IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit

FILED
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Charles R. Fulbruge III
Clerk

No. 06-41774

ROZLYN ACKERMANN,
Individually and as Personal Representative of
Martin Lindsey Ackermann, Deceased

Plaintiff-Appellant

v.

WYETH PHARMACEUTICALS

Defendant-Appellee

Appeal from the United States District Court
for the Eastern District of Texas

Before JONES, Chief Judge, and WIENER and CLEMENT, Circuit Judges.

EDITH H. JONES, Chief Judge:

Appellant Rozlyn Ackermann ("Ackermann") challenges the district court's grant of summary judgment dismissing her claim that Wyeth Pharmaceuticals ("Wyeth") failed adequately to warn about the drug-induced risk of suicide from its drug Effexor, and this deficiency led to her husband's suicide. Because Ackermann has failed to demonstrate causation under the learned-intermediary doctrine, we affirm.

I. BACKGROUND

In November 2001, Martin Ackermann ("Martin"), a 53-year-old businessman, suffered from clinical depression brought on by severe business

and family problems. Martin initially sought treatment from his personal physicians and began taking the prescription antidepressant drug Celexa.

Acting on a friend's advice, Martin sought treatment from psychiatrist Dr. Thomas Sonn on January 4, 2002. Martin saw Dr. Sonn four times in the following eight days. During that time, Dr. Sonn changed Martin's medication and gave him a sample trial pack[1] of another antidepressant, Effexor XR.[2] Sonn instructed Martin to take one low-dose 37.5-milligram pill each day as he monitored him. Martin took one 37.5-milligram pill for three days, then took one therapeutic-dose 75-milligram pill each day from January 9 to January 12.

On January 12, Martin complained to Dr. Sonn of various side effects he attributed to Effexor, including akathisia[3] and anxiety. Martin announced he would no longer take the medication and terminated his relationship with Dr. Sonn. Nevertheless, Dr. Sonn changed Martin's medication from Effexor to Celexa because of the side effects. Martin continued to take Celexa for five days until January 17, 2002, when he committed suicide with a revolver. At the time of his death, Martin had detectable levels of Celexa, but not Effexor, in his bloodstream.

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[1] The sample trial pack, supplied by Wyeth, included seven 37.5-milligram pills, and seven 75 milligram pills. The range of recommended doses for treating depression with Effexor is from 75 to 225 milligrams.

[2] Effexor is a member of the class of drugs referred to as "selective serotonin and norepinephrine reuptake inhibitors" ("SNRI"). SNRIs are used to treat major depressive disorder, obsessive-compulsive disorder, panic disorder, premenstrual dysphoric disorder, and social anxiety disorder. The FDA generally groups Effexor with the selective serotonin reuptake inhibitor ("SSRI") class of antidepressants, which includes Celexa, Prozac, Paxil, and Zoloft. "XR" simply stands for "extended release."

[3] Akathisia, or inability to sit still, is a neurological phenomenon with characteristics of intense internal restlessness, agitation, and feelings of unease or discomfort.

Rozlyn Ackermann, his widow, sued Wyeth, the manufacturer of Effexor, in July 2004, pleading causes of action under strict liability, negligence (including failure to warn), and implied warranty theories under common law and the TEXAS DECEPTIVE TRADE PRACTICES-CONSUMER PROTECTION ACT ("DTPA").[4] She also pleaded breach of express warranty, fraud, and misrepresentation.

Wyeth initially moved for partial summary judgment, arguing that Ackermann's failure-to-warn claims conflicted with and were preempted by federal law. Dr. Sonn then testified at deposition that he believed the package insert for Effexor as it existed in January 2002 adequately warned him of the risks of suicide and that he would continue to prescribe the drug to depressed patients. In June 2006, Wyeth filed a separate motion for summary judgment on all claims. Regarding the warnings-based claims, Wyeth asserted a defense based on the learned-intermediary doctrine and, alternatively, on the statutory presumption of non-liability created by section 82.007(a) of the TEXAS CIVIL PRACTICE & REMEDIES CODE. Wyeth argued that summary judgment was appropriate for Ackermann's implied and express warranty claims under common law and the DTPA because no sale of the product had occurred, and

