REL: 2/29/08
REL: 9/19/08, as modified on denial of rehearing

SUPREME COURT OF ALABAMA

OCTOBER TERM, 2007-2008

1051748

Springhill Hospitals, Inc., d/b/a Springhill Memorial Hospital

v.

Sharon Larrimore, as administratrix of the estate of Luther Shelton Larrimore, deceased

Appeal from Mobile Circuit Court
(CV-02-3205)

SEE, Justice.

Sharon Larrimore, as administratrix of the estate of her husband, Luther Shelton Larrimore ("the estate"), sued Springhill Hospitals, Inc., d/b/a Springhill Memorial Hospital

("SMH"), among others, alleging wrongful death resulting, at least in part, from the negligence of SMH's pharmacist, H. Gregory Weeks. The jury returned a general verdict in favor of the estate for $4 million in punitive damages. We hold that the learned-intermediary doctrine cuts off SMH's liability for Weeks's alleged breach of a duty of care. We, therefore, reverse the trial court's judgment and render a judgment as a matter of law in favor of SMH.

Facts and Procedural History

On August 15, 2001, Luther, accompanied by his wife, Sharon, went to the SMH emergency room complaining of severe knee pain. The attending physician, Dr. John M. McMahon, Jr., a physician with approximately 22 years of experience who had performed emergency-room services at SMH since about 1988, conducted a physical examination and ordered a blood test, a uric acid test, and an X-ray. Dr. McMahon diagnosed Luther's pain as an attack of gout in his knee. Dr. McMahon discussed three possible options for treatment by medication. Luther rejected the first two options because he was concerned that

they would aggravate his existing medical problems.[1] He accepted the third option, treatment with colchicine, which he had taken in small doses in the past when he had suffered from attacks of gout in his toe. The last time Dr. McMahon had prescribed colchicine was 17 years earlier. Dr. McMahon testified that after referring to the Physician's Desk Reference ("the PDR"), which he had in his office, he sent a prescription to the SMH pharmacy for Luther, prescribing a loading dose[2] of 2 mg. of colchicine to be taken orally.[3]

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[1]Luther rejected Indocin, because he was afraid it would aggravate his ulcerative colitis. He also rejected prednisone, because it had previously caused aseptic necrosis in his hips.

[2]A "loading dose" is "a comparatively large dose given at the beginning of treatment to start getting the effect of a drug, especially one with slow clearance thus requiring a long period to achieve stable blood levels without a high initial dose." Stedman's Medical Dictionary 538 (27th ed. 2000).

[3]In addition to the PDR, Dr. McMahon had various other sources available to him, including at least four additional medical reference books that described how to dose colchicine for the treatment of gout. Dr. McMahon also had the option of walking to the hospital pharmacy to review pharmaceutical references. Dr. McMahon did not use any of these additional methods for obtaining information regarding administering colchicine.

[substituted p. 3]

When Weeks received the prescription,[4] he telephoned Dr. McMahon to tell him that although 2 mg. is the proper loading dosage when colchicine is administered intravenously, it is not the proper loading dosage when the drug is administered orally.[5] Weeks also informed Dr. McMahon that the pharmacy stocked colchicine in tablet form only, not for intravenous administration. Dr. McMahon asked Weeks what the proper oral

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[4]Although Weeks has no specific recollection of any of the pertinent facts, it is undisputed that he was the only SMH pharmacist on duty at the time of Luther's initial visit to the emergency room, and he would have been the pharmacist who received Dr. McMahon's prescription for 2 mg. of colchicine to be administered orally to Luther in the emergency room.

[5]At the time Luther was treated at SMH, SMH had in effect a written policy applicable to its pharmacy entitled "Interventions." That policy applied to both inpatients and outpatients:

> "Purpose: To define a collaborative patient monitoring system which is necessary to assure appropriateness and continuity of care and provide the information necessary for creating an accurate medication history and profile.
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> "Policy: The prescribing physician shall be called for consultation whenever the pharmacist deems it necessary upon reviewing a medication order to prevent any unwanted outcome.
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> "These consultations shall be termed 'interventions' and shall be reviewed by the Pharmacy and Therapeutic Committee."

dosage was and what the proper prescription dosage was. Weeks informed Dr. McMahon that the proper oral loading dosage of colchicine would be 0.5 to 1.2 mg. and a prescription dosage would be a 0.5 to 0.6 mg. tablet to be taken every hour until the symptoms lessened or until the onset of gastrointestinal problems such as cramping, nausea, vomiting, and/or diarrhea. Dr. McMahon testified that Weeks did not ask him any questions about Luther, nor did Dr. McMahon volunteer any information.

