United States District Court for the Southern District of Texas

Elizabeth ANDERSON and Eric Anderson, Individually, and on Behalf of Michael Anderson, A Minor, Plaintiffs,
v.
SANDOZ PHARMACEUTICALS CORP., Defendant

No. Civ.A. G-97-646

Decided Dec. 17, 1999.

Counsel:

Ted C. Litton, Royston Rayzor Vickery Williams, Houston, TX, for Ted Litton, mediator.

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Earl B Austin, Baker & Botts, Dallas, TX, Mark L. Walters, Baker and Botts, Houston, TX, Joe G. Hollingsworth, Spriggs & Hollingsworth, Washington, DC, Katharine R. Latimer, Spriggs & Hollingsworth, Washington, DC, Thomas F. Urban, II, Spriggs & Hollingsworth, Washington, DC, Bruce Berger, Spriggs & Hollingsworth, Washington, DC, for Sandoz Pharmaceutical Corporation, defendant.

ORDER DENYING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

KENT, District Judge.

Plaintiffs bring this products liability suit against Defendant Sandoz Pharmaceutical Corp. ("Sandoz") for injuries resulting from the administration of the drug Parlodel. Specifically, Plaintiffs claim that the warnings given by Defendant Sandoz regarding the use of Parlodel were inadequate and improper. Now before the Court is Defendant's Motion for Summary Judgment, filed October 15, 1999. For the reasons stated below, Defendant's Motion for Summary Judgment is DENIED.

I. FACTUAL SUMMARY

In May 1996, Plaintiff Elizabeth Anderson met with her primary care physician, Dr. Byron Holt regarding her attempts at becoming pregnant. Following an examination, Dr. Holt diagnosed Ms. Anderson with a condition known as reactive hyperprolactimia, [FN1] which he believed was preventing her from being able to conceive. To treat her condition, Dr. Holt prescribed, among other medications, the drug bromocriptine mesylate, which Defendant markets under the brand name Parlodel. While Parlodel is typically used to treat dysfunctions associated with hyperprolactimia, Defendant does not recommend that physicians prescribe this drug to treat nonpregnant women with reactive hyperprolactimia. Consequently, Defendant does not warn doctors that Parlodel may cause vasoconstriction in patients suffering from reactive hyperprolactimia--even though Defendant may have known that physicians such as Dr. Holt had been prescribing Parlodel for the "off-label" use of treating reactive hyperprolactimia.

Ms. Anderson began taking the medication on May 21, 1996, as directed by Dr. Holt. Unfortunately, five months later, on October 10, 1996, Ms. Anderson suffered sudden cardiac arrest and was transported to Hermann Hospital in Houston, Texas. Tests taken at the hospital revealed that Ms. Anderson had suffered acute myocardial infarction from a coronary artery spasm, which, Plaintiffs speculate, was caused by Ms. Anderson's use of Parlodel. As a result of the cardiovascular injuries sustained, Ms. Anderson now suffers permanent brain injury, including irreversible neurological deficits.

On November 13, 1997, Plaintiffs filed suit against Defendant alleging a variety of Texas state-based claims stemming from negligence and breach of warranty. Specifically, Plaintiffs claim that Defendant informed neither Dr. Holt nor Ms. Anderson that Parlodel had been associated with myocardial infarction in patients suffering from reactive hyperprolactimia, and that using the drug to treat such conditions could have a vasoconstrictive effect. As a result, Plaintiffs assert that Defendant failed to adequately or properly warn Dr. Holt who, without adequate knowledge of the dangers involved in prescribing Parlodel, administered it, thereby causing Plaintiff's injuries. Because diversity

