2011 IL App (1st) 093306

FIRST DIVISION
September 30, 2011

No. 1-09-3306

GILBERTO HERNANDEZ and RUTH ELIZONDO,	)	Appeal from the
	)	Circuit Court of
Plaintiffs-Appellants,	)	Cook County.
	)	
v.	)	
	)	No. 04 L 9028
SCHERING CORPORATION, SCHERING-PLOUGH	)	
CORPORATION and VICTORIA MCGILL,	)	Honorable
	)	Marcia Maras,
Defendants-Appellees.	)	Judge Presiding.

JUSTICE HALL delivered the judgment of the court, with opinion.

Presiding Justice Hoffman and Justice Karnezis concurred in the judgment and opinion.

O P I N I O N

¶ 1 The plaintiffs, Gilberto Hernandez and his wife, Ruth Elizondo, filed a complaint against the defendants, Schering Corporation, Schering-Plough Corporation (collectively Schering) and Victoria McGill, R.N., (hereinafter Nurse McGill)[1] seeking damages for bodily injuries stemming from Mr. Hernandez's use of PEG-Intron, a drug manufactured and sold by Schering. The circuit court granted the defendants' motion for summary judgment as to six of the counts of the complaint but denied summary judgment on the remaining counts.[2] The circuit court granted

[1] "Defendants" will refer to Schering and Nurse McGill.

[2] Count VII alleging common law fraud and count VIII alleging statutory fraud are not

the plaintiffs' motion for a finding pursuant to Illinois Supreme Court Rule 304(a) (eff. Jan. 1, 2006), and the plaintiffs filed a timely notice of appeal. Subsequently, this court granted the motion of the Illinois Trial Lawyers Association (ITLA) to file an *amicus curiae* brief in support of the plaintiffs.

¶ 2 On appeal, the plaintiffs contend that the circuit court erred in granting summary judgment to the defendants on the strict liability, product liability negligence and negligence in performing a voluntary undertaking counts. They maintain that genuine issues of material fact precluded the summary resolution of these counts of their fourth amended complaint.

¶ 3 BACKGROUND

¶ 4 Counts I through IV of the plaintiffs' fourth amended complaint alleged causes of action in strict liability and product liability negligence and loss of consortium claims against Schering. Counts V and VI alleged negligence in performing a voluntary undertaking and a loss of consortium claim against Schering and Nurse McGill. The following pertinent facts are taken from the materials submitted by the parties in connection with the summary judgment proceedings, as well as other relevant evidence in the record.

¶ 5 In December 2001, Mr. Hernandez tested positive for hepatitis C (HCV), as well as exposure to hepatitis A and hepatitis B. Mr. Hernandez was referred to Dr. Suleiman Hindi, a physician specializing in diseases of the liver and digestive tract.

¶ 6 In his deposition, Dr Hindi testified as follows.[3] After further tests, the doctor diagnosed

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involved in this appeal.

[3]Dr. Hindi was deceased at the time of summary judgment proceedings.

Mr. Hernandez with HCV. The treatment for HCV with the best results was a drug combination, PEG-Intron/Rebetol, consisting of an interferon called Pegylated and Rebetron, an oral medication. While there was another interferon on the market, Dr. Hindi specified PEG-Intron/Rebetol, manufactured by Schering, for his patients because it had been on the market longer and prescribed more frequently.

¶ 7 Dr. Hindi was responsible for ordering the medication for Mr. Hernandez. As part of the medication regime, Dr. Hindi also expected his patients to attend an educational class sponsored by Schering. The class was an additional way to instruct patients how to use the medication and about any possible side effects. Dr. Hindi's nurse would arrange for the classes when there were enough patients for a class to be held.

¶ 8 Dr. Hindi acknowledged that, as a physician prescribing medication, the standard of care required him to inform patients as to the potential side effects of the medication. He did not believe that Schering's class relieved him of his duty to provide information as to the side effects of the medication. He did advise his patients that the majority of individuals taking the PEG-Intron medication suffered some side effects . Though Dr. Hindi had attended seminars and educational programs, he did not recall learning that there were vision-related side effects to PEG-Intron. Since he was unaware of them, he would not have warned Mr. Hernandez of the vision-related side effects of PEG-Intron. Had he been aware that there was a risk the medication could result in blindness, he would have mentioned that fact to the patient.