Dr. McMahon testified that among Luther's other health problems, Luther suffered from "renal insufficiency," or kidney impairment. Dr. McMahon also testified that he knew that the dosage of colchicine for a patient with renal problems should be lower than for a patient whose kidney function is normal. In fact, as the trial court pointed out in its order denying SMH's postjudgment motions, the proper dosage of colchicine for a patient with normal kidney function is a single 0.5 or 0.6 mg. tablet taken every hour until the

gout pain lessens or gastrointestinal symptoms appear (whichever happens first), but not to exceed a total of 6 mg. The proper dosage for a patient with a history of "renal insufficiency" is a single 0.5 to 0.6 mg. tablet taken every hour until the gout pain lessens or gastrointestinal symptoms appear (whichever happens first), but not to exceed a total of 3 mg. Colchicine is contraindicated for patients with severe renal impairment.

At the conclusion of Dr. McMahon's conversation with Weeks, he altered Luther's prescription and prescribed a loading dose of one 0.6 mg. tablet of colchicine, which the SMH pharmacy sent to Dr. McMahon and which Luther took while he was at the hospital. Dr. McMahon also wrote Luther a prescription for sixteen 0.6 mg. tablets, which could be refilled twice. Weeks was not aware that Dr. McMahon was going to prescribe any tablets for Luther beyond the one tablet dispensed by the SMH pharmacy or that Dr. McMahon was providing any treatment for Luther beyond the emergency room. Dr. McMahon's prescription for sixteen 0.6 mg. tablets of colchicine did not indicate the maximum number of pills that could be taken. Dr. McMahon testified that he prescribed more

medication than Luther was supposed to take for the gout attack in his knee so that if he had of another attack, Luther would not have to pay another co-pay to have the medication refilled. Dr. McMahon further testified that he did not specify in the prescription the maximum number of pills or milligrams of colchicine Luther should take because he had repeatedly emphasized to Luther and his wife during their discussions that Luther should stop taking the colchicine as soon as he experienced either a lessening of the gout symptoms or the onset of gastrointestinal symptoms such as cramping, nausea, vomiting, and/or diarrhea. Luther chose to fill the prescription for 16 colchicine tablets at a local drugstore, independent of SMH. There is no evidence in the record indicating that the pharmacist at the local drugstore contacted Dr. McMahon with concerns about the dosage or that that pharmacist was ever named as a defendant in this action.

On August 15, 2001, Luther took the loading dose at SMH and then, after returning home that same night, continued taking one tablet every hour throughout the night, taking a total of 7.2 mg of colchicine. On August 16, 2001, Luther returned to the SMH emergency room, complaining of vomiting,

nausea, diarrhea, fever, abdominal pain, and abdominal cramping. His attending physician that morning, Dr. Michael Mahoney,[6] diagnosed him with a viral syndrome and a drug reaction to colchicine and sent him home. Luther's symptoms continued to worsen. He was admitted to the Mobile Infirmary Medical Center on August 17, 2001, and he died two days later.

The estate brought a wrongful-death action against several defendants, including Dr. McMahon, Dr. Mahoney, and SMH, alleging that the defendants had negligently failed to provide Luther "reasonably proper and adequate medical care and treatment." A summary judgment was eventually entered for Dr. Mahoney and all the other defendants, except Dr. McMahon and SMH. On January 9, 2006, the first day of the first trial of this case, Dr. McMahon entered into a pro tanto settlement agreement with the estate for $200,000, the existence and amount of which was admitted into evidence at trial, leaving SMH as the only defendant. The first trial ended in a mistrial when the jury could not return a unanimous verdict.

In the second trial, the jury returned a general verdict

[6]Dr. McMahon and Dr. Mahoney were not employees of SMH; they were members and employees of a physicians' professional corporation.

against SMH for $4 million in punitive damages. SMH moved the trial court for, in the alternative, a judgment as a matter of law, a new trial, or a remittitur of the punitive-damages award. The trial court denied the motions, and SMH now appeals to this Court.

