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publication in the Pacific Reporter.*

IN THE SUPREME COURT OF THE STATE OF UTAH

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Steven Downing,
Plaintiff and Appellant,

No. 20060771

v.

Hyland Pharmacy dba United
Drug Hyland Pharmacy,
Defendant and Appellee.

F I L E D

September 16, 2008

Third District, Salt Lake
The Honorable Tyrone E. Medley
No. 040917216

Attorneys: D. David Lambert, Leslie W. Slauch, Provo,
for plaintiff
Jesse C. Trentadue, Kevin D. Swenson, Salt Lake City,
for defendant

DURHAM, Chief Justice:

INTRODUCTION

¶1 This appeal raises two related questions: (1) whether a pharmacy may be held liable in negligence for continuing to fill prescriptions for a drug that has been withdrawn from the market by the Food and Drug Administration (FDA) and/or the manufacturer; and (2) whether a pharmacy may be held liable in negligence for failing to warn the patient of the drug's status. The district court granted summary judgment to Hyland Pharmacy on both questions, concluding that this court's decision in Schaerrer v. Stewart's Plaza Pharmacy, Inc., 2003 UT 43, 79 P.3d 922, precluded the plaintiff's claims. We reverse.

BACKGROUND AND PROCEDURAL HISTORY

¶2 In early 1996, Dr. Jerry Poulson began prescribing fenphen,¹ an appetite suppressant medication, for Steven Downing.

¹ According to the FDA,

(continued...)

From February 1996 until September 2000, Hyland filled Downing's prescriptions for fen-phen.

¶3 On August 16, 2004, Downing brought negligence claims against Hyland for continuing to fill prescriptions for fenfluramine, brand name Pondimin, after it was withdrawn from the market by the FDA and the manufacturer, Wyeth-Ayerst Laboratories (Wyeth). Downing alleged that the pharmacy negligently filled his fen-phen prescriptions and failed to remove Pondimin from its shelves and inventory after the withdrawal. Hyland subsequently filed a summary judgment motion arguing that it was entitled to judgment as a matter of law because it acted as a reasonable prudent pharmacy in filling Downing's prescription and thus did not breach any duty owed to him. The trial court granted Hyland's summary judgment motion, holding that Schaerrer protects pharmacists from liability if they fill a prescription as directed by the manufacturer or physician. See Schaerrer, 2003 UT 43, ¶¶ 33, 35. We have jurisdiction pursuant to Utah Code section 78A-3-102(3)(j) (Supp. 2008).

STANDARD OF REVIEW

¶4 In reviewing a district court's grant of summary judgment, we afford no deference to the lower court's legal

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[f]en-phen refers to the . . . combination of fenfluramine and phentermine. Fenfluramine ("fen") and phentermine ("phen") are prescription medications . . . approved by the FDA for many years as appetite suppressants for the short-term (a few weeks) management of obesity. Phentermine was approved in 1959 and fenfluramine in 1973 [S]ome physicians . . . prescribed fenfluramine or dexfenfluramine in combination with phentermine, often for extended periods of time, for use in weight loss programs. Use of drugs in ways other than described in the FDA-approved label is called "off-label use." In the case of fen-phen . . . no studies were presented to the FDA to demonstrate either the effectiveness or safety of the drugs taken in combination.

Questions and Answers about Withdrawal of Fenfluramine (Pondimin) and Dexfenfluramine (Redux), <http://www.fda.gov/cder/news/phen/fenphenqa2.htm> (last visited August 26, 2008).

conclusions and review them for correctness. Schaerrer, 2003 UT 43, ¶ 14. The granting of summary judgment is appropriate only in the absence of any genuine issue of material fact and where the moving party is entitled to judgment as a matter of law. Utah R. Civ. P. 56(c). Thus, in reviewing a district court's grant of summary judgment, we review the facts and all reasonable inferences in the light most favorable to the nonmoving party. Surety Underwriters v. E & C Trucking, Inc., 2000 UT 71, ¶ 15, 10 P.3d 338.

