



Wyeth-Ayerst Laboratories Co. v. Medrano

28 S.W.3d 87 (2000) | Cited 15 times | Court of Appeals of Texas | August 7, 2000

Date Argued: July 13, 2000

OPINION

This is an appeal from a judgment rendered on behalf of Emilia Medrano in a products liability case against Wyeth-Ayerst Laboratories Company, et al. (Wyeth). Four women who used the Norplant System contraceptive alleged that they suffered injuries as a result of Wyeth's failure to adequately warn of the side effects associated with this product. A jury trial was held, and the jury found that three of the women suffered no injuries or actual damages. The trial court rendered a take-nothing judgment as to those three plaintiffs. The jury, however, awarded the fourth woman, Medrano, \$15,000.00 in mental anguish damages and additional damages of \$20,000.00. ¹ The trial court rendered judgment in accordance with the jury's verdict. We reverse and render judgment for Wyeth.

The Norplant System is a fairly new method of birth control, and it is only available through a prescription. It consists of six thin, flexible capsules, which contain the synthetic hormone levonorgestrel. These capsules are inserted into the woman's upper arm, and the hormone is slowly released. To insert the capsules, a small incision is made in the woman's arm, which usually takes place in a minor, in-office surgical procedure, and once inserted, the capsules can provide effective birth control for up to five years. However, at any time during the five-year period, the woman can choose to have the contraceptive removed, and soon thereafter she will return to a state of fertility.

Medrano is a twenty-nine-year-old mother of two. After the birth of Medrano's first child, she began to use birth control pills as her form of contraception. However, while she was still using the birth control pills, Medrano became pregnant with her second child. Therefore, Medrano decided that she needed to consider other contraceptive options. Approximately four weeks after the birth of her second child, Medrano went to her doctor's office and met with Bonnie George, an advanced practice nurse, concerning Norplant. During this visit, Medrano was given a booklet, shown a videotape, and spoke with Nurse George regarding the Norplant System. Medrano then went home, spoke with her husband, and ultimately decided that she did want Norplant to be her method of birth control.

Approximately three weeks after this initial visit, Medrano returned to her doctor's office to have Norplant inserted. At this second office visit, she and Nurse George once again discussed Norplant. Nurse George explained the procedure and answered some of Medrano's questions about the potential side effects associated with taking this contraceptive. Then, before the implantation procedure took place, Medrano signed a consent form, which stated that she had been counseled



Wyeth-Ayerst Laboratories Co. v. Medrano

28 S.W.3d 87 (2000) | Cited 15 times | Court of Appeals of Texas | August 7, 2000

about Norplant and that she understood the risks associated with the Norplant System. Medrano admits that at the time of implantation she was aware of the potential side effects that can be associated with Norplant, and she nonetheless made the decision to receive the Norplant System.

Approximately fifteen months after Medrano had Norplant inserted into her arm, she chose to have it removed. In this suit against Wyeth, Medrano claims that Wyeth failed to adequately warn her of the potential side effects associated with Norplant by failing to communicate to her information and knowledge it had about the risks and side effects of using the Norplant System. However, Medrano does admit that all of the side effects she suffered were listed in the warning booklet in some form.

At the conclusion of Medrano's evidence, Wyeth moved for a directed verdict. It alleged that the learned intermediary doctrine should apply; therefore, it argued that as a matter of law Medrano had produced no evidence that Wyeth's warnings were inadequate or that they were the producing cause of her alleged injuries. Medrano claims that the learned intermediary doctrine should not apply and that the question of whether a warning is adequate is generally considered an issue for the trier of fact.

The learned intermediary doctrine states that, in some situations, a warning to an intermediary fulfills a supplier's duty to warn ultimate consumers. *Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588, 591 (Tex. 1986). In Texas, the most common use of this doctrine is in prescription drug cases. See *Bean v. Baxter Healthcare Corp.*, 965 S.W.2d 656, 662 (Tex. App.-Houston [14th Dist.] 1998, no pet.); *Rolen v. Burroughs Wellcome Co.*, 856 S.W.2d 607, 609 (Tex. App.-Waco 1993, writ denied); *Gravis v. Parke-Davis & Co.*, 502 S.W.2d 863, 870 (Tex. Civ. App.-Corpus Christi 1973, writ ref'd n.r.e.); see *Cooper v. Bowser*, 610 S.W.2d 825, 830-31 (Tex. Civ. App.-Tyler 1980, no writ); see also *Reyes v. Wyeth Lab.*, 498 F.2d 1264 (5th Cir. 1974); *In re Norplant Contraceptive Prods. Liab. Lit.*, 955 F.Supp. 700, 703 (E.D. Tex. 1997), *aff'd*, 165 F.3d 374 (5th Cir. 1999). In prescription drug cases, the courts have found that it is reasonable for the manufacturer to rely on the health care provider to pass on its warnings. This is reasonable because the learned intermediary understands the propensities and dangers involved in the use of a given drug, and as the prescriber, he stands between this drug and the ultimate consumer. *Gravis*, 502 S.W.2d at 870. In the *Reyes* opinion, the Fifth Circuit further explained that:

