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UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

CHAROLETTE PAYNE; BRENT PAYNE,
Plaintiffs-Appellants,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,
Defendant-Appellee.

No. 13-6266

Appeal from the United States District Court
for the Eastern District of Tennessee of Chattanooga
No. 1:12-cv-00077—Curtis L. Collier, Chief District Judge.

Argued: August 1, 2014

Decided and Filed: August 18, 2014

BEFORE: CLAY and STRANCH, Circuit Judges; BLACK, District Judge.[*]

COUNSEL

ARGUED: Clinton L. Kelly, THE KELLY FIRM, Hendersonville, Tennessee, for Appellants. Eric G. Lasker, HOLLINGSWORTH LLP, Washington, D.C., for Appellee. **ON BRIEF:** Clinton L. Kelly, F. Dulin Kelly, THE KELLY FIRM, Hendersonville, Tennessee, for Appellants. Eric G. Lasker, Katharine R. Latimer, HOLLINGSWORTH LLP, Washington, D.C., Dwight E. Tarwater, PAINE, TARWATER, AND BICKERS LLP, Knoxville, Tennessee, for Appellee.

[*]The Honorable Timothy S. Black, United States District Judge for the Southern District of Ohio, sitting by designation.

OPINION

JANE BRANSTETTER STRANCH, Circuit Judge. Charolette Payne and her husband sued Novartis for failing to warn her doctor that two of the drugs it manufactures, Aredia and Zometa, could cause serious damage to a patient's jaw bones. Payne took both and subsequently had to have part of her jaw removed. Under Tennessee law, the question of whether Novartis's failure to warn was a cause of Payne's injuries is for a jury to determine. We therefore REVERSE the district court's grant of summary judgment for Novartis.

I. INTRODUCTION

Answering the question presented by this failure-to-warn claim requires that we "unravel the tangled skein of fact and policy" that goes by the deceptively unassuming name "causation." Wex S. Malone, *Ruminations on Cause-in-Fact*, 9 Stan. L. Rev. 60, 60 (1956). Causation issues in failure-to-warn cases present particularly knotty problems. First, they involve a series of counterfactual constructs—had you known certain facts, what would you have done?—that we use to determine "cause in fact." Restatement (Third) of Torts: Phys. & Emot. Harm § 28 cmt b. Would the doctor have changed his behavior if he had known about the drug's side effect? If so, would the doctor's actions have altered the patient's? And would the patient's altered actions have reduced the harm the drug caused her? These, like all causation issues, are "ordinarily jury questions, unless the uncontroverted facts and inferences to be drawn from them make it so clear that all reasonable persons must agree on the proper outcome." *Haynes v. Hamilton Cnty.*, 883 S.W.2d 606, 612 (Tenn. 1994); *see also* 63A Am. Jur. 2d Prod. Liab. §1138 (May 2014).

Because the answers to such questions are essentially unknowable and clouded by hindsight biases and credibility concerns (and thus especially suitable for the jury), at summary judgment these kinds of cases often hinge on the mix of moral intuition and policy judgments we call "proximate cause." *See* Dobbs' Law of Torts § 185; *Waste Mgmt. Inc. of Tenn. v. S. Cent. Bell Tel. Co.*, 15 S.W.3d 425, 430 (Tenn. Ct. App. 1997). Plaintiffs must show, among other things, that the drug manufacturer's failure to warn was a "substantial factor" in the harm the

drug caused the patient. *Hale v. Ostrow*, 166 S.W.3d 713, 719 (Tenn. 2005). This is also normally a question for the jury. *See Haynes*, 883 S.W.2d at 612. The legal significance of the warning's absence may also be dependent on particular facts such as dosage prescribed, prescription time frame, the patient's medical profile—to list a few common considerations.

Not only are these cases enormously fact-specific and fact-intensive, they are *state*-specific: the same set of facts that could get a plaintiff to the jury in one jurisdiction could very well result in summary judgment for the drug manufacturer in another. Woe to the party in a failure-to-warn case who thinks that cases from other jurisdictions will guarantee victory in her own. States have adopted a variety of legal rules that simplify the causation analysis; some rules benefit the pharmaceutical company (and shift liability to the prescribing doctor), some the injured patient. *See, e.g.*, *Giles v. Wyeth, Inc.*, 500 F.Supp.2d 1063, 1065–69 (S.D. Ill. 2007); *see also Garside v. Osco Drug, Inc.*, 976 F.2d 77, 82–83 (1st Cir. 1992); 1 Madden & Owen on Prod. Liab. § 9:11 (3d ed. 2000).

