experience, training or specialized knowledge within the realm of an expert, but because of the particularized knowledge that the witness has by virtue of his or her position in the business."); *Versai Mgmt. Corp. v. Clarendon Am. Ins. Co.*, 597 F.3d 729, 737 (5th Cir. 2010) (per curiam) (company president was permitted "a broader range of testimony than a traditional lay witness . . . when testifying to matters concerning [the value of the] business").

Following similar reasoning, the district court treated Dr. Kopreski's testimony as lay testimony, not expert testimony. And we agree that, as in *Valencia*, much of Dr. Kopreski's testimony reflected his personal knowledge and experience gained while employed as Sanofi's associate vice president of global pharmacovigilance and epidemiology. He testified that in this role, he regularly reviewed scientific literature, abstracts, adverse event reports, and clinical trials and studies. Sanofi also designated Dr. Kopreski as its company designee, even though he was no longer a Sanofi employee, in response to Earnest's Rule 30(b)(6) deposition notice, which expressly sought to examine Sanofi's company designee about TAX316.[9] A corporate designee

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[9] Earnest's second amended Rule 30(b)(6) notice stated in part that Sanofi was required "to designate and fully prepare" an officer with regard to:

> 1. Reports of any kind between 01/01/1992 and 12/31/2004 regarding persisting alopecia being associated and/or related in any way with the use of TAXOTERE (alone or in combination) regardless of the source of such report(s)[.]
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> . . . .
>
> 3. The identity of each patient, by reference number, who reportedly experienced persisting alopecia while enrolled as a participant in the TAX316 . . . so that it can be determined whether each such patient is included[.]
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> . . . .

"has the authority to speak on behalf of the corporation with respect to the areas within the notice of deposition" and that authority extends "to facts, . . . subjective beliefs[,] and opinions." *Brazos River Auth. v. GE Ionics, Inc.*, 469 F.3d 416, 433 (5th Cir. 2006) (citation omitted).

But even with that latitude, a Rule 30(b)(6) witness does not have license, without more, to opine as an expert. Assuming that Sanofi's corporate designee could offer Rule 701 "lay witness" opinion testimony, Dr. Kopreski's "testimony in the form of an opinion [remained] limited to [opinions] . . . not based on scientific, technical, or other specialized knowledge within the scope of Rule 702." FED. R. EVID. 701(c). The TAX316 clinical trials were conducted during Dr. Kopreski's tenure with Sanofi and he had personal knowledge of the study. His testimony describing the TAX316 study is thus the type of testimony generally admissible under Rule 30(b)(6) and Rule 701. Up to a point.

While parts of Dr. Kopreski's testimony fall within the parameters of Rule 701, he also strayed beyond "facts, . . . subjective beliefs[,] and opinions," *GE Ionics, Inc.*, 469 F.3d at 433, within either his personal knowledge or his capacity as Sanofi's corporate designee. He testified regarding highly specialized and technical information related to Taxotere, the TAX316 study, and drug studies in general. During its examination, Sanofi transparently sought Dr. Kopreski's opinions about the TAX316 data "as a board certified oncologist," as much as a former Sanofi employee. And Dr. Kopreski's testimony is littered with his interpretation and analysis of the

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6. The findings regarding alopecia as [treatment-emergent adverse events] persisting into the follow-up period in TAX316 at the median follow-up of 55 months.

TAX316 study data, which he prepared during litigation in response to Earnest's Rule 30(b)(6) deposition notice.

When questioned about his review of TAX316, Dr. Kopreski explained his methodology:

> I looked at the patients from the 29 that were considered to be ongoing [i.e., with hair loss], and I asked of those if there was documentation that answered two questions, two simple questions: Number 1, did we have documentation, either from what was provided in the [case report forms] or what was provided in terms of . . . clinical trial datasets, that were produced from the [case reports forms] that showed documentation that the alopecia was still present six months after the last chemotherapy. So that was—that was the first criteri[on]: Was the alopecia still present six months after the last chemotherapy that was received.
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> The second criteri[on]: Was there any evidence of resolution of that alopecia? If there was any resolution, then it would not be considered persistent. So that—that, very simply, is—is the process. It was a very straightforward process. It was looking to see if—if there was documentation for any of those two characteristics.