[4] Notably, she declined to name Forest Laboratories, Inc., the manufacturer of Celexa, as a party to this lawsuit or in a separate lawsuit. The Complaint indicates that "[p]ursuant to a presuit agreement between the parties, limitations was contractually tolled to explore settlement possibilities," and that the suit against Wyeth was timely filed within the extended limitations period. Only an incomplete explanation is given by Ackermann regarding the omission of Forest Laboratories as a party:

> [B]ecause this claim was initiated on the eve of limitations, and further because Wyeth chose not to name Forest Laboratories, Inc., the manufacturer of Celexa as a "responsible third party" within the meaning of § 33.004(a), TEX. CIV. PRAC. & REM. CODE, Forest Laboratories could not be joined and the jury would not be permitted to allocate fault or causation to Celexa.

because she had failed to identify an express warranty that had been breached. Finally, Wyeth argued that summary judgment was appropriate regarding her fraud and misrepresentation claims because she had failed to identify specific misrepresentations.

The magistrate judge first recommended that the district court grant Wyeth's motion for partial summary judgment based on preemption. Subsequently, the magistrate judge recommended that the district court grant Wyeth's June 2006 motion for summary judgment on all claims, adopting, inter alia, Wyeth's learned-intermediary doctrine theory for the failure-to-warn claims. Ackermann filed various objections. The district court overruled her objections, adopted the magistrate judge's recommendation to grant summary judgment for all claims — including the failure-to-warn claims based on the learned-intermediary doctrine — and dismissed the lawsuit. The magistrate judge, in turn, vacated as moot his report recommending partial summary judgment based on preemption.

Ackermann timely appealed. The only issue before this court is whether the learned-intermediary doctrine bars her strict-liability and failure-to-warn claims. She does not challenge the district court's conclusions regarding her express and implied warranty, fraud, and misrepresentation claims. Wyeth responds that the district court correctly applied the learned-intermediary doctrine, but it alternatively requests that this court affirm the district court on preemption grounds, should we hold that the learned-intermediary doctrine is inapplicable.

II. DISCUSSION

We review a grant of summary judgment de novo. Ford Motor Co. v. Tex.

Dep't of Transp., 264 F.3d 493, 498 (5th Cir. 2001). "Summary judgment is proper '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)). "The evidence and inferences from the summary judgment record are viewed in the light most favorable to the nonmovant." Minter v. Great Am. Ins. Co. of N.Y., 423 F.3d 460, 465 (5th Cir. 2005). But "[w]here 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." Whiting v. Univ. of S. Miss., 451 F.3d 339, 344 (5th Cir. 2006) (quoting Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986)).

The learned-intermediary doctrine states that, in some situations, a warning to an intermediary fulfills a supplier's duty to warn consumers. See Alm v. Aluminum Co. of Am., 717 S.W.2d 588, 591–92 (Tex. 1986). "In Texas, the most common use of this doctrine is in prescription drug cases." Wyeth-Ayerst Labs. Co. v. Medrano, 28 S.W.3d 87, 91 (Tex. App.-Texarkana 2000, no writ) (citations omitted). Under the doctrine, a patient-purchaser's doctor stands between the patient and the manufacturer, professionally evaluating the patient's needs, assessing the risks and benefits of available drugs, prescribing one, and supervising its use. Id. If the doctor is properly warned of the possibility of a side effect and is advised of the symptoms normally accompanying the side effect, it is anticipated that injury to the patient will be avoided. Accordingly, the doctrine excuses a drug manufacturer "from warning

each patient who receives the product when the manufacturer properly warns the prescribing physician of the product's dangers." Porterfield v. Ethicon, Inc., 183 F.3d 464, 467–68 (5th Cir. 1999).

The learned-intermediary doctrine is not an affirmative defense. Under Texas law, it delineates to whom a defendant — usually a prescription drug manufacturer — owes the duty to warn, but it is not used to show that the plaintiff has no valid case. Medrano, 28 S.W.3d at 94; see also Harrison v. Am. Home Prods. Corp. (In re Norplant Contraceptive Prods. Liab. Litig.), 165 F.3d 374, 378 (5th Cir. 1999) (making an Erie guess that the Texas Supreme Court would hold that the learned-intermediary doctrine is a common-law doctrine rather than a common-law defense). Thus, "when the warning to the intermediary is inadequate or misleading, the manufacturer remains liable for injuries sustained by the ultimate user." Alm, 717 S.W.2d at 592.