Here, two factual issues carry the plaintiffs past summary judgment: Payne's doctor made clear that he would have warned Payne had he known that Aredia and Zometa can destroy a patient's jaw bones, and Payne testified that she would not have taken the drugs had she been aware of the risk of this side effect.

II. BACKGROUND

Aredia and Zometa "are prescription biophosphonate drugs produced by Novartis that are given intravenously, most often to patients with cancerous conditions. The drugs are effective as preventing pathological fractures . . . and other bone pains." *Patterson v. Novartis Pharm. Corp.*, 451 F. App'x, 495, 496 (6th Cir. 2011). They are, however, associated with osteonecrosis of the jaw (ONJ). "Osteonecrosis of the jaw results in the gums being eaten away until the bone is exposed" and then dies from lack of blood. *Id.* The connection between biophosphonates and ONJ began to come to light to the medical community in the early 2000's. Courts in other bisphosphonate cases found to be probative evidence that Novartis was aware of the risk of ONJ years earlier. *See, e.g.*, *Mahaney ex rel. estate of Kyle v. Novartis Pharm. Corp.*, 835 F.Supp.2d 299, 311 (W.D. Ky. 2011); *Rowland v. Novartis Pharm. Corp.*, --- F.Supp.2d ----, 2014 WL 1316351, at *3 (W.D. Penn. 2014). Other ONJ plaintiffs have "presented evidence showing that

Novartis's high-ranking officials knew about the drugs' side effects and subverted medical inquiries into such effects." *Fussman v. Novartis Pharm. Corp.*, 509 F. App'x 215, 224 (4th Cir. 2013) (per curiam); *see also Davids v. Novartis Pharm. Corp.*, 977 F.Supp.2d 171, 183 (E.D.N.Y. 2013). "Novartis knew of the risk of ONJ as early as 2002, but instructed its sales force not to mention the disease when making calls to physicians." *Winter v. Novartis Pharm. Corp.*, 739 F.3d 405, 409 (8th Cir. 2014).

In 1999 Charolette Payne's breast cancer spread to her bones. That same year, her physician, Dr. Darrell Johnson, prescribed Aredia, unaware of the risk of the ONJ. In 2001, Dr. Johnson switched her to Zometa; again, Dr. Johnson was not aware of the risk of ONJ. In 2005, Dr. Johnson noticed something wrong with Payne's jaw and advised her to see a dentist. He also suspended her Zometa treatment. He later explained why:

> There were some data coming out about that time that Aredia and Zometa can be associated with complications of the mandible that can increase the risk of what we call osteonecrosis of that jaw and I believe that—you know, within a year or so of that there were some data coming out and saying that if you have a patient that you're suspicious of something like that possibly going on[,] holding the medication may be wise while they're undergoing evaluation by a dentist.

Payne had several teeth removed but "was displeased with her oral surgeon's performance and continued to feel pain in the area from which her teeth were extracted." In 2007, Dr. Johnson noticed that one of Payne's teeth was partially necrotic. Payne's oral surgeon diagnosed her with biophosphonate-induced ONJ. Her condition progressed; part of Payne's jaw had to be removed in 2009.

"Had I been warned that Aredia and Zometa may cause Osteonecrosis of the jaw, I would not have taken those drugs," Payne later stated in an affidavit. Dr. Johnson testified that he continues to prescribe Aredia and Zometa but now warns his patients about the risk of ONJ and recommends that they get a dental exam before they start treatment.

Payne and her husband sued Novartis in 2008, alleging in relevant part that her ONJ was the result of Novartis's failure to provide adequate warnings about the link between biophosphonates and the disease. Payne's was one of many such suits. The judicial panel on multidistrict litigation transferred her case to the Middle District of Tennessee for consolidated

proceedings. The MDL court remanded her case in March 9, 2012, and it was subsequently transferred to the Eastern District of Tennessee.

