United States Court of Appeals
FOR THE EIGHTH CIRCUIT

Nos. 02-3933/03-1057

Ryan P. Ehlis; Angie Moreno, individually, and as surviving parents of Tyra Lynn Ehlis, deceased,	*	
Appellants/Cross Appellees,	*	
v.	*	Appeals from the United States District Court for the District of North Dakota.
Shire Richwood, Inc., now known as Shire US, Inc.,	*	
Appellee/Cross Appellant,	*	
Shire Pharmaceuticals Group, PLC,	*	
Defendant.	*	
Product Liability Advisory Council, Incorporated; Pharmaceutical Research and Manufacturers of America,	*	
Amici on Behalf of Appellee.	*	

Submitted: October 22, 2003
Filed: May 18, 2004

Before RILEY, BEAM, and SMITH, Circuit Judges.

RILEY, Circuit Judge.

Ryan Ehlis (Ehlis) and Angie Moreno (Moreno)[1] appeal the district court's[2] grant of summary judgment in favor of Shire US, Inc. (Shire).[3] Ehlis and Moreno sought damages from Shire for its failure to warn about the effects of Adderall, a drug Shire manufactures. Moreno argues the district court erred (1) in applying the learned intermediary doctrine to bar the plaintiffs' claims and ruling Shire adequately warned Ehlis's treating physician about psychosis resulting from ingestion of Adderall and (2) in ruling their claims are preempted by the Food, Drug and Cosmetic Act (FDCA). Shire cross-appeals, arguing the district court erred (1) in deciding the plaintiffs presented expert testimony sufficient to meet their burden of proof and (2) in finding the plaintiffs presented sufficient evidence to rebut the presumption against defects contained in North Dakota's Product Liability Act, N.D. Cent. Code section 28-01.3-09. Concluding the district court did not err in ruling the learned intermediary doctrine barred the plaintiffs' claims, we affirm.

I. BACKGROUND

Ehlis, a student at the University of North Dakota having difficulties with a class, went to see Dr. Thomas Peterson (Dr. Peterson), a psychiatrist. Ehlis told Dr. Peterson that, as a child, Ehlis had been diagnosed with Attention Deficit Hyperactivity Disorder (ADHD) and had taken Ritalin. Following a 45-minute office visit, Dr. Peterson prescribed for Ehlis a pharmaceutical called Adderall, which

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[1]The appellants state that, because Ehlis assigned his claims to Moreno to hold in trust for Tyra Lynn Ehlis's siblings, only Moreno is pursuing this appeal.

[2]The Honorable Karen K. Klein, United States Magistrate Judge for the District of North Dakota, to whom this case was referred for final disposition by consent of the parties pursuant to 28 U.S.C. § 636(c) (2000).

[3]According to the appellee, Shire Richwood Inc., the defendant in the district court, is now known as Shire US, Inc.

contains amphetamine salts and is manufactured for treating ADHD in children and narcolepsy in adults. Adderall is approved by the Food and Drug Administration (FDA).

Ehlis began taking Adderall shortly after receiving the prescription, and took the prescribed dosage for two days. Ehlis then reduced the dosage due to the "strong" effect it had on him. Ehlis took no Adderall over the next weekend and felt normal, but resumed taking the prescribed amount of the drug the following week. On Friday morning of the second week, Ehlis ingested the remaining pills of the thirty-day prescription. Moreno, who is Ehlis's girlfriend and the mother of his children, testified at a summary judgment hearing that Ehlis did not act like himself from the first day he took Adderall. Moreno testified Ehlis awoke frightened, and she would give him Adderall to calm him. Ehlis described delusions, hallucinations, and "out-of-body" experiences, including talking with God and with his dead grandfather, after he ingested the remainder of the Adderall. Claiming to be acting on God's orders, Ehlis shot his five-week-old daughter, then turned the gun on himself. Ehlis survived his shooting, but his daughter did not. Neither Ehlis nor Moreno contacted Dr. Peterson to discuss the alleged side effects Ehlis experienced when taking Adderall. Ehlis was charged with murder, but the charges were dismissed after various doctors testified about Ehlis's mental condition, reporting Ehlis suffered from an "Amphetamine-Induced Psychotic Disorder" and did not have the necessary criminal responsibility.

