SUPREME COURT OF ALABAMA

Walls v. Alpharma USPD, Inc.

887 So. 2d 881 (Ala. 2004) · No. 1010645 · Decided March 5, 2004

OPINION

PER CURIAM.

887 So.2d 881 (2004) Judith D. WALLS, as mother and natural guardian of Brittany N. Adams v. ALPHARMA USPD, INC., f/k/a Barre-National, Inc., et al. 1010645. Supreme Court of Alabama. March 5, 2004. *882 Stephen W. Drinkard and Dana G. Taunton of Beasley, Allen, Crow, Methvin, Portis & Miles, P.C., Montgomery, for plaintiff. Steven F. Casey and Jenelle R. Evans of Balch & Bingham, LLP, Birmingham, for defendants Alpharma USPD, Inc., and Alphama, Inc. Jack B. Hinton, Jr., and Andrew W. Christman of Gidiere, Hinton & Herndon, Montgomery, for defendant Revco.

J. Kenneth Guin, Jr., Carbon Hill, for amicus curiae Alabama Pharmacy Association, Inc., in support of the defendants. JOHNSTONE, Justice. By an order dated February 8, 2002, this Court accepted certified questions from the United States District Court for the Northern District of Alabama, Western Division.

The questions, as certified by the federal court, read as follows: "A. Does a pharmacist have a duty to warn of foreseeable injuries from the use of the prescription drug he/she is dispensing under AEMLD [Alabama Extended Manufacturer's Liability Doctrine], common-law negligence or other Alabama law? "B. If so, is the duty to provide adequate warnings limited to possible injuries to the pharmacy's customer or does it extend to third-parties whose injuries are reasonably foreseeable at the time the prescription is filled?"

The United Stated District Court supplied the following facts: "In 1986, Ms. Judith Walls and her husband, Alan Adams, were treated for scabies by Dr. Cynthia Lucy. Dr. Lucy prescribed Lindane lotion for Mr. Adams, but prescribed a different treatment for Ms. Walls, who was pregnant. Mr. Adams's prescription was filled at a Revco pharmacy. At some later time, when Ms. Walls informed Dr. Lucy her treatment was not working, Dr. Lucy directed Ms. Walls to use Mr. Adam's Lindane lotion and Ms. Walls did use the Lindane lotion prescribed to her husband.

On January 21, 1987, Ms. Walls gave birth to Brittany Adams, who suffers from numerous medical conditions. Ms. Walls claims Brittany's medical problems were caused by Ms. Walls' use of Lindane lotion during the pregnancy.

The defendants are the alleged manufacturer and sellers of the Lindane lotion. "Previously, this court determined Ms. Walls' and Brittany's claims against the pharmacies were not covered by the

Alabama Medical Liability Act because there was no patient/healthcare provider relationship. Thomasson v. Diethelm, 457 So.2d 397 (Ala.1984). Ms. Walls' claims were dismissed on statute of limitations grounds.

Brittany's remaining claims are under the AEMLD and common-law negligence theory. "The plaintiffs allege the defendant pharmacies negligently and wantonly placed a defective and unreasonably dangerous product, Lindane, into the stream of commerce and failed to provide adequate warnings of the risks associated with Lindane and failed to issue notice or recall regarding the alleged hazard.

The defendants claim a pharmacy's duty is limited to accurately filling the prescription as provided by a physician and that the physician, as a learned intermediary, is the conduit for providing manufacturer's warnings to the patient. They further argue any duty to warn does not extend to the fetus of the wife of the pharmacy's customer whose prescription was filled by the pharmacy."

The plaintiff and the defendants have briefed an issue critical to the questions *883 certified by the federal court. The critical issue is whether the learned-intermediary doctrine forecloses the existence of a duty upon a pharmacist filling a prescription to warn foreseeable consumers of the risks or potential side effects of the prescribed medication. This Court has not previously addressed this particular issue.

"In cases involving complex products, such as those in which pharmaceutical companies are selling prescription drugs, the learned intermediary doctrine applies. Under the learned intermediary doctrine, a manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the use of its product.

This standard 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.' As such, we rely on the expertise of the physician intermediary to bridge the gap in special cases where the product and related warning are sufficiently complex so as not to be fully appreciated by the consumer.... `Under the "learned intermediary doctrine" the adequacy of [the defendant's] warning is measured by its effect on the physician,... to whom it owed a duty to warn, and not by its effect on [the consumer].'" Toole v. Baxter Healthcare Corp., 235 F.3d 1307, 1313-14 (11th Cir.2000) (citations omitted; emphasis added).

In Stone v. Smith, Kline & French Laboratories, 447 So.2d 1301 (Ala.1984), this Court applied the learned-intermediary doctrine to the issue of the existence of a duty upon manufacturers of prescription medications to warn ultimate consumers (patients of physicians).

In Stone, this Court addressed the following question, among others, certified by the United States Court of Appeals for the Eleventh Circuit: "If the adequacy of the warning determines whether an

unavoidably unsafe prescription drug is unreasonably dangerous, is an adequate warning to the prescribing physician, but not to the ultimate consumer, sufficient as a matter of law?"