A. Summary Judgment Standard

Summary judgment is appropriate if no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law. See Fed.R.Civ.P. 56(c); Celotex Corp. v. Catrett, 477 U.S. 317, 323, 106 S.Ct. 2548, 2552-53, 91 L.Ed.2d 265 (1986). When a motion for summary judgment is made, the nonmoving party must set forth specific facts showing that there is a genuine issue for trial. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250, 106 S.Ct. 2505, 2510, 91 L.Ed.2d 202 (1986). Issues of material fact are "genuine" only if they require resolution by a trier of fact. See id. at 248, 106 S.Ct. at 2510. The mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment. Only disputes over facts that might affect the outcome of the lawsuit under governing law will preclude the entry of summary judgment. See id. at 247-48, 106 S.Ct. at 2510. If the evidence is such that a reasonable fact-finder could find in favor of the nonmoving party, summary judgment should not be granted. See id.; see also Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 106 S.Ct. 1348, 1356, 89 L.Ed.2d 538 (1986); Dixon v. State Farm Fire & Cas. Co., 799 F.Supp. 691, 693 (S.D.Tex.1992) (noting that summary judgment is inappropriate if the evidence could lead to different factual findings and conclusions). Determining credibility, weighing evidence, and drawing reasonable inferences are left to the trier of fact. See Anderson, 477 U.S. at 255, 106 S.Ct. at 2513.

Procedurally, the party moving for summary judgment bears the initial burden of "informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrates the absence of a genuine issue of material fact." Celotex Corp., 477 U.S. at 323, 106 S.Ct. at 2553; see also Fed.R.Civ.P. 56(c). The burden then shifts to the nonmoving party to establish the existence of a genuine issue for trial. See Matsushita, 475 U.S. at 585-87, 106 S.Ct. at 1355-56; Wise v. E.I. DuPont de Nemours & Co., 58 F.3d 193, 195 (5th Cir. 1995). The Court must accept the evidence of the nonmoving party and draw all justifiable inferences in favor of that party. See Matsushita, 475 U.S. at 585-87, 106 S.Ct. at 1355-56. However, to meet its burden, the nonmovant "must do more than

B. Does the Learned Intermediary Doctrine Apply?

The Court must first consider whether the doctrine of the learned intermediary applies in this case. The doctrine provides that the duty of prescription drug manufacturers to warn of possible dangers associated with a particular drug extends only to physicians and not to patients. See Hurley v. Lederle Labs., 863 F.2d 1173, 1178 (5th Cir. 1988) (noting that when a patient receives a drug through a physician who, after weighing the risks and benefits, decides to administer it, "the fact that the manufacturer had adequately warned the prescribing physician will protect it from liability to the patient for failure to warn"); Swayze v. McNeil Labs. Inc., 807 F.2d 464, 472 (5th Cir. 1987) ("Drug manufacturers must adequately warn physicians of the potential side-effects of their prescription drugs; thereafter, the physician, with his special knowledge of the patient's needs, assumes the burden of presiding over the patient's best interests."); Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir. 1974) ("[W]here prescription drugs are concerned, the manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use." (emphasis omitted)); Rolen v. Burroughs Wellcome Co., 856 S.W.2d 607, 609 (Tex.App.--Waco 1993, writ denied) (commenting that Texas courts have long recognized the validity of the learned intermediary doctrine). Here, there is no doubt that a physician-patient relationship existed between Dr. Holt and Ms. Anderson and that Ms. Anderson relied upon Dr. Holt to prescribe the proper medication to treat her condition. Consequently, the Court finds that Dr. Holt, as Ms. Anderson's treating physician, assumed the role of learned intermediary, thereby extinguishing Defendant's duty to warn Ms. Anderson directly.

Finding that the learned intermediary doctrine attaches does not, however, end the inquiry. The Court must now evaluate whether Defendant's warnings adequately apprised Dr. Holt of the risks attending Parlodel. The ultimate question then is whether Dr. Holt made an informed choice in deciding to prescribe Parlodel to Ms. Anderson.