Ehlis and Moreno filed this lawsuit, contending Shire knew Adderall can induce psychosis and failed adequately to warn of the associated risks. Ehlis and Moreno also claimed Shire and Shire Pharmaceuticals Group illegally marketed and advertised the drug. The district court granted Shire's motion for summary judgment on the claims, ruling the learned intermediary doctrine barred the claims and the claims were preempted by the FDCA. On appeal, Moreno argues the district court

erred. Shire cross-appeals a number of issues, which we do not reach because the learned intermediary doctrine bars the plaintiffs' claims against Shire.

II. DISCUSSION

A. Standard of Review

"We review the district court's grant of summary judgment de novo." Gray v. AT&T Corp., 357 F.3d 763, 765 (8th Cir. 2004). "We will affirm a district court's grant of summary judgment 'if the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits . . .' demonstrate that no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law." Id. (quoting Fed. R. Civ. P. 56(c)). "As we exercise our power under diversity jurisdiction, we must interpret the forum state's law." Id. (citation omitted). North Dakota law applies to this diversity case, and we review de novo the district court's interpretation of North Dakota law. Triton Corp. v. Hardrives, Inc., 85 F.3d 343, 345 (8th Cir. 1996). We attempt to predict how the highest court in North Dakota would resolve the issues before us. Nordyne, Inc. v. Int'l Controls & Measurements Corp., 262 F.3d 843, 846 (8th Cir. 2001).

B. Learned Intermediary Doctrine

The learned intermediary doctrine provides that a pharmaceutical manufacturer has a duty to warn a physician of the risks involved with a pharmaceutical, and the physician then acts as a "learned intermediary" between the manufacturer and the physician's patient. Kirsch v. Picker Int'l, Inc., 753 F.2d 670, 671 (8th Cir. 1985). "Thus, a warning to the [physician] is deemed a warning to the patient; the manufacturer need not communicate directly with all ultimate users of prescription drugs." Id.

> This [learned intermediary] doctrine states that adequate warnings to prescribing physicians obviate the need for manufacturers of prescription products to warn ultimate consumers directly. The doctrine

> is based on the principle that prescribing physicians act as "learned intermediaries" between a manufacturer and consumer and, therefore, stand in the best position to evaluate a patient's needs and assess risks and benefits of a particular course of treatment. The learned intermediary doctrine has been adopted in most jurisdictions . . . .

Desmaris v. Dow Corning Corp., 712 F. Supp. 13, 17 (D. Conn. 1989) (citing Basko v. Sterling Drug, Inc., 416 F.2d 417, 426 (2d Cir. 1969)). The Ohio Supreme Court has explained that, as a learned intermediary, "[t]he physician has the duty to know the patient's condition as well as the qualities and characteristics of the drugs or products to be prescribed for the patient's use." Tracy v. Merrell Dow Pharm, Inc., 569 N.E.2d 875, 878 (Ohio 1991). Thus, the physician stands in the best position "to balance the needs of patients against the risks and benefits of a particular drug or therapy, and then to supervise its use." Id.

Under the learned intermediary doctrine, the manufacturer's failure to provide the physician with adequate warnings of the risks associated with a particular prescription product "is not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warning should have communicated." Christopher v. Cutter Labs., 53 F.3d 1184, 1192 (11th Cir. 1995). "Thus, the causal link between a patient's injury and the alleged failure to warn is broken when the prescribing physician had 'substantially the same' knowledge as an adequate warning from the manufacturer should have communicated to him." Id. We have previously recognized the rationale supporting this doctrine in the context of pharmaceuticals:

> There are several arguments supporting the application of this [learned intermediary rule] exception to prescription drug products. First, medical ethics and practice dictate that the doctor must be an intervening and independent party between patient and drug manufacturer. Second, the information regarding risks is often too technical for a patient to

> make a reasonable choice. Third, it is virtually impossible in many cases for a manufacturer to directly warn each patient.

Hill v. Searle Labs., 884 F.2d 1064, 1070 (8th Cir. 1989).