To recover for failure to warn under this doctrine, a plaintiff must show that (1) the warning was defective, and (2) the failure to warn was a producing cause of the injury. Porterfield, 183 F.3d at 468.[5] 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." McNeil, 462 F.3d at 372 (internal quotations omitted). If, however, "the physician was aware of the possible risks involved in the use of the

[5] The Complaint alleges both strict-liability and negligence claims. "Negligence requires a showing of proximate cause, while producing cause is the test in strict liability." Union Pump Co. v. Allbritton, 898 S.W.2d 773, 775 (Tex. 1995). But "[c]ommon to both proximate and producing cause is causation in fact, including the requirement that the defendant's conduct or product be a substantial factor in bringing about the plaintiff's injuries." Id. The learned-intermediary doctrine applies to both strict-liability and negligence claims. Burton v. Am. Home Prods. Corp. (In re Norplant Contraceptive Prods. Liab. Litig.), 955 F. Supp. 700, 709 (E.D. Tex. 1997), aff'd 165 F.3d 374 (5th Cir. 1999).

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. Porterfield, 183 F.3d at 468. "Even if the physician is not aware of a risk, 'the plaintiff must show that a proper warning would have changed the decision of the treating physician, i.e., that but for the inadequate warning, the treating physician would have not used or prescribed the product.'" Dyer v. Danek Med., Inc., 115 F. Supp. 2d 732, 741 (N.D. Tex. 2000) (quoting Willett v. Baxter Int'l, Inc., 929 F.2d 1094, 1099 (5th Cir. 1991)); see also Burton v. Am. Home Prods. Corp. (In re Norplant Contraceptive Prods. Liab. Litig.), 955 F. Supp. 700, 710–11 (E.D. Tex. 1997) (applying the Willett standard to Texas law); Medrano, 28 S.W.3d at 95.

"In prescription drug cases involving the learned intermediary doctrine, . . . when 'a warning specifically mentions the circumstances complained of, the warning is adequate as a matter of law.'" McNeil, 462 F.3d at 368 (quoting Rolen v. Burroughs Wellcome Co., 856 S.W.2d 607, 609 (Tex. App.-Waco 1993, writ denied)). Here, the January 2002 package insert warning mentions the risk for suicide twice.[6] The first instance states that suicide risk is "inherent in depression and may persist until significant remission occurs," and cautions that "[c]lose supervision of high-risk patients should accompany initial drug therapy." More importantly, the second instance identifies the frequencies of suicidal behavior observed in patients taking Effexor and lists "suicide attempt" as occurring "infrequent[ly]." "Infrequent" occurrences are defined as those "occurring in 1/100 to 1/1000 patients" in Wyeth's premarketing assessment.

[6] It should be noted that Wyeth did change the warning label for Effexor in 2003 and 2004, the latter requested by the FDA, but both changes occurred after Martin's death.

Suicide ideation or attempts were not listed as adverse events documented in postmarketing reports.[7]

Ackermann nonetheless contends that "there was nothing in the Effexor label to suggest that Effexor 'may produce' suicidality or any of its known precursors," and characterizes this as a "no warnings" case. She is incorrect. The package insert identified the possible risk for suicide twice, including listing suicide attempt as infrequent and quantifying the risk according to its pre-marketing research. Taken together, the insert's discussions of suicide establish that at least some risk of suicide exists when a patient takes Effexor. But "if the manufacturer decides to label a risk as 'comparatively rare' and also to provide a numerical quantification of that risk, that number must be within a certain degree of accuracy. . . . The issue is therefore whether there is a genuine issue of material fact as to whether the label was misleading." McNeil, 462 F.3d at 368–69.

An issue of fact may exist regarding whether there were significant differences between the disclosed risk and the actual risk of suicide known by Wyeth in January 2002. We need not determine, however, whether the warning for risk level of suicide was misleading, because, as Wyeth contends, this appeal is resolved on the second prong of the analysis, namely, whether any defect in the Effexor warning was a substantial cause of Martin's death. Porterfield, 183 F.3d at 468.