1. Did the Parlodel Labeling Adequately Warn Dr. Holt of the Drug's Risk?

Plaintiffs contend that Defendant failed to provide an adequate warning concerning the dangers of Parlodel, and that this failure was a producing cause of the injury to Ms. Anderson. In Technical Chemical Co. v. Jacobs, 480 S.W.2d 602 (Tex.1972), the Texas Supreme Court stated that in a failure to warn case, the plaintiff has the burden of proving (1) a defective warning, and (2) that the failure to warn was a producing cause of the plaintiff's condition or injury. Id. at 605. This principle has been specifically applied to the duties of a manufacturer of pharmaceutical products; thus, as has been noted previously, drug makers, such as Defendant, must warn the physician of the dangers of its product, and once the physician is warned, the choice of which drugs to use and the duty to explain the risks become that of the physician. See Crocker v. Winthrop Labs., 514 S.W.2d 429 (Tex.1974); Gravis v. Parke-Davis & Co., 502 S.W.2d 863 (Tex.Civ.App.-- Corpus Christi 1973, writ ref'd n.r.e.). Applying these principles, Plaintiffs must adduce evidence that the warning provided by Defendant was inadequate and that the failure of Defendant to give an adequate warning was a producing cause of Plaintiff's injury.

Defendant first contends that there has been no evidence that the warnings given by Defendant with regard to its product were inadequate. In this case, the warning included in the Parlodel drug package details several potential dangers associated with the medication. [FN2] The package insert as well as the 1996 PDR entry for Parlodel contain the following statement: "Although a causal relationship between Parlodel (bromocriptine mesylate) administration and hypertension, seizures, strokes, and myocardial infarction in postpartum women has not been established, use of the drug for prevention of physiological lactation, or in patients with uncontrolled hypertension is not recommended." See Defs.' Mot. for Summ.J.Ex. F at 1; Id. at 6. Because these warnings specifically mention the circumstances complained of by Ms. Anderson (i.e., myocardial infarction), Defendant argues that the warnings provided to Dr. Hall are adequate as a matter of law. The Court disagrees.

Although the warnings included the "reaction" suffered by Ms. Anderson, myocardial infarction was only referenced in the context of physiological lactation or uncontrolled hypertension. The warnings did not connect myocardial infarction to Ms. Anderson's particular diagnosis--reactive hyperprolactimia. Therefore, despite the fact that the package insert and the PDR allude to a possible connection between Parlodel and myocardial infarction, neither specifically warns that women who take Parlodel to treat reactive hyperprolactimia face the risk of myocardial infarction. See also Dep. of Dr. Byron Hall at 33. [FN3] Based on this evidence, the Court holds that a factual issue exists as to whether either the package insert or the 1996 PDR entry adequately warned of the injuries Ms. Anderson suffered as a result of her use of Parlodel. [FN4] See Stewart v. Janssen Pharm., Inc., 780 S.W.2d 910, 912 (Tex.App.--El Paso 1989, writ denied) (speculating that such testimony "would be sufficient to raise a fact issue as to the adequacy of the warning and, if found inadequate, whether this was a proximate cause of any injury" to the plaintiff). But to prevail against the drug manufacturer in this suit, Plaintiff must show that, in addition to the warnings being inadequate, Dr. Holt was unaware of the risks associated with Parlodel.

2. Does the Evidence, as a Matter of Law, Show That Dr. Holt Was Aware of the Risks Associated with the Use of Parlodel?

Assuming arguendo that Defendant failed to give Dr. Holt adequate warnings, the Court must determine whether such a deficiency altered Dr. Holt's decision, as a learned intermediary, to use the drug Parlodel. If Dr. Holt "was aware of the possible risks involved in the use of the drug, yet chose to use it regardless of the adequacy of the warning, then, as a matter of law, the adequacy of the warning was not a producing cause of" Plaintiff's injury. Stewart, 780 S.W.2d at 912; accord Cooper v. Bowser, 610 S.W.2d 825, 832 (Tex.App.--Tyler 1980, no writ) (noting that under the learned intermediary doctrine, the plaintiff must show not only that the drug manufacturer's warnings were inadequate, but also that the treating physician would have acted differently in a manner that could have prevented the plaintiff's injury); see also Jacobs, 480 S.W.2d at 605 (noting that in a failure-to-warn case, the plaintiff must show that the warning was defective and that this failure to warn was the producing cause of the plaintiff's injuries). But according to the learned intermediary doctrine, Defendant's liability may only be relieved "once the doctor has been informed" of the risks. Gravis, 502 S.W.2d at 870. Here, the Court posits that a factual issue could exist in the minds of reasonable jurors regarding whether Dr. Holt was fully aware of all the risks involved in prescribing Parlodel to reactive hyperprolactimia patients.