447 So.2d at 1303. Answering this question in the affirmative, the Court explained: "Cholestatic jaundice is a risk known to attend the use of Thorazine, even though the jaundice occurs only in a small percentage of patients for whom the drug is prescribed.

In seeking a determination of liability on the part of Smith, Kline & French, plaintiffs-appellants have not indicated that they are prepared to prove that the risk is unreasonable, but only that it materialized in the course of Amy Stone's treatment with Thorazine. They concede that Amy Stone's physician was adequately warned of the adverse side effects, including cholestatic jaundice, which sometimes accompany the use of Thorazine.

Nevertheless, they contend that the warnings issued are of no consequence, because prescribing physicians cannot accurately predict which of their patients will develop jaundice as a result of treatment with Thorazine.

In essence, they assert that Amy Stone's physician was incapable of making an informed choice to prescribe Thorazine, because he was unable to predict the occurrence of an adverse reaction. We disagree. "Plaintiffs-appellants misconceive the physician's role in prescribing ethical drugs, and the significance of a drug manufacturer's warnings in undertaking that responsibility.

A proper understanding of that role has been articulated *884 by the United States Court of Appeals for the Fifth Circuit as follows: "`We cannot quarrel with the general proposition that where 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.

This special standard for prescription drugs is an understandable exception to the Restatement's general rule that one who markets goods must warn forseeable ultimate users of dangers inherent in his products. See Restatement (Second) of Torts, Section 388 (1965). 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. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.'

"Reyes v. Wyeth Laboratories, 498 F.2d [1264] at 1276 [(5th Cir.1974)].... Accord, Timm v. Upjohn Co., 624 F.2d 536, 538 (5th Cir.1980)...." Stone, 447 So.2d at 1304-05 (footnote omitted; first emphasis original; second emphasis added).

Although the appellate courts of Alabama have not addressed the issue whether a pharmacist filling a prescription owes a duty to warn his or her customers, or other ultimate consumers, of the risks or potential side effects of prescribed medications, various other state appellate courts have addressed the issue or some of its aspects. These decisions are persuasive authority on the issue of whether to extend the learned-intermediary doctrine to pharmacists.

In Nichols v. Central Merchandise, Inc., 16 Kan.App.2d 65, 817 P.2d 1131 (1991), the Kansas Court of Appeals cited the application of the learned-intermediary doctrine to manufacturers of prescription medications and then extended the application of the doctrine to pharmacists filling prescriptions for medications: "Manufacturers of prescription drugs do have a duty to warn of dangerous side effects and risks associated with the drugs.

Wooderson v. Ortho Pharmaceutical Corp., 235 Kan. 387, 409, 681 P.2d 1038, cert. denied 469 U.S. 965, 105 S.Ct. 365, 83 L.Ed.2d 301 (1984). Kansas has also adopted the learned intermediary doctrine, under which the manufacturer's duty to warn is satisfied when the prescribing doctor is informed of a drug's inherent risks. Humes v. Clinton, 246 Kan. 590, Syl. ¶ 5, 792 P.2d 1032 (1990).

"As the learned intermediary between manufacturer and patient, the doctor must inform himself or herself of a drug's characteristics and determine what facts should be told to the patient. 246 Kan. at 600-02, 792 P.2d 1032. "In the present case, because the doctor is the learned intermediary between the manufacturer and the patient, the patient should rely on the doctor; the pharmacist, at least under the facts of this case, has no legal duty to warn the patient of potential consequences from the use of the drug prescribed by the *885 doctor.

See, e.g., Pysz v. Henry's Drug Store, 457 So.2d 561 (Fla.Dist.Ct.App.1984); Eldridge v. Eli Lilly & Co., 138 Ill.App.3d 124, 92 Ill.Dec. 740, 485 N.E.2d 551 (1985); Ingram v. Hook's Drugs, Inc., 476 N.E.2d 881 (Ind.App.1985); Kinney v. Hutchinson, 449 So.2d 696 (La.App.1984); Stebbins v. Concord [Wrigley] Drugs[, Inc.], 164 Mich.App. 204, 416 N.W.2d 381 (1987); Makripodis v. Merrell-Dow Pharm., Inc., 361 Pa.Super.

589, 523 A.2d 374 (1987); McKee v. American Home Products [Corp.], 113 Wash.2d 701, 782 P.2d 1045 (1989). "We emphasize that Gantanol was not contraindicated for use during early pregnancy; the package insert merely stated its effect on a fetus had not been determined. "Because the decision to prescribe a specific drug involves an analysis of the patient's unique condition and a balancing of the risks and benefits of a given drug, the cases extending the learned intermediary doctrine to pharmacists reason that imposing a duty to warn on the pharmacist would

intrude on the doctor-patient relationship and would force the pharmacist to practice medicine without a license.

See Eldridge, 138 Ill.App.3d at 127, 92 Ill.Dec. 740, 485 N.E.2d 551. In addition, it would be both illogical and unreasonable to impose a greater duty on the pharmacist dispensing the drug than on the manufacturer of the drug. Ramirez v. Richardson-Merrell, Inc., 628 F.Supp. 85, 88 (E.D.Pa.1986). "We agree with the Washington Supreme Court, which surveyed the jurisdictions extending the learned intermediary doctrine to pharmacists and concluded: "`The pharmacist still has a duty to accurately fill a prescription [citation omitted] and to be alert for clear errors or mistakes in the prescription.