¶5 The question of whether a pharmacist owes a legal duty in prescribing drugs that have been withdrawn from the market by the FDA and/or the manufacturer is a question of law, which we review for correctness, granting no deference to the trial court's conclusions. Palmer v. Oregon Short Line R. Co., 98 P. 689, 696 (Utah 1908); State v. Blake, 2002 UT 113, ¶ 6, 63 P.3d 56.

ANALYSIS

¶6 It appears from the record that the trial court assumed for purposes of its summary judgment ruling that the allegations in plaintiff's complaint regarding the withdrawal of the drug from the market by the manufacturer at the request of the FDA were true. Hyland nowhere in its argument or pleadings in the trial court or in this court specifically denied the accuracy of that assertion, although it did raise foundational objections to exhibits offered by plaintiff in connection with the summary judgment proceedings establishing that fact, and raised the possibility with the trial judge that Hyland had not in fact received notice of the withdrawal. In any event, as mentioned above, the trial judge apparently premised his holding on the legal conclusion that under no set of circumstances could Hyland be held liable for negligence in filling prescriptions issued by a physician under Schaerrer. We disagree.

¶7 Schaerrer involved a products liability claim based on a pharmacy's failure to warn of general side effects and/or dangerousness of an FDA-approved drug (fen-phen, prior to the time of its alleged removal from the market) prescribed by a licensed physician. 2003 UT 43, ¶ 20. We adopted the learned intermediary rule for purposes of exempting pharmacists from strict products liability, noting the classic concerns that the rule is intended to address. Id. ¶ 22. We also made it clear, however, that the rule made sense in the context of a highly regulated distribution system for prescription drugs:

So long as a pharmacist's ability to
distribute prescription drugs is limited by

the highly restricted, FDA-regulated drug distribution system in this country, and a pharmacist cannot supply a patient with prescription drugs without an intervening physician's prescription, we will not impose a duty upon the pharmacist to warn of the risks associated with the use of prescription drugs.

Id. Many courts examining the learned intermediary rule have applied it to negligence as well as products liability claims. See, e.g., Koenig v. Purdue Pharma Co., 435 F. Supp. 2d 551, 554-55 (N.D. Tex. 2006) (applying the intermediary rule to strict products liability and negligence claims brought against pharmaceutical companies under a failure to warn theory); Krasnopol'sky v. Warner-Lambert Co., 799 F. Supp. 1342, 1345 (E.D.N.Y. 1992) ("With regard to the liability of drug manufacturers, 'where the theory of liability is failure to warn, negligence and strict liability are equivalent.'" (quoting Fane v. Zimmer, Inc., 927 F.2d 124, 130 (2d Cir. 1991))); Kirk v. Michael Reese Hosp. & Med. Ctr., 513 N.E.2d 387, 396 (Ill. 1987) (finding that the protection afforded by the learned intermediary rule in strict products liability claims also extended to negligence claims for failure to warn); Elliott v. A.H. Robins Co. (In re New York County Diet Drug Litig.), 691 N.Y.S.2d 501, 502 (N.Y. App. Div. 1999) ("Since there is no allegation that the pharmacy defendants failed to fill the prescriptions precisely as they were directed by the manufacturers and physicians . . . there is no basis to hold the pharmacists liable under theories of negligence, breach of warranty or strict liability."). We agree with these courts that the rule makes sense in negligence as well as strict liability contexts.

¶8 The majority of recent decisions discussing the rule, however, have recognized limits or exceptions to its scope in the negligence context, concluding that its protections extend only to warnings about general side effects of the drugs in question, but not to specific problems known to the pharmacist such as prescriptions for excessively dangerous amounts of the drug or for drugs contraindicated by information about a patient. These holdings attempt to account for the nature of modern pharmacy practice and to apply traditional common law negligence rules to that practice.²