The learned-intermediary doctrine bars Ackermann's claims if she cannot show that the allegedly inadequate warning was a producing cause of her

[7] The 2002 version of the Physician's Desk Reference upon which Dr. Sonn relied reiterated the same general and specific warnings given in the Effexor package insert.

husband's death. There must be a genuine issue of material fact whether Dr. Sonn would have prescribed Effexor had the warning been "adequate." To carry her burden in defeating summary judgment, Ackermann first argues that Dr. Sonn's testimony about the certainty of his decision to prescribe Effexor even with a more complete warning was inconsistent. Alternatively, she contends that a Texas "read-and-heed" presumption overcomes the doctor's testimony by presuming that when an adequate warning is given by the manufacturer, it is heeded by the learned intermediary. We address each argument in turn.

A. Dr. Sonn's Testimony

In her opposition to Wyeth's summary judgment motion, Ackermann proposed a specific warning for suicide risk that she contended Wyeth should have provided in January 2002.[8] Because Dr. Sonn had not been examined by either party regarding that proposed warning in his December 2005 deposition, Wyeth obtained permission from Ackermann to ask Dr. Sonn ex parte to review the postulated warning.[9] Dr. Sonn then executed a sworn declaration stating

[8] The proposed warning was framed in a hypothetical question directed to Dr. Sonn to determine whether he would have acted differently had he been given a different warning regarding Effexor's risk for suicide, which is a key element in evaluating a learned-intermediary defense. The pleading proposed this question:

> "Dr. Sonn, if my client had issued a prominent warning to caution you that, in a 'small vulnerable sub-population' of patients, Effexor can trigger suicide, and had 'brought home' that warning to you via (i) bold faced or 'black boxed' wording in the package insert, (ii) a 'Dear Doctor' letter, and/or (iii) visits from your Wyeth sales representative, would you have (a) heeded that warning, or (b) ignored it?"

[9] Ackermann insinuates throughout her briefs that this ex parte contact taints the relevance and trustworthiness of the statement. But she does not challenge the district court's consideration of this evidence on summary judgment. In particular, Ackermann did not move under Rule 56(f) to depose Dr. Sonn again. Therefore, any issue related to the ex parte communications between Wyeth and Dr. Sonn is waived. See Askanase v. Fatjo, 130 F.3d 657,

that he had reviewed the proposed warning and concluded:

> If the [proposed] warning . . . had been communicated to me effectively and in a prominent manner before I prescribed Effexor XR to Martin Ackermann in January 2002, I would have considered or heeded it just as I consider or heed any warning, but it would not have changed my decision to prescribe Effexor XR to Martin Ackermann to treat his depression, beginning with low-dose pills. It also would have not changed my decision to monitor and observe Martin Ackermann closely for suicide-related risks as I did by, among other things, (a) seeing him in person four times in the eight days he was my patient, and (b) providing contact information and asking that I be informed immediately of any changes in his behavior.

Dr. Sonn continued:

> If there were a legal requirement that I communicate the [proposed] warning . . . directly to a patient, I would comply with that requirement. Otherwise, and as I did with Martin Ackermann, I would address the suicide-related risks reflected in that warning by close monitoring and observation, rather than through discussions with the patient expressly mentioning the risk of suicide or drug-triggered suicide.

Ackermann relies on this court's reasoning in McNeil to suggest that these statements are in conflict and create an issue of fact regarding causation. In McNeil, the prescribing doctor gave conflicting testimony regarding whether he would have prescribed Reglan had he known of significant risks associated with the drug. 462 F.3d at 372. He said he would have prescribed the drug and alerted the patient to "significant" risks had he been aware of them, but he also stated that he would not have prescribed the drug had the label stated that the

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668 (5th Cir. 1997) ("All issues not briefed are waived."); see also Edwards v. Johnson, 209 F.3d 772, 776 n.1 (5th Cir. 2000) (if petitioner does not assign error to certain findings of the district court in its initial brief on appeal, then "any challenge to these findings has been abandoned on appeal").

benefits decrease while the risks increase with prolonged use. Id. On this basis, the court held there was a genuine issue concerning whether the doctor would have prescribed Reglan if given a proper warning.