Issue

SMH argues that the trial court erred in denying its motion for a judgment as a matter of law by refusing to apply the learned-intermediary doctrine, which, SMH alleges, cuts off Weeks's liability -- and therefore SMH's vicarious liability -- to the estate.[7]

Standard of Review

> "This Court reviews de novo the grant or denial of a motion for a [judgment as a matter of law], determining whether there was substantial evidence, when viewed in the light most favorable to the nonmoving party, to produce a factual conflict warranting jury consideration. Alfa Life Ins. Corp. v. Jackson, 906 So. 2d 143, 149 (Ala. 2005) (citing Ex parte Helms, 873 So. 2d 1139, 1143-44 (Ala. 2003)). '"'[S]ubstantial evidence is evidence of such weight and quality that fair-minded persons in the exercise of impartial judgment can reasonably infer the existence of the fact sought to be

[7]SMH alleges eight other instances of error on the part of the trial court; however, our reversal of the trial court's judgment on this first issue pretermits consideration of the other alleged errors.

proved.'"'"

Jones Food Co. v. Shipman, [Ms. 1051322, December 15, 2006] ___ So. 2d ___, ___ (Ala. 2006). Because SMH's argument is that the trial court erred when it denied SMH's postjudgment motion for a judgment as a matter of law, our review is de novo.

Analysis

SMH argues that the trial court erred in denying its motion for a judgment as a matter of law because, it argues, the learned-intermediary doctrine cuts off any duty Weeks may have owed Luther. The estate, however, argues that the learned-intermediary doctrine does not apply in this case because, it says, the doctrine "exists as a defense in products liability cases" and this is a "simple medical negligence case based on breaches of the standard of care." Estate's brief at 31.

Although we disagree that the learned-intermediary doctrine is limited to products-liability cases,[8] the facts of

[8]In Walls v. Alpharma USPD, Inc., 887 So. 2d 881, 882 (Ala. 2004), the United States District Court for the Northern District of Alabama, presented to this Court the following certified question: "Does a pharmacist have a duty to warn of foreseeable injuries from the use of the prescription drug

this case do require an analysis outside the traditional setting in which we have applied the doctrine. This Court adopted the learned-intermediary doctrine in Stone v. Smith, Kline & French Lab., 447 So. 2d 1301 (Ala. 1984), a case addressing whether a manufacturer's duty to warn extends beyond the prescribing physician to the physician's patients who would ultimately use the drugs. Then, in Walls v. Alpharma USPD, Inc., 887 So. 2d 881, 882 (Ala. 2004), we applied the doctrine to address whether a pharmacist has a "duty to warn of foreseeable injuries from the use of the prescription drug he/she is dispensing." In those cases, the duty at issue was a drug manufacturer's or a drug dispenser's

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he/she is dispensing under AEMLD [Alabama Extended Manufacturer's Liability Doctrine], common-law negligence or other Alabama law?" Walls, 887 So. 2d at 882. The plaintiff in Walls, who was pregnant, took prescription medication that she alleged caused her child to be born with numerous medical conditions. The plaintiff sued both the prescribing physician and the pharmacist who dispensed the prescribed drugs. After discussing the principles underlying the learned-intermediary doctrine, we answered the federal court's question in the negative and concluded that the doctrine "forecloses any duty upon a pharmacist filling a physician's prescription ... to warn the physician's patient, the pharmacist's customer, or any other ultimate customer of the risks or potential side effects of the prescribed medication." Walls, 887 So. 2d at 886. We did not limit our review or our holding to products-liability issues.

duty to warn customers. Here, the duty at issue is not a duty to warn a customer, Luther, of potential risks or side effects, but a duty of care, allegedly breached by Weeks when he gave Dr. McMahon allegedly incomplete dosing information for colchicine. The learned-intermediary doctrine is more than just a narrow rule of law regarding a manufacturer's or pharmacist's limited duty to warn. It addresses questions of liability in light of the relationships between the parties involved in the distribution, prescribing, and use of prescription drugs. We discussed in Walls the policies underlying the learned-intermediary doctrine:

> "'The relationship between 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).
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> "'In Young v. Key Pharmaceuticals, Inc., 112 Wash. 2d 216, 770 P.2d 182 (1989), we stated "[The physician's standard of care regarding] proper dosages of medication is not within the scope of matters on which nonphysicians are competent ...." Young, at 230, 770 P.2d 182.

"'....

> "'Neither manufacturer nor pharmacist has 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. ... 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.'"

Walls, 887 So. 2d at 885-86 (quoting McKee v. American Home Prods. Corp., 113 Wash. 2d 701, 782 P.2d 1045, 1051 (1989)). See also Stone, 447 So. 2d at 1305 ("'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 knowledge of both patient and palliative.'" (quoting Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir. 1974))). On the basis of those underlying policies, we determined in Walls that 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." 887 So. 2d at 886.