¶ 9 According to their deposition testimonies, on April 10, 2002, the plaintiffs attended the class taught by Nurse McGill on behalf of Schering. The class took about an hour to an hour

and a half. Nurse McGill distributed a document to the class attendees entitled "Understanding the Side Effects of Interferon Therapy" and informed the class that she would discuss all of the side effects of PEG-Intron. This document did not list blindness as a side effect, and Nurse McGill did not mention any vision-related side effects. In deciding whether to go on the PEG-Intron medication, Mr. Hernandez relied on the information in that document and what Nurse McGill stated in the class about side effects. Had he been aware that the side effects included blindness or other vision-related problems, he would not have taken the medication.

¶ 10 Additional documents were distributed at the class: the PEG-Intron/Rebetol package insert, the medication guide for PEG-Intron, a "frequently asked questions booklet" and a pamphlet entitled " Your PEG-Intron Dose." Among the reported adverse reactions, the package insert listed vision disorders, with blindness occurring in less than 1% of patients. The medication guide stated that persons taking PEG-Intron medication should call their doctors immediately if they experienced decreased vision. The booklet and the pamphlet warned that "serious or clinically significant adverse effects" including "retinal hemorrhages and cotton wool spots" were reported by less than 1% of the patients. The plaintiffs went through all the documents distributed at the class. According to Mr. Hernandez, neither he nor his wife understood the package insert which specifically warned of blindness.

¶ 11 In her deposition, Nurse McGill testified that her role was to educate the patients on how to mix and inject the medication, how to manage the basic side effects and the importance of follow-up visits with their physicians. Basic side effects included flu-like symptoms, fatigue, nausea and injection-site reaction. Nurse McGill did not discuss in detail other potential side

effects, because that was the treating physician's role. She did emphasize the importance of following up with the patient's own doctor. The doctor would be the one to identify the side effects once the patient is on the drug therapy. Nurse McGill did not specifically mention visual problems to the patients in the class. However, the patients were instructed to read all the materials they were given.

¶ 12 Mr. Hernandez began taking PEG-Intron/Rebetol in August 2002. At the time he filled the prescription at a Walgreens Drug store, he received a standard sheet of side effects. He did not recall a warning on the sheet to contact his doctor immediately if, among other things, he experienced vision problems. In the middle of September, he was brushing his teeth when he threw up, and the vision in his right eye became blurred. Initially, he did nothing, believing it would resolve itself. After about four days, he went to the emergency room at MacNeal Hospital. It is uncontested that as a result of taking PEG-Intron, Mr. Hernandez sustained optic nerve damage and permanent vision loss.

¶ 13 In granting summary judgment to Schering on the product liability counts, the circuit court found as a matter of law that the warnings Schering provided to Dr. Hindi in the product insert were adequate. The product insert "delineated the exact problems" suffered by Mr. Hernandez. The court further found that, even if the warning was not adequate, the plaintiffs could not establish proximate cause. According to Dr. Hindi's deposition testimony, had the doctor known of the risk of blindness, he would have told Mr. Hernandez. The doctor never testified that he would have changed the prescription.

¶ 14 In granting summary judgment to the defendants on the "voluntary undertaking" counts,

the court found that whether there was a duty on the part of the defendants was a question of law and that in making such a determination, the court could consider public policy considerations. Noting that there was no Illinois decision in which a drug manufacturer was found to have a duty under the voluntary undertaking theory of liability, the court reasoned that it was because the learned intermediary doctrine recognized the close bond between the physician and the patient. The court therefore declined to recognize a voluntary undertaking as an exception to the learned intermediary doctrine.

¶ 15 The circuit court made a finding pursuant to Illinois Supreme Court Rule 304(a) (eff. Jan. 1, 2006). The plaintiffs filed a timely notice of appeal.

¶ 16 ANALYSIS

¶ 17 I. Standard of Review

¶ 18 This court reviews the grant of summary judgment *de novo*. *Millennium Park Joint Venture, LLC v. Houlihan*, 241 Ill. 2d 281, 309 (2010).