Dr. Sonn gave no such contradictory testimony; his testimony was unequivocal. In his deposition and in his later declaration, Dr. Sonn affirmed that he would have prescribed Effexor to Martin and adhered to the treatment regimen he used regardless whether he had received the proposed stronger warning.[10] In December 2005, he testified that he would not have warned Martin about the possibility of an increased risk of suicide primarily based on his belief that the suggestion would either plant seeds in the patient's mind that suicide was an option or would discourage the patient from pursuing pharmacological treatment. He testified that his medical training regarding clinical depression and his experience from treating other patients with Effexor made him aware of the need to monitor depressed patients for suicide ideation, but that he also read the warnings regarding the risk of suicide and believed they were adequate and did not provide him with new information. Other than some possible future legal requirement mandating that he tell patients about potential increased risk for suicide, Dr. Sonn stated that he would continue his normal practice of balancing the risks and benefits of the drug with the treatment needs of the patient when deciding what to disclose to patients.[11]

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[10] This was established so many times during the deposition that when counsel for Wyeth asked Dr. Sonn toward the end of the deposition whether, given everything he knew in December 2005, would he still have prescribed Effexor to Martin, Ackermann's counsel objected on the grounds that the question was "hopelessly, hopelessly repetitive."

[11] Dr. Sonn knew about ongoing discussions regarding the possible suicide-inducing effects of drugs such as Effexor, and that some patients on Effexor had exhibited suicide ideation when he prescribed Effexor to Martin. But based on his analysis of Martin, and the

Dr. Sonn was asked to review the warning label accompanying Effexor that was in effect at the time of his deposition in December 2005, which included a "black box" warning for potential increased suicide in children and adolescents.[12] When asked if the black box warning would change his practice with adults, he responded that he "wouldn't feel medically that [providing specific suicide warnings] was indicated." When asked a follow-up question in August 2006 about a proposed similar warning for adults, Dr. Sonn reiterated his prior testimony and confirmed that "it would not have changed [his] decision to prescribe Effexor XR to Martin Ackermann to treat his depression."

Ackermann argues that Dr. Sonn's testimony, like the doctor's testimony in McNeil, is conflicting. She points to his comment: "If there were a legal requirement that I communicate the warning set forth . . . . directly to a patient, I would comply with that requirement." She contends that a legal requirement

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normally accepted medical procedure for monitoring such patients and slowly building their exposure to drugs such as Effexor, he stated additional warnings would not have changed his decision to prescribe the drug. Dr. Sonn's testimony is unwavering that whatever the warning, short of a legally mandated warning, he would have adhered to the accepted medical practice of refraining from mentioning suicide ideation to a depressed patient, prescribing the drug, and monitoring the patient's condition and dosage amounts.

The record is also clear that Dr. Sonn only gave Martin extremely low dosage, non-therapeutic amounts of Effexor in order to first monitor his reaction to the drug. Dr. Sonn also acknowledged that Effexor had a much better professional reputation vis-a-vis other similar drugs, and he took the drug himself. Thus, Ackermann's argument that Dr. Sonn's testimony is unclear whether he would have prescribed the same low dosage Effexor if it carried a different warning is unsupported by the record.

[12] A "black box" warning is the strongest warning that the U.S. Food and Drug Administration requires. Black-box warnings reveal "[c]ertain contraindications or serious warnings, particularly those that may lead to death or serious injury" and "ordinarily must be based on clinical data." 21 C.F.R. § 201.57(c)(1). In January 2002, Wyeth was forbidden from providing a "black box" warning because "[t]o ensure the significance of boxed warnings in drug labeling, they are permitted in labeling only when specifically required by the FDA." Labeling and Prescription Drug Advertising; Content for Format for Labeling for Human Prescription Drugs, 44 FED. REG. 37,434 at 37,448 (June 26, 1979) (codified at 21 C.F.R. pts. 201–02).