Moreno admits "it is likely that North Dakota will adopt some version of the 'learned intermediary' doctrine." Moreno contends that, regardless of whether North Dakota would adopt the learned intermediary doctrine, Dr. Peterson was not adequately warned of the dangers of prescribing Adderall under either a subjective or objective standard. Shire argues North Dakota would adopt the doctrine and apply that doctrine to bar Moreno's claims, because Dr. Peterson knew the risks associated with Adderall when he prescribed Adderall for Ehlis.

We believe the district court correctly determined North Dakota would adopt the learned intermediary doctrine for two reasons. First, the district court observed that North Dakota had adopted section 402A of the Restatement (Second) of Torts, from which the learned intermediary doctrine evolves. The district court reasoned that, because North Dakota has adopted other comments from section 402A "North Dakota would recognize the learned intermediary doctrine as the rule of law in cases where the adequacy of the warning as to a prescription drug is at issue." In Hill, we recognized the existence of the learned intermediary doctrine in Arkansas after finding "the Arkansas Supreme Court has often referred to the comments of section 402A, implicitly adopting them." Hill, 884 F.2d at 1067. Similarly, the North Dakota Supreme Court has discussed and adopted comments to section 402A on several occasions. See, e.g., Clarys v. Ford Motor Co., 592 N.W.2d 573, 574 n.1 (N.D. 1999) ("This Court adopted the rule of strict liability in tort under Section 402A, Restatement (Second) of Torts"); Bachmeier v. Wallwork Truck Ctrs., 507 N.W.2d 527, 534 n.3 (N.D. 1993) (citing section 402A for elements of prima facie products liability case); Butz v. Werner, 438 N.W.2d 509, 517 (N.D. 1989) (adopting Restatement (Second) of Torts § 402A, Comment j (1965), and noting "[o]ur strict

products liability caselaw has relied heavily upon Section 402A"); Morrison v. Grand Forks Hous. Auth., 436 N.W.2d 221, 223-24 & n.3-n.6 (N.D. 1989) (citing various subsections of section 402A); Johnson v. Am. Motors Corp., 225 N.W.2d 57, 66 (N.D. 1974) (recognizing cause of action for strict liability in tort as encompassed in section 402A).

Second, the district court noted an overwhelming majority of jurisdictions have adopted the learned intermediary doctrine. One district court, collecting cases addressing the doctrine, observed "the doctrine either applies or is recognized . . . in 48 states, the District of Columbia, and Puerto Rico." In re Norplant Contraceptive Prods. Liab. Litig., 215 F. Supp. 2d 795, 806 (E.D. Tex. 2002). Because the precedent is truly overwhelming and the policy enunciated by the learned intermediary doctrine is sound, we conclude the district court correctly ruled the North Dakota Supreme Court would adopt the learned intermediary doctrine.

C. Learned Intermediary Doctrine Bars Moreno's Claims

We next ask whether the learned intermediary doctrine bars Moreno's claims. Moreno argues a genuine issue of material fact exists as to Dr. Peterson's knowledge about Adderall's side effects. Moreno contends Dr. Peterson was not adequately warned of the dangers of prescribing Adderall to Ehlis under a subjective standard. Moreno also contends the warnings for Adderall were insufficient under an objective standard.

Viewing the evidence under a subjective standard leads to the inescapable conclusion Dr. Peterson knew the risks of prescribing Adderall for Ehlis. Dr. Peterson clearly stated the warnings were adequate, and he knew the risks of prescribing Adderall for Ehlis. Dr. Peterson explained that, before prescribing a stimulant to a patient, he would analyze a patient's symptoms and other characteristics, as well as evaluate risks and side effects of a particular stimulant. Dr. Peterson kept current with medical knowledge and information about medications and

treatments, and appears conscientious about remaining current with the state of medicine in psychiatry. Dr. Peterson stated he would review the Physicians Desk Reference (PDR) before prescribing stimulant medications, including Adderall. With new drugs, Dr. Peterson would read the PDR, talk to pharmacy representatives, try to read a "double-blind study" about a medication, and roughly half the time talk to colleagues about their experiences with the medication.

