IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit

FILED
March 30, 2009

Charles R. Fulbruge III
Clerk

No. 08-40170

BEATRIZ E EBEL, Individually and as Personal Representative of the Estate of Philip Wayne Ebel, Deceased, and as Next Friend of Eric Fernando Ebel and Gabriela Nicole Ebel, Minors

Plaintiff - Appellant

v.

ELI LILLY & CO

Defendant - Appellee

Appeal from the United States District Court for the
Southern District of Texas, Brownsville
USDC No. 1:04-CV-194

Before KING, BENAVIDES, and CLEMENT, Circuit Judges.

PER CURIAM:[*]

Plaintiff–Appellant Beatriz Ebel brings this suit against Eli Lilly & Company on behalf of herself, her late husband's estate, and her two children. She claims that Eli Lilly & Company failed to warn that its drug, Zyprexa, can cause akathisia—a feeling of severe restlessness—and suicide and that, as a result, her husband, Philip Ebel, committed suicide on November 11, 2002. The

[*] Pursuant to 5TH CIR. R. 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIR. R. 47.5.4.

district court dismissed her claim on summary judgment, concluding both that Zyprexa's warning was adequate as a matter of law and that Beatriz Ebel failed to present evidence that the warning was the producing cause of Philip's death. We agree that Beatriz Ebel has failed to point to evidence demonstrating that Zyprexa's warning was the producing cause of Philip's death; therefore, we affirm the district court's judgment.

I. FACTUAL AND PROCEDURAL BACKGROUND

Philip Ebel battled chronic and severe headaches that significantly interfered with both his professional and personal life. Over the course of that battle, he tried roughly forty-seven different medications, the last of which were Zyprexa and Paxil.[1] After taking Zyprexa for nearly four months, Philip tragically ended his own life on November 11, 2002, by a self-inflicted gunshot wound. He left behind his two children and wife, Beatriz Ebel ("Ebel"). Ebel now brings this suit against Eli Lilly & Company ("Lilly") on behalf of herself, her children, and Philip's estate; she alleges Zyprexa's label did not warn that the drug may cause akathisia and suicide and that the drug caused Philip's suicide.

Beginning in February 2001, Philip sought treatment from Dr. Robert Nett, who is located in San Antonio, Texas, and is board-certified in pain management. After trying numerous combinations of prescription drugs that only marginally increased Philip's quality of life, Dr. Nett recommended that Philip obtain an appointment at Dr. Joel Saper's Michigan Headache & Neurological Institute, a clinic specializing in the treatment of severe headaches.

[1] This suit addresses only those claims concerning Zyprexa; an additional suit was brought against GlaxoSmithKline, the maker of Paxil, but the parties have since settled those claims.

Philip took this advice and attended the Michigan clinic for three weeks in December 2001. Unfortunately, he returned no better off than when he left. Back in Dr. Nett's care, Philip was present when Dr. Nett conferred over the telephone with Dr. David Gordon from the Michigan clinic in order to ascertain additional treatment options available to Philip. Dr. Gordon suggested prescribing one of two possible drugs: Pamelor or Zyprexa. Dr. Nett described the decision to prescribe Zyprexa in his deposition:

> [B]asically, [Philip] was saying that [Nardil, the current drug,] was not working, side effects were becoming intrusive and, you know, that's when it was like he was on no medication. So it was, okay, let's call Ann Arbor, Joe [sic] Saper's practice, get someone on the phone to say, okay, look, I'm—I have a fellow here that now is declaring himself that he realizes he's at the end of his rope. What else can we try?
>
> And that's when Gordon took time, reviewed the case, and he said, look, Bob, you know, Zyprexa is worth a trial, and for completeness, Pamelor. I didn't think Pamelor would be a real viable option, because [Philip] had been on Tofranil for so long, and amitryptyline in the past, that the similarities of those compounds, I would go with Zyprexa. . . .

Zyprexa, which is the trade name for olanzapine, is an atypical antipsychotic drug produced by defendant Lilly and approved by the Food and Drug Administration (the "FDA") for the treatment of schizophrenia and bipolar disorder. The drug has the additional effect of reducing the severity of headaches in some patients, and it is for this off-label use that Dr. Nett prescribed it to Philip. However, Zyprexa is not without its side effects: under the heading "Precautions," the drug's 2002 label states:

> Suicide—The possibility of a suicide attempt is inherent in schizophrenia and in bipolar disorder, and close supervision of high-risk patients should accompany drug therapy.