The district court granted summary judgment for Novartis on one ground: That Novartis's alleged failure to warn was not a proximate cause of Payne's ONJ. Under Tennessee's "learned intermediary doctrine," the court stated, the question was whether a jury could find that Dr. Johnson would have done something differently had he known about the risk of ONJ and, if so, whether that difference could have prevented Payne's ONJ. The court dismissed as "entirely speculative" Payne's statement that she would have refused biophosphonates if she had been warned about the risk of ONJ.

On appeal, the Paynes argue that a jury could find that Payne would not have developed ONJ if Novartis had warned Dr. Johnson about the risk. The Paynes' argument is straightforward: If Novartis had warned Dr. Johnson, Dr. Johnson would have warned Payne and Payne would have refused to take biophosphonates. Novartis focuses on what it characterizes as the district court's evidentiary decision to "exclude" Payne's statement that she would not have taken Aredia or Zometa had she known the risk. As Novartis's counsel said at oral argument, this case "does rise and fall on whether or not the district court acted within its discretion . . . to disregard the affidavit as being entirely speculative."

III. DISCUSSION

A. Standard of Review

The panel reviews the district court's grant of summary judgment de novo. *Laster v. City of Kalamazoo*, 746 F.3d 714, 726 (6th Cir. 2014). Summary judgment is appropriate only if the pleadings, depositions, answers to interrogatories, and affidavits show there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(a) & (c). The burden to show that there are no genuine issues of material fact falls on the parties seeking summary judgment. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23, (1986). "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge[.]" *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). We consider the evidence in the light most favorable to the non-

moving parties, drawing all justifiable inferences in their favor. *Id.* The ultimate question is whether the evidence presents a sufficient factual disagreement to require submission of the case to the jury, or whether the evidence is so one-sided that the moving parties should prevail as a matter of law. *Id.* at 251–52.

We sit in diversity and must apply Tennessee substantive law. *Hayes v. Equitable Energy Res. Co.*, 266 F.3d 560, 566 (6th Cir. 2001). In resolving issues of Tennessee law, we look to "the final decisions of that state's highest court, and if there is no decision directly on point, then we must make an *Erie* guess to determine how that court, if presented with the issue, would resolve it." *Conlin v. Mortg. Elec. Registration Sys., Inc.*, 714 F.3d 355, 358–59 (6th Cir. 2013). The decisions of the Tennessee Court of Appeals "are also viewed as persuasive unless it is shown that the state's highest court would decide the issue differently." *Id.* (quoting *Savedoff v. Access Grp., Inc.*, 524 F.3d 754, 762 (6th Cir. 2008)).

B. The Learned Intermediary Doctrine

"[M]anufacturers of prescription drugs, like manufacturers of any other unavoidably dangerous product, have a duty to market and distribute their product in a way that minimizes the risk or danger." *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 428 (Tenn. 1994). Prescription drug manufacturers typically fulfill their duty by warning "those who foreseeably could be injured by the use of their products" of any harmful side effects. *Id.* Novartis thus had a continuing duty to warn the users of Aredia and Zometa about the side effects of these "unavoidably dangerous" products. *Id.*

In Tennessee, "the learned intermediary doctrine is applicable in failure to warn suits where a physician is the intermediary between a defendant pharmaceutical . . . manufacturer and an injured patient." *Nye v. Bayer Cropscience, Inc.*, 347 S.W. 686, 701 (Tenn. 2011). "The doctrine constitutes a defense by pharmaceutical manufacturers in cases where a plaintiff has suffered injury from a medication prescribed by a doctor." *Id.* A prescription drug manufacturer's duty to warn can be discharged if it provides adequate warnings to the physican regarding the drug's risk. *Id.* The doctrine is based on the understanding that physicians play a "pivotal role . . . in the unique system used to distribute prescription drugs," and can stand between the drug manufacturer and the patient. *Pittman*, 890 S.W.2d at 429. At base, the

doctrine can shift liability from drug companies to doctors: If the drug company adequately warned and instructed the doctor but the doctor did not adequately warn and instruct the patient, the patient's quarrel is with the doctor rather than the drug company. *See State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 917–18 (W.Va. 2007) (Maynard, J., concurring); Victor E. Schwartz et al., *Marketing Pharmaceutical Products in the Twenty-First Century*, 32 Harv. J.L. & Pub. Pol'y 333, 367–69 (2009).