¶ 19 II. Summary Judgment Principles

¶ 20 Our review of a grant of summary judgment is guided by the well-settled principle that "[s]ummary judgment is proper if, and only if, the pleadings, depositions, admissions, affidavits and other relevant matters on file show that there is no genuine issue of material fact and that the movant is entitled to judgment as a matter of law." *Illinois Farmers Insurance Co. v. Hall*, 363 Ill. App. 3d 989, 993 (2006). Since summary judgment is a drastic measure, a court should grant summary judgment only when the moving party's right to judgment is free and clear from doubt. *Bourgonje v. Machev*, 362 Ill. App. 3d 984, 994 (2005). The court must consider all the evidence

in the light most favorable to the nonmoving party. *Bourgonje*, 362 Ill. App. 3d at 994. A triable issue of fact precluding summary judgment exists where the material facts are disputed or, where the material facts are undisputed, reasonable persons might draw different inferences from the undisputed facts. *Gilbert v. Sycamore Municipal Hospital*, 156 Ill. 2d 511, 518 (1993).

¶ 21 A defendant moving for summary judgment bears the initial burden of production, which may be met either by presenting evidence that, left unrebutted, would entitle the moving party to a judgment as a matter of law or by demonstrating that the plaintiff will be unable to prove an element of its cause of action. *Bourgonje*, 362 Ill. App. 3d at 994. If the defendant produces facts entitling it to a judgment as a matter of law, the burden of production shifts to the plaintiff. The plaintiff must present some evidence allowing the imposition of liability on the defendant and supporting each element of his cause of action, thereby defining a genuine issue of material fact to be determined at trial. *Williams v. Covenant Medical Center*, 316 Ill. App. 3d 682, 689 (2000).

¶ 22 III. Discussion

¶ 23 A. *Voluntary Undertaking*

¶ 24 In order to prevail in an action for negligence, the plaintiff must establish that the defendant owed a duty of care to the plaintiff. *Adams v. Northern Illinois Gas Co.*, 211 Ill. 2d 32, 43 (2004). In the absence of a duty owed to the plaintiff, no recovery is possible as a matter of law, and summary judgment for the defendant is proper. *Bourgonje*, 362 Ill. App. 3d at 995.

¶ 25 Whether a defendant has voluntarily undertaken a duty to a plaintiff is a question of law for the court. *Bourgonje*, 362 Ill. App. 3d at 995. If there is a dispute as to a material fact

affecting the existence of the undertaking of a duty, summary judgment is improper. *Bourgonje*, 362 Ill. App. 3d at 995.

¶ 26 The plaintiffs contend that conducting classes on PEG-Intron was a voluntary undertaking by the defendants to warn patients of the side effects of PEG-Intron. Liability based on a "voluntary undertaking" is set forth in sections 323 and 324A Restatement (Second) of Torts. Restatement (Second) of Torts §§ 323, 324A (1965). Section 323 deals with the negligent performance of an undertaking to render services, while section 324A deals with the liability to a third person for negligent performance of a voluntary duty. The plaintiffs rely on section 324A , which provides as follows:

> "One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to protect his undertaking, if
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> (a) his failure to exercise reasonable care increases the risk of such harm, or
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> (b) he has undertaken to perform a duty owed by another to the third person, or
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> (c) the harm is suffered because of reliance of the other or the third person upon the undertaking." Restatement (Second) of Torts § 324A (1965).[4]

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[4]The defendants maintain that section 323 of the Restatement (Second) of Torts applies rather than section 324A. Section 323 addresses when the injured party is the person for whom the voluntary undertaking was made. *Bourgonje*, 362 Ill. App. 3d at 996. In the present case, the defendants are alleged to have undertaken the duty owed by Dr. Hindi to Mr. Hernandez, the

¶ 27 The parties agree that, under the learned intermediary doctrine, the duty to warn of the side effects of a drug is owed by the manufacturer to the patient's physician, not the patient. The learned intermediary doctrine provides that "manufacturers of prescription drugs have a duty to warn prescribing physicians of the drugs' known dangerous propensities, and the physicians, in turn, using their medical judgment, have a duty to convey the warnings to their patients." *Kirk v. Michael Reese Hospital & Medical Center*, 117 Ill. 2d 507, 517 (1987).

¶ 28 The plaintiffs argue that by offering the classes on PEG-Intron, which purported to instruct patients, such as Mr. Hernandez, on all of the side effects of PEG-Intron, the defendants chose to forgo the protection of the learned intermediary doctrine and assumed the physician's duty to warn. See *Kasin v. Osco Drug, Inc.*, 312 Ill. App. 3d 823 (2000) (pharmacist lost the protection of the learned intermediary doctrine by voluntarily warning of some but not all side effects).