Under the same heading and the subheading "Other Adverse Events Observed During the Clinical Trial Evaluation of Olanzapine," suicide attempt is identified as a "frequent" event—an event that occurs "in at least 1/100 patients." With regard to akathisia, in the section entitled "Adverse Reactions," four of six tables delineate akathisia as a side effect that occurs more often in clinical-trial participants taking olanzapine than in those taking the placebo.

Dr. Nett demonstrated his awareness of these side effects in his deposition. Questions from Lilly's attorney revealed the doctor's knowledge that Zyprexa may cause akathisia:

> Q [D]o you remember this class of antipsychotic medications can cause some restlessness, or what's sometimes called akathisia?
>
> [Dr. Nett] Yes.
>
> Q And at the time you prescribed that for [Philip], you were aware of that?
>
> A Yes. Akathisia is fairly rare as far as, you know, fullblown. But it's the irritability that it's kind of like a ca—I described it as you might get irritable as though you had two extra cups of coffee and you're kind of jumpy a little bit. And I wanted him to report that.

Dr. Nett's understanding that using Zyprexa entailed a risk of suicide was demonstrated during the examination by Ebel's attorney:

> Q In July of 2002 when you prescribed it, what did you know about the side effect profile of Zyprexa? And if you'd give me some specifics, you know, what it caused—
>
> [Dr. Nett] It can cause—
>
> Q —frequency of cause—of what it caused. Those types of things is what I'm getting at.
>
> A I mean, I would have to get a [Physicians' Desk Reference] to be exact—

Q Sure.

A —to the amount of sedation. But sedation, lightheadedness, dizziness, moodiness, irritability, agitation, can be easily observed with this product. They tend to be mild to moderate. They tend to be transient. . . . And he was to report any rage, violent anger, intrusive thoughts.

* * *

Q Had anyone from Eli Lilly ever discussed with you the potential for Zyprexa induced suicides, or suicidality?

A I believe that's been brought up, specially in the context of the adolescent data with antidepressants and new warnings of heightened suicide likelihood in younger—in younger patients. So I think that's been on the forefront of detailing.

Q [W]e really need to focus on July 2002. . . .

A Yeah, I mean, I am reasonably sure that such dialogue had occurred. And I would say that because of this heightened awareness by all companies when they are detailing antidepressants and atypicals, that the enhanced rate of suicide . . . needs to be of a concern in prescribing the product.

So, you know, specifically in 2001 and 2002, and 2003, I mean, I'm reasonably sure that those dialogues have occurred. To try to look back five years ago and cite specifically without reservation, that becomes more difficult, Fred.

And, again when questioned by Ebel's attorney, Dr. Nett further indicated that he communicated the risks of akathisia and suicide to Philip and that, given Philip's circumstances and Dr. Nett's self-described awareness of the drug's risks, the risk–benefit analysis favored prescribing Zyprexa:

Q [I]s it accurate to state that you are aware of the suicide issue and the akathisia issue?

[Dr. Nett] I'm aware of akathisia enhanced suicides if I'm going to prescribe a product. There's been heightened awareness over the

> last several—several years in that regard. And I am certainly using a product that has that potential last, or i.e., Nardil, and atypicals. Because of enhanced concerns for side effects, including suicide, risk benefit in Philip at that time was valuable to try.
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> Q I understand. But—
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> A He would have been told, as illustrated in chart notes, concerns for irritability and agitation that go beyond that. He was asked specifically for depression, suicidal thoughts, intrusive thoughts—

Philip began taking Zyprexa in July 2002. He additionally obtained a prescription for Paxil from a different physician on November 9, 2002. Two days later, on November 11, 2002, Philip ended his life.

Ebel subsequently filed the current complaint, arguing that, under theories of strict liability, negligence, and breach of warranty, Lilly was liable for Philip's death because its warning that Zyprexa may cause akathisia and suicide was defective. Lilly filed a motion for summary judgment alleging that, under the learned intermediary doctrine, (1) Zyprexa's warning was adequate as a matter of law and (2) Ebel failed to present evidence that Zyprexa's label was the producing cause of the harm. The district court agreed with Lilly on both grounds. Applying Texas law and the learned intermediary doctrine, the court first determined that Zyprexa's warning was adequate as a matter of law under Texas Civil Practice and Remedies Code Annotated § 82.007(a) and that § 82.007(b)'s overpromotion exception did not apply. Second, the district court concluded that Ebel had failed to present evidence establishing that Zyprexa's warning was the producing cause of the harm and that the read-and-heed presumption did not apply so as to put the burden of negating causation on Lilly.