This special standard for prescription drugs is an understandable exception to the Restatement's general rule that one who markets goods must warn foreseeable ultimate users of dangers inherent in his products. Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. *Reyes*, 498 F.2d at 1276 (citations omitted).



Wyeth-Ayerst Laboratories Co. v. Medrano

28 S.W.3d 87 (2000) | Cited 15 times | Court of Appeals of Texas | August 7, 2000

Additionally, it is important to remember that the learned intermediary doctrine does not absolve a prescription drug manufacturer from liability any time a warning is given to a physician. The warning still must be adequate, and if "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, citing Bristol-Myers Co. v. Gonzales, 561 S.W.2d 801 (Tex. 1978); Crocker v. Winthrop Lab., 514 S.W.2d 429 (Tex. 1974).

Medrano argues that there are a number of reasons why this doctrine should not apply to this case. First, Medrano claims that all prescription contraceptives should be excepted from the learned intermediary doctrine. She argues that in the prescription contraceptive context, the patient actually makes the decision as to which contraceptive she wishes to use, and the intermediary merely abides by the woman's choice; therefore, there is no real medical decision being made by the intermediary, and thus the learned intermediary doctrine should not apply. However, in Texas, even when a physician makes no individualized judgment in prescribing and administering a prescription drug, this doctrine has been applied as long as a physician-patient relationship is in existence. See Bean, 965 S.W.2d at 662, citing Hurley v. Lederle Lab., 863 F.2d 1173, 1178-79 (5th Cir. 1988); Swayze v. McNeil Lab., Inc., 807 F.2d 464, 471-72 (5th Cir. 1987).

It is undisputed that a woman cannot receive the Norplant System without a prescription. Since prescription contraceptives, such as Norplant, can reach a patient only by way of a learned intermediary, we see no reason why the doctrine should not apply to contraceptives. Additionally, in the case of the Norplant System, it is even more logical for the learned intermediary doctrine to apply, because not only is an intermediary necessary to prescribe the contraceptive, but he is also necessary for implantation of the system into the woman's arm.

Further, in a recent federal case, *In re Norplant*, which dealt with the exact situation that is presently before this Court, the court noted that many courts outside of Texas have already dealt with this argument, and "[o]nly a single jurisdiction, Massachusetts, recognizes an exception to the doctrine for prescription contraceptives." *In re Norplant*, 955 F.Supp. at 704-05. We agree with the other jurisdictions that have held against creating an exception to the learned intermediary doctrine for prescription contraceptives. The fact that a woman may have a voice in the choice of her contraceptive product, even if it is in fact the deciding voice, should not be enough to exempt this prescription drug from the learned intermediary doctrine.

Next, Medrano contends that even if the learned intermediary doctrine should apply in prescription contraceptive cases, it should not apply in this particular instance because Medrano was not treated by a physician. It is undisputed that Medrano received counseling about the risks and side effects of Norplant, a prescription, and an implantation of the Norplant System; however, it is also undisputed that she did not receive this treatment from her doctor. Medrano was treated by Nurse George, an advanced practice nurse who works for Medrano's long-time obstetrician/gynecologist, Dr. Charles Moses.² Medrano claims that since the crucial consideration in determining when to apply the



Wyeth-Ayerst Laboratories Co. v. Medrano

28 S.W.3d 87 (2000) | Cited 15 times | Court of Appeals of Texas | August 7, 2000

learned intermediary doctrine is the existence of a physician-patient relationship, and since no physician was involved, the learned intermediary doctrine cannot apply.