The pharmacist does not, however, have a duty to question a judgment made by the physician as to the propriety of a prescription or to warn customers of the hazardous side effects associated with a drug, either orally or by way of the manufacturer's package insert.' McKee v. American Home Products, 113 Wash.2d at 720, 782 P.2d 1045. "In the present case, the pharmacist accurately filled Nichols' prescription for Gantanol.

There were no clear errors on the face of the prescription, Gantanol was not contraindicated for use by Nichols, and Dr. VandeGarde's decision to prescribe the drug was within the realm of his professional judgment. "Under the facts of this case, Super D Drugs and its pharmacist owed no duty to warn Juanita Nichols or the doctor. Summary judgment was proper."

Nichols, 16 Kan.App.2d at 67-68, 817 P.2d at 1133-34 (first emphasis original; other emphasis added). Accord Cottam v. CVS Pharmacy, 436 Mass. 316, 764 N.E.2d 814 (2002); Moore ex rel. Moore v. Memorial Hosp. of Gulfport, 825 So.2d 658 (Miss.2002); Coyle v. Richardson-Merrell, Inc., 526 Pa. 208, 584 A.2d 1383 (1991); Johnson v. Walgreen Co., 675 So.2d 1036 (Fla.Dist.Ct.App.1996); Walker v. Jack Eckerd Corp., 209 Ga.App.

517, 434 S.E.2d 63 (1993); Fakhouri v. Taylor, 248 Ill.App.3d 328, 187 Ill.Dec. 927, 618 N.E.2d 518 (1993); Kinney v. Hutchinson, 449 So.2d 696 (La.Ct.App.1984); Adkins v. Mong, 168 Mich.App. 726, 425 N.W.2d 151 (1988); Ferguson v. Williams, 101 N.C.App. 265, 399 S.E.2d 389 (1991); Griffith v. Blatt, 158 Or.App. 204, 973 P.2d 385 (1999); Morgan v. Wal-Mart Stores, Inc., 30 S.W.3d 455 (Tex.App.2000); Silves v. King, 93 Wash.App.

873, 970 P.2d 790 (1999). *886 In McKee v. American Home Products Corp., 113 Wash.2d 701, 782 P.2d 1045 (1989), the Washington Supreme Court stated: "The relationship between the physician-patient-manufacturer applies equally to the relationship between the physician-patient and pharmacist.

In both circumstances the patient must look to the physician, for it is only the physician who can relate the propensities of the drug to the physical idiosyncrasies of the patient. `It is the physician who is in the best position to decide when to use and how and when to inform his patient

regarding risks and benefits pertaining to drug therapy.' W. Keeton, R. Keeton & D. Owen, Prosser and Keeton on Torts § 96, at 688 (5th ed.1984).

"In Young v. Key Pharmaceuticals, Inc., 112 Wash.2d 216, 770 P.2d 182 (1989), we stated, `proper dosages of medication is not within the scope of matters on which nonphysicians are competent....' Young, at 230, 770 P.2d 182.

We went on to hold that `pharmacists are not doctors and are not licensed to prescribe medication because they lack the physician's training in diagnosis and treatment.' Young, at 230, 770 P.2d 182. "Neither manufacturer nor pharmacist has the medical education or knowledge of the medical history of the patient which would justify a judicial imposition of a duty to intrude into the physician-patient relationship.

In deciding whether to use a prescription drug, the patient relies primarily on the expertise and judgment of the physician. Proper weighing of the risks and benefits of a proposed drug treatment and determining what facts to tell the patient about the drug requires an individualized medical judgment based on knowledge of the patient and his or her medical condition....

Requiring the pharmacist to warn of potential risks associated with a drug would interject the pharmacist into the physician-patient relationship and interfere with ongoing treatment. We believe that duty, and any liability arising therefrom is best left with the physician." 113 Wash.2d at 711-12, 782 P.2d at 1051.

On the basis of the foregoing authority and persuasive authority, we hold as follows. The learned-intermediary doctrine forecloses any duty upon a pharmacist filling a physician's prescription, valid and regular on its face, to warn the physician's patient, the pharmacist's customer, or any other ultimate consumer of the risks or potential side effects of the prescribed medication except insofar as the prescription orders, or an applicable statute or regulation expressly requires, that an instruction or warning be included on the label of the dispensed medication or be otherwise delivered.

To the extent that the learned-intermediary doctrine applies, foreseeability of injury is eliminated as a basis for liability upon the pharmacist. To the extent that the learned-intermediary doctrine applies, the duty to determine whether the medication as prescribed is dangerously defective is owed by the prescribing physician and not by the pharmacist filling the prescription.

Any question of what persons are due the duty owed by the prescribing physician is not before us. Accordingly, both questions certified to us are answered in the negative. QUESTIONS ANSWERED. HOUSTON, SEE, LYONS, BROWN, HARWOOD, WOODALL, and STUART, JJ., concur.