Consequently, the district court granted Lilly's motion for summary judgment in its January 29, 2008 order. Ebel timely appealed.

II. STANDARD OF REVIEW

We review de novo a grant of summary judgment. *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 207 (5th Cir. 2008). Summary judgment is appropriate "'if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the 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.'" *McNeil v. Wyeth*, 462 F.3d 364, 367 (5th Cir. 2006) (quoting FED. R. CIV. P. 56(c)). We view the evidence in the light most favorable to the nonmovant, but no genuine issue of material fact exists where "the non-moving party fails to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Ackermann*, 526 F.3d at 207 (internal quotation marks omitted); *see also Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 263 (5th Cir. 2002) ("[I]f the non-moving party can point to nothing in the record supporting its claim, summary judgment is appropriate.").

III. DISCUSSION

Summary judgment is proper in this case. Where the learned intermediary doctrine applies, a plaintiff must show both that the drug's warning was defective and that the warning was the producing cause of the injury. Ebel has failed to present evidence in support of the latter requirement, and because this alone is sufficient to support the grant of summary judgment favoring Lilly, we need not address Ebel's arguments concerning whether Lilly's warning was defective.

The learned intermediary doctrine applies to Texas products-liability suits involving prescription drugs. *See Harrison v. Am. Home Prods. Corp.* (*In re Norplant Contraceptive Prods. Liab. Litig.*), 165 F.3d 374, 379 (5th Cir. 1999) ("Two of our cases applying Texas law in [the prescription drug] area have concluded that, as long as a physician–patient relationship exists, the learned intermediary doctrine applies."); *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999) ("The learned intermediary doctrine applies in medical products liability actions in Texas."); *cf. Humble Sand & Gravel, Inc. v. Gomez*, 146 S.W.3d 170, 185 (Tex. 2004) ("In *Alm v. Aluminum Co. of America*, [717 S.W.2d 588, 591 (Tex. 1986),] we recognized that 'a manufacturer or supplier may, in certain situations, depend on an intermediary to communicate a warning to the ultimate user of a product.'"). This doctrine dictates whom a manufacturer must warn—the learned intermediary as opposed to the final user—and "is not an affirmative defense." *Ackermann*, 526 F.3d at 207; *see also Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1178 (5th Cir. 1988) ("[T]he learned intermediary doctrine relates only to the issue of whom the manufacturer warned.").

When, as here, the learned intermediary doctrine applies,[2] "a plaintiff must show that (1) the warning was defective, and (2) the failure to warn was a producing cause of the injury." *Ackermann*, 526 F.3d at 208 (citing *Porterfield*, 183 F.3d at 468). Regarding the first requirement, Lilly asserts that Zyprexa's warning is not defective and is, instead, adequate as a matter of law under TEXAS CIVIL Practice and Remedies Code Annotated § 82.007(a) because the FDA approved the drug's label.[3] Ebel counters that the statute should not apply, arguing that Lilly altogether failed to provide a warning that the drug may cause akathisia or suicide because it tied such indications of akathisia and

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[2] Ebel contests that an overpromotion exception to the learned intermediary doctrine should apply because Lilly allegedly promoted off-label uses of Zyprexa to doctors. As support, Ebel points to an internal presentation of Lilly's that purportedly planned to market Zyprexa by increasing primary-care physicians' awareness of the drug. Ebel, however, does not point to any Texas case law adopting an overpromotion exception to the learned intermediary doctrine, nor can we find a Texas case doing so. Additionally, though we are skeptical that a Texas court would adopt such an exception in the first place, *see Harrison*, 165 F.3d at 379 (refusing to apply the different, but similar direct-to-consumer-marketing exception to Texas's learned intermediary doctrine because "as long as a physician–patient relationship exists, the learned intermediary doctrine applies"), we need not decide the issue because, as the district court indicated, Ebel has failed to produce evidence demonstrating that the alleged marketing plan in fact resulted in overpromoting Zyprexa's off-label uses and that Dr. Nett ever received any such marketing material overpromoting Zyprexa, *see id.* (stating that the argument to apply a direct-to-consumer-marketing exception "is critically weakened by the absence of any evidence on the record that any of the five plaintiffs actually saw, yet alone relied[] on[,] any marketing materials issued to them by [defendant]"). Besides arguing that this exception should apply, Ebel does not challenge the application of the learned intermediary doctrine.