Defendant argues that Dr. Holt's own knowledge acquired independently of warnings forwarded by Defendant was such that Defendant's alleged failure to warn him was not a sole or contributing proximate cause of Ms. Anderson's injuries. Plaintiffs, however, claim that Dr. Holt was not adequately informed—by

any source--about the medical problems connected with Parlodel. Therefore, according to Plaintiffs, there does exist a factual dispute concerning the sufficiency of Dr. Holt's independent knowledge of the risks Parlodel presented to Ms. Anderson. And, Plaintiffs argue,

had Defendant made Dr. Holt aware of all of the existing evidence linking Parlodel to patients diagnosed with reactive hyperprolactimia, Dr. Holt may have heeded such a warning, just as he had when Defendant removed Parlodel from the market for the indication of postpartum lactation. See Dep. of Dr. Byron Holt at 25. In response, Defendant's contend that a proper warning would not have avoided Plaintiff's injuries, because Dr. Holt admits that he would have prescribed the drug regardless of any such warning. In other words, according to Defendant, the faulty labeling, if that in fact was the case, was not a cause of the injury. The Court, however, does not find Defendant's position so cut-and- dry.

Despite the wealth of evidence provided by Defendants on this issue, the fact remains that Dr. Holt may not have been fully apprised of all the attendant risks associated with reactive hyperprolactimia patients who take Parlodel. And while Defendants urge the Court to rely exclusively upon that portion of Dr. Holt's deposition testimony in which he states that at the time he prescribed Parlodel to Ms. Anderson he had ample knowledge from alternative sources about the risks associated with the drug, the Court nevertheless

notes other portions of his deposition testimony in which Dr. Holt admits having no knowledge of a variety of studies concerning Parlodel and stroke and myocardial infarction. See Dep. of Dr. Byron Holt at 24, 30-31; Pls.' Resp. to Def.'s Mot. for SummJ.Ex. 3-6. [FN5] And, because some of these studies may have been sponsored by Defendant, the Court finds it possible to conclude that Dr. Holt was not in a position to fully appreciate Parlodel's risks--even through independent knowledge--at the time he prescribed the drug to Ms. Anderson. Moreover, had such information been provided to Dr. Holt, Texas law supplies a presumption that an adequate warning (from whatever source) would have been read and "heeded" by Dr. Holt. See, e.g., Jacobs, 480 S.W.2d at 604. [FN6]

Thus, a reasonable-minded jury may choose to disbelieve or disregard Dr. Holt's testimony that he would not have changed his mind about prescribing Parlodel to Ms. Anderson regardless of any warning from Defendant, and ultimately find Defendant liable for failure to provide an adequate warning. [FN7] Thus, Dr. Holt's assurances must be evaluated in light of the totality of the evidence--some of which points to Dr. Holt's lack of overall knowledge of Parlodel's risks.

As a result of the conflicting evidence, the Court cannot conclusively resolve the issue of producing cause as a matter of law. Accordingly, Defendant's Motion for Summary Judgment is DENIED.

III. CONCLUSION

By not sharing all available research with Dr. Holt regarding the risks connected to Parlodel (this, despite the fact that Defendant may have known about Dr. Holt's use of Parlodel for off-label use), Defendant may have, in effect, prevented Dr. Holt from making an informed choice, thereby piercing Defendant's shield from liability under the learned intermediary doctrine. Consequently, Defendant's Motion for Summary Judgment is DENIED; however, as pointed out throughout this opinion (and especially in footnote 6), the Court has taken a rather expansive view of the facts presented, so as to acknowledge the catastrophic injuries suffered by Ms. Anderson and her family. That said, the fact remains that Plaintiffs face an uphill battle at trial. Consequently, the Court strongly admonishes Plaintiffs to earnestly consider the possibilities of entering into a reasonable settlement of this case.

The parties are ORDERED to file no further pleadings on these issues in this Court, including motions to reconsider and the like, unless justified by a compelling showing of new evidence not available at the time of the instant submissions. Instead, the parties are instructed to seek any further relief to which they feel themselves entitled in the United States Court of Appeals for the Fifth Circuit, as may be appropriate in due course.