Regardless of whether it was a "very straightforward process" to Dr. Kopreski, his refinement of the TAX316 data in the context of litigation was the product of "scientific, technical, or other specialized knowledge" and application of scientific "principles and methods" within the scope of Rule 702, not simply lay opinion testimony based on his perceptions, as allowed by Rule 701. Therefore, it was erroneous for the district court to allow Dr. Kopreski to testify about his "re-analysis" of the TAX316 data without first enforcing its "basic gatekeeping obligation" under Rule 702 and *Daubert*. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999).

Of course, "even if a district court has abused its discretion, [this court] will not reverse unless the error affected 'the substantial rights of the parties.'" *Heinsohn*, 832 F.3d at 233 (quoting *Nunez*, 604 F.3d at 844). Here, the prejudice sustained by Earnest is evident. Sanofi effectively smuggled inadmissible opinion testimony past the expert-disclosure and expert-discovery obligations imposed by the discovery and evidentiary rules by offering Dr. Kopreski as a lay witness. Then Sanofi used that inadmissible testimony to bootstrap yet more expert testimony from Dr. Glaspy. Sanofi then relied on its only two witnesses' testimony to argue during closing that the plaintiff's "whole case fails." *Cf. Carlson*, 822 F.3d at 202 (concluding that improper testimony "relied upon during the defendants' closing arguments" was prejudicial). It is hard for us to see how Sanofi's approach did not thus unfairly influence the jury and thereby "affect[] 'the substantial rights of [Earnest].'" *Heinsohn*, 832 F.3d at 233 (quoting *Nunez*, 604 F.3d at 844).

Moreover, we do not find Sanofi's alternative argument, that Earnest first opened the door to Dr. Kopreski's testimony by offering parts of his testimony herself, to be persuasive. For this proposition, Sanofi presents only *United States v. Delk*, 586 F.2d 513 (5th Cir. 1978). But that case is very different from this one. In *Delk*, we stated an uncontroversial proposition about rebuttal testimony: "[I]t is well settled that the purpose of rebuttal testimony is to explain, repel, counteract, or disprove the evidence of the adverse party and if [a party] opens the door to the line of testimony, [she] cannot successfully object to the [other party] accepting the challenge and attempting to rebut the proposition asserted." 586 F.2d at 516 (quotation marks omitted). But the TAX316 "re-analysis" Dr. Kopreski presented in Sanofi's case-in-chief was not in rebuttal to anything Earnest had offered. It was expert opinion, offered by Sanofi on offense, not on defense. As such, even to the extent Earnest opened the door for rebuttal evidence, that did not

allow Sanofi to jump the gate provided by Rule 702 and *Daubert* in presenting its case-in-chief.

B.

Earnest next argues that the district court abused its discretion by admitting Dr. Glaspy's expert testimony to the extent it was based on Dr. Kopreski's review of the TAX316 study. Earnest does not challenge Dr. Glaspy's qualifications as an expert witness. Instead, she takes issue with Dr. Glaspy's failure to compare TAX316's actual data with Dr. Kopreski's "re-analysis" of TAX316. According to Earnest, Dr. Glaspy's expert testimony violated Rule 702 and *Daubert* because he did not independently validate Dr. Kopreski's review of the data. She points to Dr. Glaspy's concession during his testimony that "if the data that Dr. Kopreski put in [his] table [aren't] accurate, then my analysis is flawed. If [they are] accurate, I will stand by it." Building on our conclusion that parts of Dr. Kopreski's testimony were improperly admitted, here too there was an abuse of discretion that prejudiced Earnest.

The Supreme Court's *Daubert* framework governing the admissibility of expert testimony is effectively codified in Rule 702:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
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> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> (b) the testimony is based on sufficient facts or data;
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> (c) the testimony is the product of reliable principles and methods; and
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> (d) the expert has reliably applied the principles and methods to the facts of the case.