Ostensibly applying the learned intermediary doctrine, the district court concluded that Novartis was entitled to summary judgment. The court determined that the Paynes could not show that Novartis's failure to warn had proximately caused Charolette's injury for two reasons—her doctor would not have meaningfully changed his prescribing practice had he been aware of the risk of the drugs and Charolette's affidavit testimony that she would have refused the drugs had she been aware of the risk was "speculative." We disagree on both counts.

Dr. Johnson testified that he now (1) warns patients about the risk of ONJ and (2) recommends that they see a dentist before staring biophosphonates. The district court correctly noted that there was no evidence that a dental exam in 1999 (when Payne started Aredia) or 2001 (when she switched to Zometa) would have prevented her ONJ. But the district court disregarded the import of Dr. Johnson's testimony that he now warns patients about the risk of ONJ, and in this respect the court erred. *See Smith v. Pfizer, Inc.*, 688 F.Supp.2d 735, 746 (M.D. Tenn. 2010) (applying Tennessee law) (denying summary judgment for Pfizer because, in part, of evidence that the decedent's doctor would have warned him about the risk of suicide).

Payne stated in her affidavit that she would not have taken either drug if she had been aware of the risk of ONJ. Viewed in the light most favorable to the Paynes, a factfinder could infer that, had he known the risk, Dr. Johnson would have warned Payne about ONJ before starting her on Aredia or Zometa and Payne would have then refused to take the drugs. But the district court considered Payne's affidavit testimony to be "entirely speculative" and therefore insufficient to prevent summary judgment. Novartis frames this conclusion as "an evidentiary ruling" that the panel reviews for abuse of discretion; we read the court's decision as simply an application of the summary judgment standard. The court did not "exclude" the affidavit; rather, it determined that the affidavit was not "significantly probative" and could not provide a basis

for the Paynes to survive summary judgment. *Anderson*, 477 U.S. at 249. As this is a diversity case, the probative value of the affidavit is determined by Tennessee law. *See McLean v. 988011 Ontario, Ltd.*, 224 F.3d 797, 800 (6th Cir. 2000).

All Tennessee law requires is evidence that a warning would have altered the doctor's actions and that the change in the doctor's actions would have averted the patient's injury. "The key inquiry is whether, 'had additional warnings been given, the plaintiff[] would not have sustained [her] injuries.'" *Smith*, 688 F.Supp.2d at 746 (quoting *King v. Danek*, 37 S.W.3d 429, 453 (Tenn. Ct. App. 2000)); *see also Cansler v. Grove Mfg. Co.*, 826 F.3d 1507, 1511 (6th Cir. 1987). Courts in other jurisdictions have considered a plaintiff's testimony that she would not have taken the drug if she had been warned of its side effects to be sufficient to prevent summary judgment. *See, e.g.*, *Gilliland v. Novartis Pharm. Corp.*, --- F.Supp.2d ----, 2014 WL 3747175, at *8 (S.D. Iowa 2014) ("The learned intermediary doctrine certainly does not allow health care professionals to substitute their judgment for that of their patients. Nor does it obviate the need to consider whether the plaintiff patient's decision concerning her recommended course of treatment would have been different, assuming that the warning at issue had been more adequate."); *In re Aredia and Zometa Prod. Liab. Litg.* (*Hogan*), No. 3:06-MD-1760, 2009 WL 2513555, at *2 (M.D. Tenn. Aug. 19, 2009) (applying Rhode Island law); *see also Fussman*, 509 F. App'x at 224. Other cases have not found such testimony from the plaintiff to be sufficient. *See, e.g.*, *Luttrell v. Novartis Pharm. Corp.*, 894 F.Supp.2d 1324, 1344–45 (E.D. Wash. 2012).