[3] Section 82.007(a) states:

> 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 . . . [is] 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 [FDA] for a product approved under the Federal Food, Drug, and Cosmetic Act, as amended . . . .

suicide to the conditions of schizophrenia and bipolar disorder and because it failed to list these side effects under the label's "Warnings" section as required by 21 C.F.R. § 201.80(e) (formerly 21 C.F.R. § 201.57(e)).[4] Failing that, Ebel contends that the statute's overpromotion exception applies; that exception states that § 82.007(a)'s presumption of no liability no longer applies when "the defendant recommended, promoted, or advertised the pharmaceutical product for an indication not approved by the [FDA]." *See* TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(b)(3)(A). However, we need not address these arguments because Ebel failed to present any evidence establishing the existence of the second requirement under the learned intermediary doctrine—that Zyprexa's 2002 label was the producing cause of Philip's death.

The failure to warn is a producing cause of the injury if "'the alleged inadequacy caused [the] doctor to prescribe the drug for [the patient].'" *Ackermann*, 526 F.3d at 208 (quoting *McNeil*, 462 F.3d at 372). "If, however, 'the physician was aware of the possible risks involved in the use of the product but decided to use it anyway, the adequacy of the warning is not a producing cause of the injury' and the plaintiff's recovery must be denied." *Id.* (quoting *Porterfield*, 183 F.3d at 468). "Even if the physician is not aware of a risk, the plaintiff must show that proper warning would have changed the decision of the treating physician, i.e., that but for the inadequate warning, the treating

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[4] That regulation states, in pertinent part:

> Warnings. Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards . . . . The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.

We do not express any opinion as to whether this regulation actually requires what Ebel asserts that it does.

physician would have not used or prescribed the product." *Id.* (internal quotation marks omitted).

Ebel has presented no evidence to suggest that Dr. Nett was unaware of the risks engendered by Zyprexa's use at the time he prescribed the drug or that an alternative warning would have changed Dr. Nett's decision to prescribe Zyprexa. Dr. Nett's deposition demonstrates that he was aware of Zyprexa's akathisia and suicide risks and that he communicated these risks to Philip. Dr. Nett did not indicate that, had he been made aware of additional information regarding the drug, his risk–benefit analysis of whether to use Zyprexa would have changed. Instead of pointing to evidence that Dr. Nett was uninformed or would have changed his prescription, Ebel argues that Lilly bears the burden of establishing that Dr. Nett was fully aware of Zyprexa's risks and that Dr. Nett's testimony was too equivocal to meet that burden. Ebel compares Dr. Nett's testimony to that of the doctor in *McNeil*, where a panel of this court reversed the grant of summary judgment that favored a pharmaceutical company.

Ebel's arguments fail, however, because she, as the plaintiff, bears the burden of establishing that the allegedly inadequate warning is the producing cause of the harm and because Dr. Nett's testimony does not resemble that of the doctor in *McNeil*. First, Ebel's argument is based on the erroneous premise that the learned intermediary doctrine is an affirmative defense, contrary to this court's statement in *Ackermann* that "[t]he learned-intermediary doctrine is not an affirmative defense." 526 F.3d at 207. Instead, under this doctrine, the "*plaintiff* must show that . . . the failure to warn was a producing cause of the

injury." *Id.* at 208 (emphasis added).[5] Lilly's motion for summary judgment alleged, among other things, that evidence demonstrating that Zyprexa's warning was the producing cause of the injury was lacking, and the district court agreed. We, too, agree, and despite Ebel's assertion to the contrary, determining that a party has failed to establish an essential element of the claim is a proper consideration on summary judgment and is not a finding of fact to be left to the jury. *See Ackermann*, 526 F.3d at 207 ("But where the non-moving party fails to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial, no genuine issue of material fact can exist." (internal quotation marks omitted)). Furthermore, placing the burden on the plaintiff to produce evidence of causation is not, as Ebel avers, "completely inimical to Texas products liability law"; indeed, it is required by Texas law. *See id.* at 208 ("In other words, '[u]nder Texas law, a plaintiff who complains that a prescription drug warning is inadequate must also show that the alleged inadequacy caused her doctor to prescribe the drug for her.'" (quoting *McNeil*, 462 F.3d at 372)).