FED. R. EVID. 702. The object of Rule 702 is to protect juries from unreliable and irrelevant expert testimony. *E.g.*, *Curtis v. M&S Petroleum, Inc.*, 174 F.3d 661, 668 (5th Cir. 1999). "To be reliable, expert testimony must 'be grounded in the methods and procedures of science and . . . be more than unsupported speculation or subjective belief.'" *Puga v. RCX Sols., Inc.*, 922 F.3d 285, 293 (5th Cir. 2019) (quoting *Johnson v. Arkema, Inc.*, 685 F.3d 452, 459 (5th Cir. 2012) (per curiam)). "To be relevant, the expert's 'reasoning or methodology [must] be properly applied to the facts in issue.'" *Id.* (alteration in original).

To support her position, Earnest cites numerous cases from our circuit and others, as well as from several district courts, that illustrate the general principle that Rule 702 and *Daubert* require an expert witness independently to validate or assess the basis for his or her assumptions. We do not disagree with this proposition, as this court has previously stated:

> [T]he party seeking to have the district court admit expert testimony must demonstrate that the expert's findings and conclusions are based on the scientific method, and, therefore, are reliable. This requires some objective, independent validation of the expert's methodology. The expert's assurances that he has utilized generally accepted scientific methodology is insufficient . . . . The proponent need not prove to the judge that the expert's testimony is correct, but she must prove by a preponderance of the evidence that the testimony is reliable.

Moore v. Ashland Chem., Inc., 151 F.3d 269, 276 (5th Cir. 1998) (en banc) (citations omitted); *but see* FED. R. EVID. 703 (permitting an expert witness to base his opinion on "facts or data . . . that the expert has been made aware of or personally observed" and to opine on inadmissible evidence if "experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject").

At trial, Sanofi offered Dr. Glaspy as an expert in oncology, breast cancer care and treatment, labeling, risk information for chemotherapy, clinical trials, and informed consent regarding side effects of chemotherapy. Following voir dire, the district court accepted Dr. Glaspy as an expert in those areas. Dr. Glaspy then testified about causation in this case. Ultimately, he opined that it is "impossible" reliably to conclude that Taxotere caused Earnest's hair loss. Dr. Glaspy based his opinion on his review of Earnest's medical records, the other experts' depositions, Dr. Kopreski's TAX316 review, and an array of scientific literature. His reliance on much of this evidence was entirely proper under Rules 702 and 703. But for his linchpin conclusion about causation, Dr. Glaspy specifically acknowledged his dependence on Dr. Kopreski's "re-analysis" of the TAX316 data, going so far as to say that "if the data that's in [Dr. Kopreski's] table is incorrect, then *none* of my opinions are valid." (Emphasis added.) Because Dr. Kopreski's "re-analysis" data amounted to improper expert opinion, Dr. Glaspy's opinion as to causation based on Dr. Kopreski's analysis was likewise tainted.[10] And for the same reasons that the admission of Dr. Kopreski's opinion testimony prejudiced Earnest, the admission of Dr.

[10] To be clear, we obviously do not conclude that an expert may never rely on inadmissible evidence. We reiterate that Rule 703 expressly permits an expert to base opinions on "facts or data . . . that the expert has been made aware of or personally observed," including inadmissible evidence if "experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject." And we likewise do not conclude that an expert may not rely on another expert's (or a lay witness's) admissible testimony. *See Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, 807 F.3d 1283, 1303 (Fed. Cir. 2015). Rather, we determine that in these particular circumstances—where the inadmissible evidence (1) is from a witness testifying at the same trial, (2) is critical to the expert's testimony, and (3) is not independently verified by the expert—the expert's testimony relying on that inadmissible evidence does not pass muster under Rules 702 and 703. We leave to the district court to decide in the first instance how best to move forward on retrial.

Glaspy's testimony derived from it affected Earnest's substantial rights as well.

C.

Even mindful of the "wide latitude" afforded to district courts in deciding the admissibility of expert testimony, *Roman v. Western Mfg., Inc.*, 691 F.3d 686, 692 (5th Cir. 2012), we conclude that the district court reversibly erred in its evidentiary rulings regarding Sanofi's two witnesses at trial. In turn, the admission of those witnesses' improper expert testimony, featured prominently in Sanofi's closing argument to the jury, prejudiced Earnest's substantial rights during trial. As a result, we reverse the judgment of the district court and remand the appealed claims for a new trial.

REVERSED and REMANDED.