In support of this argument, Medrano cites *Mazur v. Merck & Co.*, 964 F.2d 1348 (3rd Cir. 1992). The Mazur court held that according to Pennsylvania law, the learned intermediary doctrine should not be extended to nurses. *Id.* at 1357-58. While this case has no binding authority on this Court, the reasoning behind the Mazur court's decision actually supports characterizing Nurse George as a learned intermediary. The Mazur court reasoned that nurses should not be considered learned intermediaries because "generally [they] are not capable of providing the degree of individualized medical judgment rendered by physicians, and [they] are not authorized [to] independently prescribe drugs." *Id.* at 1357. However, under Texas law, as an advanced practice nurse, Nurse George is given the right to prescribe medication and to treat patients without the supervision of a physician. See Tex. Rev. Civ. Stat. art. 4514, § 7; ³ Tex. Rev. Civ. Stat. art. 4514, § 8; ⁴ see also 22 Tex. Admin. Code § 222.1, et. seq. (1998).

Texas jurisprudence has never dealt with the question of whether nurses can be considered learned intermediaries; however, given the qualifications of an advanced practice nurse, it is logical that the rule should be extended to include them as well. In the past, a physician-patient relationship has been crucial to the question of whether the learned intermediary doctrine should be applied. See *Hurley*, 863 F.2d at 1178-79; *Swayze*, 807 F.2d at 471-72. It is clear, though, that the basis of this requirement is that as a physician, a person is assumed to have the requisite knowledge and skill that is necessary to offer individualized medical counseling to a patient who is seeking a prescription drug. See *Bean*, 965 S.W.2d at 662-63; see also *Reyes*, 498 F.2d at 1276. Therefore, it follows that since Texas law allows a nurse to become certified to prescribe drugs without a doctor's supervision, when she is performing that task the law must view her as being capable of offering this individualized medical treatment.

Texas law gives Nurse George the authority to prescribe and implant the Norplant System. As a physician would do, when she prescribed this drug, she counseled, informed, and advised Medrano of the risks and side effects associated with this contraceptive. In other words, Medrano received individualized medical treatment. Since Nurse George serves the same purpose that a physician in this position would, we will not create an exception to the learned intermediary doctrine merely because she holds the title "advanced practice nurse" rather than physician.

Medrano also contends that the learned intermediary doctrine should not apply where, as here, the manufacturer provides information to the intermediary but gears it directly at the patient. She admits that she received and relied on information that came directly from her health care provider. She argues, however, that Wyeth's conduct in providing the information to the intermediary, but gearing it directly at the patient, created a separate duty directly to her, the consumer, regardless of from whom she received the information. We do not agree. Irrespective of the origin of the information, it still went through the learned intermediary to get to Medrano. Since the information reached



Wyeth-Ayerst Laboratories Co. v. Medrano

28 S.W.3d 87 (2000) | Cited 15 times | Court of Appeals of Texas | August 7, 2000

Medrano because of the physician-patient relationship, we still apply the learned intermediary doctrine. See *In re Norplant*, 955 F.Supp. at 705-06, citing *Hurley*, 863 F.2d 1178-79. ⁵

We hold that the learned intermediary doctrine does apply to this prescription contraceptive case; however, we must now determine if it should be applied to all of Medrano's causes of action. Medrano contends that the learned intermediary doctrine is a common-law defense, and as such, may not preclude a cause of action under the Deceptive Trade Practices Act (DTPA). Medrano reasons that since the doctrine finds no basis in any statute, and one Texas case stated that it was "distantly related" to the tort concept of "superseding cause," it is clearly a common-law defense. See *Rolen*, 856 S.W.2d at 609.

It is undisputed that common-law defenses may not be applied to causes of action under the DTPA.

In *Smith v. Baldwin*, 611 S.W.2d 611 (Tex. 1981), the Texas Supreme Court ruled that because a DTPA cause of action is specifically created by statute, only the defenses set forth in the statute apply. The Court reasoned that common-law defenses to the traditional tort and contract causes of action are not material in DTPA cases because the DTPA is not a codification of common law, but rather a statutory creation. *Kuehnhoefer v. Welch*, 893 S.W.2d 689, 692 (Tex. App.-Texarkana 1995, writ denied).

However, no Texas state courts have specifically addressed whether the learned intermediary doctrine is a common-law defense. There are, however, at least two Texas appellate courts that have applied the learned intermediary doctrine to causes of action under the DTPA. See *Bean*, 965 S.W.2d at 664; *Jordan v. Geigy Pharm.*, 848 S.W.2d 176 (Tex. App.-Fort Worth 1992, no writ).