[5] In her argument, Ebel points to *Garside v. Osco Drug, Inc.*, 976 F.2d 77 (1st Cir. 1992), as support for the requirement that the defendant drugmaker bears the burden of disproving causation by providing evidence that the prescribing doctor was aware of all the information that a sufficient warning would include. In that case, the First Circuit first determined that the read-and-heed presumption—"a rebuttable presumption in favor of the plaintiff that a physician would have heeded an adequate warning"—applied and, for that reason, the burden shifted to the defendant to show that the doctor would not have heeded the warning because he was already fully aware of the drug's risks. *See id.* at 80–83. Such a presumption, however, has not been applied by this court to Texas products-liability cases involving the application of the learned intermediary doctrine. *See Ackermann*, 526 F.3d at 214 ("[T]he read-and-heed presumption does not apply to Texas cases involving learned intermediaries.").

Second, Dr. Nett's deposition testimony does not resemble that of the doctor in *McNeil*. There, the drug's warning was allegedly inadequate because it under-represented the frequency with which a side effect occurred when the drug was used for more than twelve weeks. *See McNeil*, 462 F.3d at 370. The prescribing doctor, Dr. Wilkinson, indicated both that "he still would have prescribed the drug had he known that the risk was 'significant'" and that "he would not have prescribed the drug had its label stated that use for longer than twelve weeks is contraindicated because the risks are significant and the benefits have not been proven." *Id*. at 372. Further, the doctor "testified that he was never informed of the significant risk" associated with the long-term use of the drug "and that such information certainly would have changed the 'risk/benefit analysis' and the conversation he would have had with [the patient] about the risks." *Id*. Those statements created a genuine issue of material fact as to whether Dr. Wilkinson would have changed his prescription had he been accurately informed of the risks associated with the particular drug—that is, whether the drug's warning was the producing cause of the harm. *Id*. at 372–73. But no such genuine issue of material fact exists here because Dr. Nett clearly indicated that he was aware of the risks of akathisia and suicide that Zyprexa engendered.[6]

[6] Ebel attempts to undermine the certainty of Dr. Nett's statements by implying that Dr. Nett was confused as to whether the risks of akathisia and suicide were attributable to "antidepressants" as opposed to "atypical antipsychotics" by pointing to Dr. Nett's statement that "I believe [the risk of akathisia and suicide has] been brought up, specially in the context of the adolescent data with *antidepressants* and new warnings." (Emphasis added.) However, in response to the very next question, Dr. Nett indicated that his awareness of these risks additionally applied to "atypicals," which include Zyprexa: "because of the heightened awareness by all companies when they are detailing antidepressants *and atypicals*, that the enhanced rate of suicide . . . needs to be of a concern in prescribing the product."

Further, Ebel presented no evidence to suggest that Dr. Nett would have changed either his decision to prescribe Zyprexa or his risk–benefit analysis had he received some alternative warning concerning Zyprexa. Indeed, the record indicates that Zyprexa was perceived to be the last remaining treatment option available to Philip after he had tried upwards of forty-five other medications to no avail. When Dr. Nett conferred with Dr. Gordon to ask "[w]hat else can we try," Dr. Gordon suggested prescribing either Zyprexa or Pamelor. Because Philip had found no relief with medicine similar to Pamelor, Dr. Nett prescribed Zyprexa. Zyprexa was, effectively, Philip's last resort, and Ebel has produced no evidence demonstrating that Dr. Nett would have prescribed anything other than Zyprexa at that time. For these reasons, Ebel has failed to show that a genuine issue of material fact exists as to whether Lilly's warning was the producing cause of Philip's death.

Alternatively, Ebel argues that the read-and-heed presumption should apply and that this presumption would satisfy her burden of showing causation. The read-and-heed presumption presumes that, were an adequate warning provided, the consumer would heed that warning; therefore, it places the burden on the manufacturer to disprove that the consumer would have heeded the warning. This detour around demonstrating causation has been made unavailable, however, by our ruling in *Ackermann* that "the read-and-heed presumption does not apply to Texas cases involving learned intermediaries." 526 F.3d at 214. Thus, Ebel's argument fails.

After considering the summary judgment record, we agree with the district court's conclusion that Ebel has failed to point to evidence establishing that

Zyprexa's warning was the producing cause of Philip's suicide. Summary judgment is therefore appropriate.

IV. CONCLUSION

For the reasons stated above, we AFFIRM the district court's judgment.