² See, e.g., Fagan v. Amerisource Bergen Corp., 356 F. Supp. 2d 198, 212 (E.D.N.Y. 2004) ("New York courts have held that absent any allegation that a pharmacy failed to fill a prescription precisely as directed by the manufacturer and/or
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physician, or that the plaintiff had a condition of which the pharmacist was aware, rendering prescription of the drug at issue contraindicated, there is no basis to hold the pharmacy liable under theories of negligence, breach of warranty, or strict liability."); Heredia v. Johnson, 827 F. Supp. 1522, 1525 (D. Nev. 1993) ("At a minimum, a pharmacist must be held to a duty to fill prescriptions as prescribed and properly label them (include the proper warnings) and be alert for plain error."); Walls v. Alpharma USPD, Inc., 887 So. 2d 881, 885 (Ala. 2004) (agreeing with the Washington Supreme Court's conclusion that a pharmacist "has a duty to accurately fill a prescription and to be alert for clear errors or mistakes in the prescription"); Lasley v. Shrake's Country Club Pharmacy, Inc., 880 P.2d 1129, 1133-34 (Ariz. Ct. App. 1994) (recognizing the possibility of liability by holding that the question of whether a pharmacist breached a standard of care by failing to warn a patient of the highly-addictive nature of a drug or of drug interactions was a question for the trier of fact); Deed v. Walgreen Co., No. CV03082365 15, 2004 Conn. Super. LEXIS 3412, at *15 (Nov. 15, 2004) (holding that a pharmacist has a duty to warn in circumstances where "(1) a pharmacy or pharmacist has specific knowledge of potential harm to specific persons in particular cases; or (2) the pharmacy or pharmacist makes a representation that they will engage in a process of evaluation of the possible effects caused by the administration of a drug or combination of drugs; or (3) there is something patently and unambiguously wrong with the prescription itself, e.g., it is or should be plain that the medication prescribed provides a fatal dose to the patient."); Dee v. Wal-Mart Stores, Inc., 878 So. 2d 426, 427 (Fla. Dist. Ct. App. 2004) ("A pharmacy must use due and proper care in filling a prescription. When a pharmacy fills a prescription which is unreasonable on its face, even though it is lawful as written, it may breach this duty of care." (citation omitted)); Happel v. Wal-Mart Stores, Inc., 766 N.E.2d 1118, 1129 (Ill. 2002) ("[A] narrow duty to warn exists where, as in the instant case, a pharmacy has patient-specific information about drug allergies, and knows that the drug being prescribed is contraindicated for the individual patient. In such instances, a pharmacy has a duty to warn either the prescribing physician or the patient of the potential danger."); Gassen v. E. Jefferson Gen. Hosp., 628 So. 2d 256, 259 (La. Ct. App. 5 Cir. 1993) ("[A] pharmacist has a limited duty to inquire or verify from the prescribing physician clear errors or mistakes in the prescription."); Cottam v. CVS Pharmacy, 764 N.E.2d 814, 823 (Mass. 2002) (finding that where a pharmacist has undertaken a duty, it was appropriate to impose upon the pharmacist "a duty commensurate with what it appeared to

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¶9 We observed in Schaerrer that pharmacists have a "generally recognized duty to possess and exercise the reasonable degree of skill, care, and knowledge that would be exercised by a reasonably prudent pharmacist in the same situation," 2003 UT 43, ¶ 35 (internal quotation marks and citation omitted), but we were

² (...continued)

have undertaken"); Stebbins v. Concord Wrigley Drugs, Inc., 416 N.W.2d 381, 387-88 (Mich. Ct. App. 1987) ("[A] pharmacist has no duty to warn the patient of possible side effects of a prescribed medication where the prescription is proper on its face"); Horner v. Spalitto, 1 S.W.3d 519, 523-24 (Mo. Ct. App. 1999) (finding that although the physician is in the best position to determine what drug to prescribe to the patient, the pharmacist's duties should not be defined as merely that of an order filler. Thus holding that pharmacists are in the best position to alert the prescribing physician where a prescription is outside a normal range or where there are any "contraindications relating to other prescriptions the customer may be taking as identified by the pharmacy records, and to verify that the physician intended such a dose for a particular patient"); Hand v. Krakowski, 453 N.Y.S.2d 121, 122-23 (N.Y. App. Div. 1982) (recognizing a possibility of a duty on a pharmacy to warn an alcoholic patient because it knew or should have known that the drug prescribed to the alcoholic patient was contraindicated for individuals who were alcoholics); Ferguson v. Williams, 374 S.E.2d 438, 440 (N.C. Ct. App. 1988) ("While a pharmacist has no duty to advise absent knowledge of the circumstances . . . once a pharmacist is alerted to the specific facts and he or she undertakes to advise a customer, the pharmacist then has the duty to advise correctly."); Riff v. Morgan Pharmacy, 508 A.2d 1247, 1253 (Pa. Super. Ct. 1986) (allowing expert testimony that the failure of the pharmacy to notify the prescribing physician of obvious inadequacies on the face of the prescription was negligent); Pittman v. Upjohn Co., 890 S.W.2d 425, 434 (Tenn. 1994) (holding that a pharmacist may have a duty to warn where he knew that the physician failed to relay to the patient certain warnings the manufacturer required be given to the patient); Morgan v. Wal-Mart Stores, Inc., 30 S.W.3d 455, 466-67 (Tex. App. 2000) (holding that although pharmacists have no general duty to warn, pharmacists may be held liable for negligently filling a prescription and neglecting information on the face of the prescription where a reasonably prudent pharmacist would have acted); McKee v. Am. Home Prods. Corp., 782 P.2d 1045, 1052-55 (Wash. 1989) (holding that a pharmacist has a duty "to be alert for clear errors or mistakes in the prescription," such as where a prescription contains obvious lethal dosages, inadequate instructions, known contraindications, or incompatible prescriptions).