IT IS SO ORDERED.

Opinion Footnotes:

FN1.According to Dr. Holt, reactive hyperprolactimia is a temporary condition in which the body produces an elevated amount of prolactin brought about by external forces such as ovulation or alcohol consumption. See Dep. of Dr. Byron Holt at 43-44.

FN2.Parlodel is a prescription drug and, as such, must have a package insert, which is approved by the Food and Drug Administration ("FDA"), describing the drug and its use. The description of each drug is prepared by the drug manufacturer, although it must be approved by the FDA. The package inserts are also complied and published in the Physicians' Desk Reference ("PDR"), which is kept reasonably current through the distribution

of periodic supplements that reflect any change in the package insert.

FN3.Dr. Hall's deposition testimony reveals that hyperprolactimia and reactive hyperprolactimia are two entirely different conditions. See Dep. of Dr. Byron Hall at 44-45.

FN4.Defendant explains that the reason the Parlodel package insert does not include information related to reactive hyperprolactimia isbecause Defendant does not recommend that physicians use Parlodel to treat this condition. The Court, however, notes that Plaintiffs have forwarded evidence suggesting that Defendant had commissioned a research study regarding the dangers associated with the use of Parlodel, which apparently was not shared with Dr. Holt. See Pls.' Resp. to Def.'s Mot. for Summ.J.Ex. 4; Dep. of Dr. Byron Hall at 24. This factual assertion may become pertinent because Plaintiffs also argue that certain representatives from Sandoz knew about Dr. Holt's off-label use of Parlodel to treat women with reactive hyperprolactimia. See Dep. of Byron Hall at 33-34. Consequently, Defendant's knowledge of the off-label use, if proven, may raise a relevant fact question concerning whether Defendant had a duty to share its research with Dr. Holt, the off-label use notwithstanding.

FN5.Even in his deposition, Dr. Holt could not characterize the extent or level of risk Parlodel presents to those diagnosed with reactive hyperprolactimia. Dr. Holt said that he had heard about isolated cases of patients suffering myocardial infarction after taking Parlodel--a description that varies greatly from the way Plaintiffs characterize the issue. See Pls.' Resp. to Def.'s Mot. for Summ.J.Ex. 4. If Plaintiffs can effectively prove this point, it is quite possible for a reasonable jury to conclude that Dr. Holt chose to administer Parlodel to Ms. Anderson without the full benefit of all available knowledge regarding the drug's risks.

FN6.The Court remains mindful of Defendant's argument that Dr. Holt's testimony--which states that he continues to prescribe Parlodel to patients with reactive hyperprolactimia--effectively rebuts this presumption as a matter of law. The Court, while recognizing the force of Dr. Holt's admission, nevertheless finds that his creditability as a witness testifying before a jury will serve as the ultimate means for evaluating whether Defendant has proven a lack of producing cause. In the meantime, the Court balances Defendant's argument against Plaintiff's assertions that Dr. Holt did not know of all the risks possibly linked to Parlodel (not to mention Dr. Holt's admission that he would expect Defendant to provide any relevant evidence about adverse drug reactions so that he can make appropriate determinations about prescribing the medication). When juxtaposed, these two opposing arguments appear to expose the existence of a material fact issue.

FN7.Indeed, after examining evidence showing that despite the fact that Defendant was aware that Dr. Holt had been prescribing Parlodel for patients with reactive hyperprolactimia, Defendant elected not to make Dr. Holt aware of its own studies showing the deleterious risks Parlodel may present to such patients. See Dep. of Dr. Byron Holt at 33-34. In fact, by his own admission, Dr. Holt acknowledged that if such scientific evidence existed, he would want to know about it. See id. at 26-29. At no point in his deposition did Dr. Holt suggest that he would have disregarded Defendant's warnings, if they had been substantiated with medical proof. One can reasonably interpret these responses to mean that Dr. Holt's blanket statement aside, he in fact would have responded to warnings, as long as they could be supported with medical proof. Plaintiffs argue that Defendant never offered Dr. Holt the opportunity to review all relevant medical studies. Given these potentially conflicting responses, the Court finds that fact questions do surround the issue of producing cause.