Although the facts of Walls differ from those here, the rationale and policies discussed in that decision are directly applicable. Here, we are asked to address the allocation of liability between the same parties involved in Walls -- the pharmacist, the physician, and the patient -- in order to answer the same ultimate question: whether a pharmacist should be liable for harm to a physician's patient resulting from medication prescribed by the physician. The rationale in Walls answers that question: the physician, not the pharmacist, has the medical education and training and the knowledge of a patient's individual medical history necessary for properly prescribing medication; therefore, it is the physician, not the pharmacist, who should bear the liability for mistakes in prescribing or dosing the medication. Walls, 887 So. 2d 886 ("'"[The physician's standard of care regarding] proper dosages of medication is not within the scope of matters on which nonphysicians are competent" ....

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.'" (quoting McKee, 113 Wash. 2d at 711, 782 P.2d at 1051, quoting in turn Young v. Key Pharm., Inc., 112 Wash. 2d 216, 230, 770 P.2d 182, 190 (1989))).

The estate maintains that Weeks breached a duty of care to Luther, which duty, the estate alleges, arose when Weeks voluntarily undertook to give Dr. McMahon information about the proper dosage in administering colchicine.[9] We have held

[9]The estate also argues that Weeks's duty of care arose from statutes and regulations related to the practice of pharmacy and pharmacists. However, as the estate itself notes, the estate "elected as a matter of trial strategy not to introduce evidence of the statutorily and regulatorily [sic] imposed duties out of concern that [it] might run afoul of caselaw holding generally that legislation regulating learned professions cannot be used to establish a private right of action in the breach." "'[T]his Court will affirm a judgment for any reason supported by the record that satisfies the requirements of due process.'" CitiFinancial Corp., LLC v. Peoples, [Ms. 1051519, May 18, 2007] ___ So. 2d ___, ___ (Ala. 2007) (quoting Smith v. Mark Dodge, Inc., 934 So. 2d 375, 380 (Ala. 2006), citing in turn Taylor v. Stevenson, 820 So. 2d 810, 814 (Ala. 2001)). By the estate's own admission, there is no evidence in the record regarding the alleged statutory or regulatory duties. Moreover, the estate has not directed us to any law or facts indicating that the actions of the SMH pharmacy with regard to the only prescription it received from Dr. McMahon, the prescription for a loading dose of 2 mg. of colchicine, violated any of the alleged duties.

that "one who volunteers to act, though under no duty to do so, is thereafter charged with the duty of acting with due care and is liable for negligence in connection therewith." Dailey v. City of Birmingham, 378 So. 2d 728, 729 (Ala. 1979). The estate argues that SMH, through its policies and procedures, voluntarily assumed a duty of care through its pharmacy, and that "SMH's pharmacy voluntarily undertook to be a drug information resource for physicians to rely upon; SMH's clinical pharmacist voluntarily undertook to intervene and consult with Dr. McMahon upon identifying the initial prescription error; and SMH's clinical pharmacist voluntarily undertook to provide dosing information when asked to do so by Dr. McMahon."

The application of the voluntary-undertaking doctrine to a pharmacist is a question of first impression for this Court. The estate argues that courts "have held in numerous factual scenarios that pharmacists voluntarily assumed duties of care." Estate's brief at 46. The estate cites Ferguson v. Williams, 101 N.C. App. 265, 399 S.E.2d 389 (1991); Baker v. Arbor Drugs, Inc., 215 Mich. App. 198, 205-06, 544 N.W.2d 727,

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Therefore, we cannot affirm the judgment on this ground.

731 (1996); and Cottam v. CVS Pharmacy, 436 Mass. 316, 764 N.E.2d 814 (2002).

The cases cited by the estate are readily distinguishable from this one and therefore unpersuasive. In each case cited, the respective court found that the pharmacy or pharmacist had voluntarily undertaken a duty to the customer based on the interactions between the pharmacist and the customer. None of those cases addresses the voluntary assumption of a duty based on a pharmacist's interaction with the customer's physician. See Ferguson, 101 N.C. App. at 272, 399 S.E.2d at 393 ("A druggist simply has the duty to act with due, ordinary care and diligence in compounding and selling drugs. ... [H]owever, ... if a pharmacist undertakes to advise a client concerning a medication, the pharmacist is under a duty to advise correctly."); Baker, 215 Mich. App. at 205-06, 544 N.W.2d at 730-31 ("[T]here is no legal duty on the part of a pharmacist to monitor and intervene in a customer's reliance on drugs prescribed by a licensed treating physician. ... [However], defendant [Arbor Drugs, Inc.] voluntarily assumed a duty of care when it implemented the Arbortech Plus [computer] system and then advertised that this system would detect harmful drug

interactions for its customers."); Cottam, 436 Mass. at 323-26, 764 N.E.2d at 821-23 ("A pharmacy, like any other person or entity, may voluntarily assume a duty ... to provide information, advice or warnings to its customers. ... [T]he scope of the duty voluntarily undertaken by a pharmacy is a fact-specific inquiry based on the totality of the pharmacy's communications with the patient and the patient's reasonable understanding, based on those communications, of what the pharmacy has undertaken to provide.").