Dr. Peterson was aware that abuse of stimulants can result in psychotic or manic experiences, acknowledging he recognized stimulants can cause psychosis as a side effect. Referring to the Diagnostic and Statistical Manual of Mental Disorders (4th ed. 1994), Dr. Peterson stated he (1) knew substance-induced psychosis was "within the DSM-IV," meaning diagnostic criteria exist for this condition, regardless of whether the psychosis is caused by a stimulant or other medication; (2) was aware some people can become psychotic without overdosing on a certain medication, including Adderall; (3) knew the risk of psychosis was listed and identified in the package insert as a side effect for Adderall when he prescribed Adderall for Ehlis; (4) believed the statement in the insert was accurate; (5) continues to prescribe stimulant medication for adults since the incident involving Ehlis; and (6) continues to prescribe Adderall, because Adderall is a good medication.

Moreno argues the court should put less weight on the subjective testimony of the prescribing physician and should apply an objective standard to determine what a reasonable prescribing physician would have done under the circumstances.[4] We need not directly decide whether an objective standard should supplant a subjective standard, because the record here would not support a violation of an objective standard in any event. Moreno provided no evidence from physicians or other experts

[4]This argument was soundly rejected in Woulfe v. Eli Lilly & Co., 965 F. Supp. 1478, 1484 (E.D. Okla. 1997), where the court found entirely proper the consideration of the treating physician's affidavit or testimony in evaluating the presumption that a different warning would have been heeded.

indicating the warnings on the Adderall label were inadequate. In the "Adverse Reactions" section of Adderall's warning label, the label warned of "[p]sychotic episodes at recommended doses." The "Warnings" section indicated Adderall may exacerbate "behavior disturbance and thought disorder" in psychotic children. The "Drug Abuse" section warned that the "most severe manifestation of chronic intoxication is psychosis," which is often indistinguishable from schizophrenia. The warning that Adderall can cause psychosis at recommended doses clearly applies equally to adults and children.

Dr. Donald Marks, Moreno's expert witness, testified during his deposition that the FDA standard "is also the standard for the pharmaceutical industry." When asked about the FDA's refusal to permit pharmaceutical manufacturers to implement a "black box"[5] warning, Dr. Marks stated the "FDA has, of course, final authority over what happens on a package insert." Finally, Dr. Marks asserted that "[i]f a standard textbook of pharmacology says that this drug class is capable of causing these neurologic symptoms, then that's common knowledge to everybody." Dr. Marks's testimony confirms, even if an objective standard were appropriate, the warnings in this case were adequate.

We conclude the district court did not err in ruling Dr. Peterson knew of and appreciated the risks associated with prescribing Adderall. Shire was responsible for informing Dr. Peterson of these risks. Shire did exactly that. As the district court observed, "Dr. Peterson understood the risks associated with prescribing Adderall and voluntarily proceeded with an educated course of conduct." Because Shire adequately warned Dr. Peterson of the risks associated with Adderall, and because Ehlis is unable to establish Adderall's allegedly insufficient warnings proximately

[5]"Special problems, particularly those that may lead to death or serious injury, may be required by the [FDA] to be placed in a prominently displayed box." 21 C.F.R. § 201.57(e) (2003). This prominently displayed box is commonly referred to as a "black box."

caused his symptoms, the learned intermediary doctrine bars legal responsibility for the effect Adderall had on Ehlis. See Christopher, 53 F.3d at 1192.

D. Other Claims

Because we conclude the learned intermediary doctrine bars all recovery, we do not address Moreno's preemption argument or Shire's cross-appeal arguments. See Jean v. Nelson, 472 U.S. 846, 854 (1985) (a fundamental rule of judicial restraint is courts must consider nonconstitutional grounds for decisions before reaching constitutional questions); Doe v. Hartz, 134 F.3d 1339, 1341 (8th Cir. 1998) (citing Jean). Shire's motion to dismiss the appeal is otherwise denied. See 8th Cir. R. 47B.

III. CONCLUSION

For the reasons stated herein, we affirm the district court's grant of summary judgment to Shire.