not required in that case to address the interface between that standard and the learned intermediary rule. We do not address that interface here, except to note that our application of the rule in Schaerrer does not mean that we will not limit its application to negligence claims when the facts and public policy require such limitation.

¶10 We conclude that this is such a case. The facts alleged here state a cause of action for negligence as a matter of law. A pharmacist owes the consumer a duty of reasonable care with respect to the sale of drugs not authorized for sale by the FDA or the manufacturer. Our declaration that a duty exists does not, however, establish what the pharmacist's standard of care is; that is a factual matter that must be examined on remand. "[W]here the question is one simply of determining, under all the facts, whether a legal duty is created, the question is one of law," Palmer, 98 P. at 696, but "[o]rdinarily, whether a defendant has breached the required standard of care is a question of fact for the jury," Jackson v. Dabney, 645 P.2d 613, 615 (Utah 1982) (citation omitted).

¶11 This difference between duty--a question of law, and standard of care is treated in Prosser and Keeton:

It is better to reserve "duty" for the problem of the relation between individuals which imposes upon one a legal obligation for the benefit of the other, and to deal with particular conduct in terms of a legal standard of what is required to meet the obligation. In other words, "duty" is a question of whether the defendant is under any obligation for the benefit of the particular plaintiff; and in negligence cases, the duty is always the same--to conform to the legal standard of reasonable conduct in the light of the apparent risk. What the defendant must do, or must not do, is a question of the standard of conduct required to satisfy the duty.

W. Page Keeton et al., Prosser and Keeton on the Law of Torts § 53 (5th ed., Lawyer's ed. 1984).

¶12 The Arizona Court of Appeals examined this problem very effectively in Lasley v. Shrake's Country Club Pharmacy, Inc., pointing out that health care providers (including pharmacists) are "held to a higher standard of care than that of the ordinarily prudent person when the alleged negligence involves

the defendant's area of expertise." 880 P.2d 1129, 1132 (Ariz. Ct. App. 1994) (citing Bell v. Maricopa Med. Ctr., 755 P.2d 1180, 1182 (Ariz. Ct. App. 1988)). Expert testimony and relevant statutory and regulatory standards will be relevant to establishing what the standard of care is for a pharmacist filling prescriptions for a drug withdrawn from the market at the request of the FDA. It will be for the fact-finder to determine what the standard is and whether it was breached in this case.

CONCLUSION

¶13 We hold that the learned intermediary rule does not preclude as a matter of law a negligence claim against a pharmacist for dispensing a prescribed drug that has allegedly been withdrawn from the market, and that pharmacists under such circumstances owe their customers a duty of reasonable care. We thus reverse the summary judgment dismissing the plaintiff's claims and remand this case to the trial court for further proceedings. This will presumably include the development of the record on the question of withdrawal of the drug and the standard of care for a reasonable pharmacist under the circumstances.

¶14 Associate Chief Justice Durrant, Justice Wilkins, Justice Parrish, and Justice Nehring concur in Chief Justice Durham's opinion.