to communicate warnings is implicit within the learned-intermediary doctrine. While the manufacturer can rely upon an intermediary to fulfill the manufacturer's duty to warn, "this reliance seems less reasonable where the learned intermediary fails to pass necessary information to the patient because the manufacturer has understated the degree of risk." McNeil, 462 F.3d at 373 n.6. Because she construes this as a "no warnings" case, she argues that Wyeth "completely sabotaged" the intermediary, who, in turn, failed to warn Martin of the risk of suicide. For this reason, she views Dr. Sonn's testimony that he would have given a required warning to mean, "if Wyeth had given me a warning, I would have warned."[13] This interpretation, however, is incompatible with Dr. Sonn's testimony that his treatment protocol would not have changed and he still would have prescribed Effexor regardless of the warning given by the manufacturer. Ackermann's interpretation fails because (1) the warnings for Effexor did include warnings of the risk of suicide, and (2) Dr. Sonn was aware of the risk for suicide, not just from reading the warning label for Effexor, which mentioned the risk for suicide twice, but also from his training and experience as a psychiatrist treating depressed patients. Under McNeil, no genuine issue of material fact exists regarding whether the inadequacy of the warning was a producing cause of her husband's death. Dr. Sonn would have prescribed Effexor even had the warning been stronger.

B. "Read-and-Heed" Presumption

Appellant also contends that, regardless of Dr. Sonn's testimony, Texas

[13] If there is any conflict in Dr. Sonn's testimony, it may be attributable to the fact that during his deposition, he appears to have been under the impression that he was required to dispense "black box" warnings to patients. But in 2002, Wyeth was forbidden by the FDA from providing a black box warning. Further, the FDA has to date required "black box" warnings for Effexor only when prescribed to pediatric patients.

law creates a presumption of supporting a causal link between Wyeth's inadequate warning and her husband's death.[14] Texas law creates no such presumption.

In general, "when a manufacturer fails to give adequate warnings or instructions, a rebuttable presumption arises that the product user would have read and heeded such warnings or instructions (the 'read and heed presumption')." Koenig v. Purdue Pharma Co., 435 F. Supp. 2d 551, 556 (N.D. Tex. 2006) (quoting Magro v. Ragsdale Bros., 721 S.W. 2d 832, 834 (Tex. 1987)); see also RESTATEMENT (Second) OF TORTS § 402A cmt. j (1977). The read-and-heed presumption's effect "is to shift the burden of producing evidence to the party against whom it operates." Gen. Motors Corp. v. Saenz ex rel. Saenz, 873 S.W.2d 353, 359 (Tex. 1993).[15]

But neither Texas nor federal courts applying Texas law have applied the read-and-heed presumption to pharmaceutical cases involving learned intermediaries. In fact, Texas has explicitly rejected the RESTATEMENT (SECOND)

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[14] Specifically, she argues that the learned intermediary is substituted as the end product user in prescription drug cases and, therefore, the read-and-heed presumption helps her fulfill her burden of establishing Wyeth's inadequate warning as the producing cause of her husband's death. The cases cited by Ackermann do not apply Texas law.

[15] Ackermann argues that a corollary to the "read-and-heed" presumption is that a defendant can rebut the presumption by offering evidence that a reasonably prudent physician would ignore the adequate warning and still prescribe the drug. In Thomas v. Hoffman-LaRoche, Inc., 949 F.2d 806, 812 (5th Cir. 1992), this court stated that under the learned-intermediary doctrine, a plaintiff may satisfy the burden of demonstrating warning causation by producing either objective evidence of how a reasonable physician would have responded to an adequate warning, or subjective evidence of how the treating physician would have responded. Thomas, however, applied Mississippi law. Even if Ackermann had argued here for the objective standard to show causation, she failed to produce any objective evidence that a reasonably prudent physician would not have prescribed Effexor had that doctor been adequately warned. And in any event, as we explain, Texas has not adopted the heeding presumption to which this corollary might allegedly apply.