Likewise, the district court in the federal *Norplant* case held that the learned intermediary doctrine should be applied to DTPA claims. It reasoned that,

[t]he gravamen of all of Plaintiffs' causes of action, including misrepresentation and violation of the DTPA, is that Wyeth failed to adequately warn of or disclose the severity of *Norplant*'s side effects. Therefore, the learned intermediary doctrine applies to all of Plaintiffs' causes of action. . . . If the doctrine could be avoided by casting what is essentially a failure to warn claim under a different cause of action such as violation of the DTPA or a claim for misrepresentation, then the doctrine would be rendered meaningless. *In re Norplant*, 955 F.Supp. at 709.

Moreover, when the Fifth Circuit Court of Appeals affirmed this decision, it was persuaded by the fact that, "Texas appeal courts have applied the doctrine in DTPA cases despite the edict not to apply common law defenses to the DTPA, . . ." and it found that this "suggests the result a Texas court would likely reach if presented with this issue." *In re Norplant Contraceptive Prods. Liab. Lit.*, 165 F.3d 374, 378 (5th Cir. 1999). We agree.



Wyeth-Ayerst Laboratories Co. v. Medrano

28 S.W.3d 87 (2000) | Cited 15 times | Court of Appeals of Texas | August 7, 2000

We do not believe that because one Texas case compares the learned intermediary doctrine to the concept of "superseding cause," this means the doctrine is a common-law defense. A defense is defined as "[a] defendant's stated reason why the plaintiff or prosecutor has no valid case." Black's Law Dictionary 430 (7th ed. 1999). When the learned intermediary doctrine is asserted in a cause of action, it is used to show to whom a defendant, usually a prescription drug manufacturer, owes the duty to adequately warn. It is not used to show that the plaintiff has no valid case. Even when the learned intermediary doctrine applies, the manufacturer still has a duty to warn, and it can still be held liable directly to the plaintiff if the warning that it gave is inadequate. See *Alm*, 717 S.W.2d at 591. The learned intermediary doctrine is not properly characterized as a common-law defense; therefore, the doctrine applies to all of Medrano's causes of action.

In any failure to warn case, the plaintiff must show both that the warning was defective and that it was the producing cause of the plaintiff's injury. *Rolen*, 856 S.W.2d at 609, citing *Technical Chem. Co. v. Jacobs*, 480 S.W.2d 602, 605-06 (Tex. 1972). Under the learned intermediary doctrine, Wyeth sustains its duty by warning the learned intermediary of the risks associated with its product. See *Gravis*, 502 S.W.2d at 870. In this case, it is undisputed that Wyeth did in fact warn the intermediary, Nurse George. Medrano contends, however, that these warnings were inadequate.⁶

In a failure to warn case that is governed by the learned intermediary doctrine, even if we assume that the plaintiff can prove that the given warnings were inadequate, the plaintiff still must prove causation. In order to prove causation, the plaintiff must show that a proper warning would have changed the decision of the intermediary to prescribe the product. See *Stewart v. Janssen Pharmaceutica, Inc.*, 780 S.W.2d 910, 912 (Tex. App.-El Paso 1989, writ denied); see also *In re Norplant*, 955 F.Supp. at 710-11. If the plaintiff fails to sustain this burden then, as a matter of law, he or she has failed to prove causation. *Stewart*, 780 S.W.2d at 912; *In re Norplant*, 955 F.Supp. at 710-11.

Nurse George testified that she received adequate warnings from Wyeth about the risks and side effects associated with Norplant. Medrano then presented evidence regarding what Wyeth had failed to disclose about its product. After hearing this evidence, Nurse George testified that this information would not have affected her decision to prescribe the contraceptive to Medrano. Therefore, as a matter of law, Medrano has failed to prove that Wyeth's warnings were the cause of her injuries. At this point, Wyeth was entitled to a directed verdict, and the trial court erred as a matter of law by not granting Wyeth's motion based on the learned intermediary doctrine. This point of error is dispositive of all Medrano's claims, and the judgment of the trial court is reversed, and judgment is hereby rendered on behalf of Wyeth.

In addition, the statute of limitations bars Medrano's claim, and mandates that judgment be reversed and rendered on Wyeth's behalf. Both sides agree that the two-year statute of limitations applies to Medrano's claims. Tex. Civ. Prac. & Rem. Code Ann. § 16.003 (Vernon Supp. 2000). Assuming, without finding, that the more liberal discovery rule applies, Medrano would have two years to file her claim from the time when she should have discovered her injuries. The jury found that Medrano



Wyeth-Ayerst Laboratories Co. v. Medrano

28 S.W.3d 87 (2000) | Cited 15 times | Court of Appeals of Texas | August 7, 2000

should have discovered her injury one year after insertion. Neither party disputes the validity of this finding; therefore, since Medrano had the Norplant inserted into her arm on September 24, 1993, her accrual date would be September 24, 1994, and her bar date would be September 24, 1996. Medrano intervened as a plaintiff in this suit on May 29, 1997. This date is clearly outside the limitations period.