Moreover, the pharmacist in Ferguson had specific knowledge related to the patient's medical history, and in Baker the pharmacy had taken steps to provide warnings based on the customer's individual medication profile. Ferguson, 101 N.C. App. at 272, 399 S.E.2d at 394 ("It is undisputed that [the pharmacist] knew that Ferguson was allergic to Percodan .... It is also clear she knew that Ferguson had suffered from an anaphylactic reaction to Percodan."); Baker, 215 Mich. App. at 205, 544 N.W.2d at 731 ("Plaintiff has presented evidence that defendant implemented, used, and advertised through the media that it used, the Arbortech Plus computer system to monitor its customers' medication profiles

for adverse drug interactions."). Here, there is no evidence indicating that Weeks knew anything of Luther's medical history.

Further, the standard of care put forward by the estate[10] would place the physician in a position adjunct to the pharmacist, resulting in exactly the situation our decisions in Walls and Stone sought to prevent, asking the pharmacist to intrude himself or herself into the physician-patient relationship and requiring the pharmacist to give advice or take actions that he or she is neither licensed nor trained to give or take. See Walls, 887 So. 2d at 886 ("'"[The physician's standard of care regarding] proper dosages of medication is not within the scope of matters on which nonphysicians are competent ...." "[P]harmacists are not doctors and are not licensed to prescribe medication because they lack the physician's training in diagnosis and treatment."'" (quoting McKee, 113 Wash. 2d at 711, 782 P.2d at 1051, quoting in turn Young, 112 Wash. 2d at 230, 770 P.2d at

[10]The estate argues that "the standard of care [in this case] required [Weeks] to ask for and obtain more information before he gave an answer to the question about how to dose [c]olchicine."

190)).[11]

In light of the foregoing, we are unpersuaded by the estate's argument that Weeks voluntarily assumed a duty of care when he answered Dr. McMahon's question about dosing colchicine. Because we find the principles articulated in Walls and Stone applicable to this case, we hold that the learned-intermediary doctrine precludes SMH's liability for harm resulting from any mistakes on Dr. McMahon's part in prescribing colchicine. In light of that holding, we hold that the estate, therefore, did not present "substantial evidence ... to produce a factual conflict warranting jury

[11]Even if we were to hold that SMH's "Interventions" policy imposed a duty of care on Weeks, the facts of this case do not demonstrate a breach of that duty. As noted previously, SMH's policy, entitled "Interventions," provided that "[t]he prescribing physician shall be called for consultation whenever the pharmacist deems it necessary upon reviewing a medication order to prevent any unwanted outcome." Weeks followed this policy when he telephoned Dr. McMahon about the only prescription he received with respect to medication to be administered to Luther, namely, one 2 mg. tablet of colchicine. Weeks caught Dr. McMahon's error in prescribing 2 mg. of colchicine to be administered orally -- an improper loading dosage for oral administration -- and informed Dr. McMahon that 2 mg. of colchicine would be a proper loading dosage for colchicine only if it was administered intravenously, and that SMH did not have colchicine available in a format to be administered intravenously.

consideration," Jones Food Co. v. Shipman, [Ms. 1051322, December 15, 2006] ___ So. 2d at ___, and that SMH was entitled to a judgment as a matter of law on this issue. Our decision on this issue pretermits consideration of the other issues argued by SMH on this appeal.

Conclusion

We hold that the principles of the learned-intermediary doctrine apply in this case to foreclose any duty of care owed by Weeks to Luther, based on Weeks's statements to Dr. McMahon regarding the dosing of colchicine. SMH, therefore, was entitled to a judgment as a matter of law, and the trial court erred in denying its postjudgment motion seeking that relief. We reverse the trial court's judgment and render a judgment as a matter of law in favor of SMH.

REVERSED AND JUDGMENT RENDERED.

Cobb, C.J., and Lyons, Woodall, Stuart, Smith, Bolin, Parker, and Murdock, JJ., concur.