OF TORTS § 402A, Comment j's "read-and-heed" presumption for policy reasons and because it has been superseded by RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2. See Uniroyal Goodrich Tire Co. v. Martinez, 977 S.W.2d 328, 336–37 (Tex. 1998). Additionally, the relevant cases show the plaintiff bore the burden of showing that the inadequacy of the warning was a producing cause of injury. See Porterfield, 183 F.3d at 468; Skotak v. Tenneco Resins, Inc., 953 F.2d 909, 912–13 (5th Cir. 1992); Koenig, 435 F. Supp. 2d at 556–57 (stating expressly that the read-and-heed presumption does not apply in cases involving learned intermediaries); Gerber v. Hoffmann-La Roche Inc., 392 F. Supp. 2d 907, 921–22 (S.D. Tex. 2005); Dyer, 115 F. Supp. 2d at 741; Medrano, 28 S.W.3d at 95; Stewart v. Janssen Pharmaceutica, Inc., 780 S.W.2d 910, 911 (Tex. App.-El Paso 1989, writ denied).[16]

Further, we doubt the Texas Supreme Court would apply such a presumption here, when it would not serve its intended purposes. The read-and-heed presumption has been justified because

> [i]t excuses plaintiff from the necessity of making self-serving assertions that he would have followed adequate instructions, simply to put the issue of causation in sufficient dispute to avoid summary judgment or directed verdict, and it assists plaintiffs in cases where the person injured has died and evidence of what he would have done is unavailable for that reason.

Saenz, 873 S.W.2d at 359. In the learned-intermediary context, however, it is

[16] But cf. Anderson v. Sandoz Pharm. Corp., 77 F.Supp. 2d 804, 809 (S.D. Tex. 1999) (stating that Texas law supplies a "read-and-heed" presumption). To support this conclusion, Sandoz cites Technical Chemical Co. v. Jacobs, 480 S.W.2d 602 (Tex. 1972). But Jacobs does not state explicitly whether Texas adopted the presumption, only stating in dicta that some have suggested it should. Id. at 606. Moreover, Jacobs was not a pharmaceuticals case involving learned intermediaries. For these reasons, Sandoz is not a reliable guide to Texas law.

Dr. Sonn, not Ackermann or her husband, who had to testify about his decision to prescribe Effexor. One federal court speculated that the Texas Supreme Court would agree with other courts, including this court, that have held "to 'read and heed,' in the context of a learned intermediary, means only that the physician would have incorporated the additional risk into his decisional calculus." Koenig, 435 F.Supp. 2d at 557.[17]

Further, even if the presumption applied, it would not change the result here. No genuine issue of material fact exists regarding whether the inadequacy of the warning was a producing cause of her husband's death because Dr. Sonn's testimony rebuts the read-and-heed presumption.[18] Dr. Sonn has remained firm in stating that even if Ackermann's proposed "black box" warning had been given to him, he "would have considered or heeded it just as [he] consider[s] or heed[s] any warning, but it would not have changed [his] decision to prescribe Effexor XR to Martin Ackermann to treat his depression." But as we note, the read-and-heed presumption does not apply to Texas cases involving learned intermediaries.

For these reasons, we conclude the district court properly granted

[17] Commenting on various cited federal cases, Koenig further stated: "In these cases, the plaintiffs bore the burden of production on causation. Though not stated specifically in the Texas cases . . . this is the likely analysis applied by Texas courts as well. *See* [Medrano], 28 S.W.3d at 95 ("In a failure to warn case that is governed by the learned intermediary doctrine . . . the plaintiff must still prove causation."). 435 F. Supp. 2d at 557 (emphasis in original; citation omitted).

[18] Appellant points to statements in Dr. Sonn's deposition testimony that he heeds other warnings even when he has no experience of patients exhibiting those side effects. For instance, Dr. Sonn heeds the warning that Ritalin may induce psychosis, even though Dr. Sonn has never had a patient demonstrate that symptom after taking Ritalin. But Ritalin would seem to be different from an antidepressant drug where patient suicide is always a risk, and where, according to Dr. Sonn, there is a specific, accepted practice of monitoring dosage and patient behavior while the drug is prescribed.

summary judgment to Wyeth on appellant's failure-to-warn and strict-liability claims because she failed to show that an inadequate warning was a producing cause of her husband's death. We pretermit discussion of Wyeth's Texas statutory and federal preemption arguments.

The judgment of the district court is AFFIRMED.