Neither the district court nor the parties have identified a Tennessee case that supports the proposition that this testimony is insufficient to forestall summary judgment. To the contrary, the Paynes note that Tennessee explicitly allows such testimony to show causation in informed consent cases. *See Ashe v. Radiation Oncology Assocs.*, 9 S.W.3d 119, 123–24 (Tenn. 1999) ("The finder of fact may consider and give weight to the patient's testimony as to whether the patient would have consented to the procedure upon full disclosure of the risks."). Causation in both types of cases—informed consent and failure to warn—ultimately rests with the patient's decision to take or reject the medication. Both types of cases address the same issue, and we can find no indication that the Tennessee Supreme Court would adopt a different standard of proof for essentially the same link in the causal chain. *Cf.* Aaron D. Twerski & Neil B. Cohen,

Resolving the Dilemma of Nonjusticiable Causation in Failure-to-Warn Litigation, 84 S. Cal. L. Rev. 125, 128 (2010) ("In both informed consent and failure-to-warn cases, (1) the plaintiff has acted without information that perhaps would have led to a different decision, and (2) . . . the cause of action requires the plaintiff to demonstrate that a different (and less harmful) decision would have been made had that information been provided.").

Both parties cite to a number of biophosphonate cases in other jurisdictions where the patient stated that she would not have taken the medication if she had known of the risk of ONJ. These cases may give the reader a sense of both the various fact patterns involved in biophosphonate litigation and the difficulty in dealing with counterfactual testimony. *Compare, e.g., D'Agnese v. Novartis Pharm. Corp.*, 952 F.Supp.2d 880, 892–93 (D. Ariz. 2013) *with Bowles v. Novartis Pharm. Corp.*, No. 3:12-cv-145, 2013 WL 5297257, at *12–13 (S.D. Ohio Sept. 19, 2013) (specifically rejecting *Payne*); *see also Kruszka v. Novartis Pharm. Corp*, --- F. Supp. 2d. ----, 2014 WL 187877 at *15 (D. Minn. 2014) (distinguishing *D'Agnese*). But they are not particularly helpful in answering whether Payne's affidavit testimony might prevent summary judgment for Novartis under Tennessee substantive law. Although many states have adopted the learned intermediary doctrine, the doctrine differs significantly from state to state when it comes to causation. *See e.g.*, Karin L. Bohmoldt, *The Heeding Presumption and Its Application*, 37 Loy. L.A. L. Rev. 461, 461–62 (2003). There appear to be two major categories. Some states have a rebuttable presumption of causation if a drug company failed to provide a warning. *See, e.g.*, *Bee v. Novartis Pharm. Corp.*, --- F. Supp. 2d ----, 2014 WL 1855632 at *12 (E.D.N.Y. 2014); *see also Coffman v. Keene Corp.*, 628 A.2d 710, 718 (N.J. 1993) (discussing the reasons for and against adopting the presumption of causation). In other states the presumption is that the doctor would have "heeded" the warning but these states do not then presume that the failure to warn actually caused the plaintiff's injury. *See, e.g.*, *Ingram v. Novartis*, 888 F. Supp. 2d 1241, 1244 (W.D. Okla. 2012). At least one state appears to have swung to the extreme, essentially presuming that the patient would have done whatever her doctor said. *See Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1098–99 (5th Cir. 1991) (applying Louisiana law).

Tennessee has not adopted any of these presumptions. It does, however, normally accept the kind of evidence that the district court rejected as "speculative." *See Ashe*, 9 S.W.3d at 123–24. Although the record is relatively spare, causation is a question for the jury "unless the uncontroverted facts and inferences to be drawn from them make it so clear that all reasonable persons must agree on the proper outcome." *Haynes*, 883 S.W.2d at 612. We cannot say that all reasonable people must agree that a warning from Novartis would not have significantly changed Dr. Johnson's actions and prevented Payne's ONJ. In this case, under Tennessee law, causation is an issue for the jury and the district court erred in concluding otherwise.

IV. CONCLUSION

Novartis argued that this case "rise[s] and fall[s]" on whether the district court properly disregarded Payne's affidavit testimony. Under Tennessee law, Payne's testimony, combined with her doctor's, could establish a sufficient causal link between Novartis's failure to warn and Payne's jaw death. A reasonable jury could conclude that Payne would not have taken Aredia or Zometa had Dr. Johnson warned her of the risk of ONJ. We **REVERSE** the district court's grant of summary judgment for Novartis and remand the case for further proceedings consistent with this opinion.