Medrano argues that her claim is not barred because the statute of limitations was tolled by a federal class action complaint filed on behalf of "all adult women who have had the Norplant inserted in their bodies and who have sustained damages." See *American Pipe and Constr. Co. v. Utah*, 414 U.S. 538, 94 S.Ct. 756, 38 L.Ed.2d 713 (1974). However, we will not address whether *American Pipe* should be construed to toll the statute of limitations in this particular case because Medrano has waived this argument on appeal by failing to cite us to any point in the record where this tolling argument was pled, or where any evidence of this class action was presented.

It is the plaintiff's burden to plead and prove facts to avoid the bar of limitations. See *Willis v. Maverick*, 760 S.W.2d 642, 647 (Tex. 1988). "A matter in avoidance of the statute of limitations not affirmatively raised by the pleadings is waived." *Dickson Constr., Inc. v. Fidelity and Deposit Co. of Maryland*, 960 S.W.2d 845, 850 (Tex. App.-Texarkana 1997, no pet.), citing *Woods v. William M. Mercer, Inc.*, 769 S.W.2d 515, 518 (Tex. 1988). The two-year statute of limitations, therefore, was not tolled and Medrano's claims are time barred as a matter of law.

The judgment is reversed, and judgment is hereby rendered for Wyeth.

Donald R. Ross Justice

Publish

1. The jury made the following findings: (1) Wyeth engaged in false, misleading, or deceptive acts or practices; (2) Wyeth engaged in unconscionable actions or courses of actions; (3) Wyeth's conduct was a producing cause of Medrano's damages; (4) Wyeth engaged in such conduct knowingly; and (5) there was a defect in the marketing of Norplant that was a producing cause of Medrano's injuries. However, the jury also found that neither Medrano's nor Wyeth's negligence was a proximate cause of Medrano's damages, but then decided that the percentages of causation attributable to Wyeth and Medrano were 0% and 100%, respectively. Both sides moved to disregard various jury findings and render judgments notwithstanding the verdict. The court granted Medrano's motion to disregard the comparative responsibility question and rendered judgment for Medrano.

2. Nurse George actually has two certifications that qualify her as an advanced nurse practitioner. She is certified with the NCC (National Certification Corporation for the Obstetric, Gynecologic and Neonatal Nursing Specialties) as an OB/Gyn nurse practitioner, and with the American Nurses Association as a family nurse practitioner. As a result of these certifications, Nurse George is allowed to prescribe medications, examine patients within her scope of practice, manage minor and chronic problems, and she is even entitled to open her own clinic.



Wyeth-Ayerst Laboratories Co. v. Medrano

28 S.W.3d 87 (2000) | Cited 15 times | Court of Appeals of Texas | August 7, 2000

3. Act of May 24, 1993, 73rd Leg., R.S., ch. 436, § 3, 1993 Tex. Gen. Laws 1750, repealed by Act of May 13, 1999, 76th Leg., R.S., ch. 388, § 6(a), 1999 Tex. Gen. Laws 2439-40.

4. Act of May 16, 1995, 74th Leg., R.S., ch. 965, § 51, 1995 Tex. Gen. Laws 4820, repealed by Act of May 13, 1999, 76th Leg., R.S., ch. 388, § 6(a), 1999 Tex. Gen. Laws 2439-40.

5. Medrano does not-and could not-argue that the intermediary doctrine should not apply because the manufacturer created an independent duty to the consumer by targeting its literature and information directly at the patient outside the physician-patient relationship. This Court can foresee a situation where a manufacturer's direct contact with the consumer could be received and relied on by that consumer outside the learned intermediary context. This case does not present us with that situation.

6. Wyeth argues that the given warnings were adequate as a matter of law because every side effect of which Medrano complained was addressed in the information distributed by Norplant to the learned intermediary. If "a warning specifically mentions the circumstances complained of, the warning is adequate as a matter of law." *Rolen v. Burroughs Wellcome Co.*, 856 S.W.2d 607, 609 (Tex. App.-Waco 1993, writ denied). However, Medrano contends that the fact that Wyeth's warnings omitted pertinent information and phrased certain warnings as possibilities rather than certainties made the warnings inadequate. We do not have to address this argument in order to decide this issue.