¶ 29 The defendants respond that the duty to warn of the side effects of medication based on a voluntary undertaking may not be imposed on a drug manufacturer because it would interfere with the physician-patient relationship if the drug manufacturer was held to have assumed that duty in place of the physician. The defendants rely on *Martin v. Ortho Pharmaceutical Corp.*, 169 Ill. 2d 234 (1996). In *Martin*, our supreme court, applying the learned intermediary doctrine, refused to impose the duty to warn on a drug manufacturer that warned of some but not all of the side effects of an oral contraceptive. The court found that the manufacturer had

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third party, injuring Mr. Hernandez (the third party). See Restatement (Second) of Torts § 324A Cmt. d (1965). Hence, section 324A applies in this case.

fulfilled its duty under Illinois law by providing an adequate warning to the physician. *Martin*, 169 Ill. 2d at 244.

¶ 30 *Happel v. Wal-Mart Stores, Inc.*, 199 Ill. 2d 179, 193 (2002), is instructive. In *Happel*, Wal-Mart filled a prescription for the plaintiff, even though it was aware of the plaintiff's drug allergies and that the prescribed medication was *"contra*indicated" given those allergies. The supreme court first addressed the learned intermediary doctrine, explaining as follows:

> "[T]he rationale underlying the learned intermediary doctrine is that because the prescribing physician has knowledge of the drugs he is prescribing and, more importantly, knowledge of his patient's medical history, it is the physician who is in the best position to prescribe drugs and monitor their use. Thus manufacturers of these drugs should not be required to warn individual patients of the dangers inherent in their use. That is the proper province of the prescribing physician, not the drug manufacturer, who has a duty only to warn the physician." *Happel*, 199 Ill. 2d at 193.

¶ 31 In light of the rationale behind the learned intermediary doctrine, the supreme court rejected Wal-Mart's argument that the doctrine precluded imposing a duty to warn of the dangers of a drug onto a pharmacy. The court found that imposing a duty to warn "would not have intruded Wal-Mart into the doctor-patient relationship, forcing it to 'practice medicine without a license.' [Citation.] We agree with the appellate court below that '[t]his is not a case in which the plaintiff is asking the pharmacist to exercise any modicum of medical judgment or to interject himself into the doctor-patient relationship.' " *Happel*, 199 Ill. 2d at 194-95 (quoting *Happel v. Wal-Mart Stores, Inc.*, 316 Ill. App. 3d 621, 627-28 (2000)).

¶ 32 Unlike *Happel*, imposing the duty to warn of the side effects of PEG-Intron on the defendants based on the classes Schering sponsored would interject the defendants into Mr. Hernandez's relationship with Dr. Hindi. In his deposition, Dr. Hindi testified that the standard of care required him to inform his patients of the potential side effects of the medication he prescribed for them. He further testified that sending his patients to the Schering class did not relieve him of his duty to provide information as to the side effects of the medication. In addition, Nurse McGill testified that the patients attending the Schering class were instructed to discuss the side effects with their physician.

¶ 33 The plaintiffs offer an alternative basis for finding that the defendants owned them a duty, relying on *Happel.* The court in *Happel* found that the pharmacy owed a duty of ordinary care to the plaintiff, based on the following elements: foreseeability that the conduct would cause harm, the likelihood of the injury, the burden of guarding against such injury and placing that burden on the defendant. *Happel*, 199 Ill. 2d at 186-87. But the court then determined that the learned intermediary doctrine did not apply under the facts of that case because imposing the duty would not interfere with the physician-patient relationship. *Happel*, 199 Ill. 2d at 194-95.

¶ 34 In the present case, the learned intermediary doctrine does apply. The evidence established that Dr. Hindi recognized and accepted the responsibility for warning the plaintiffs about the side effects of PEG-Intron. In this case, to hold that the defendants voluntarily undertook to warn of the side effects of PEG-Intron would violate the learned intermediary doctrine.

¶ 35 Finally, the ITLA *amicus curiae* urges this court to recognize an exception to the learned

intermediary doctrine where a manufacturer and seller of a drug replaces the patient's physician as the primary provider of information as to the risks and benefits of a drug. However, such an exception would not apply here as this case does not involve direct-to-consumer advertising. There was no evidence that prior to taking Schering's class, Mr. Hernandez had ever heard of PEG-Intron until Dr. Hindi prescribed it for him or that he requested that Dr. Hindi prescribe PEG-Intron to treat his HCV.

¶ 36 We conclude as a matter of law that providing classes dealing with PEG-Intron was not a voluntary undertaking and thus, the issue was properly resolved by summary judgment.

¶ 37 B. *The Product Liability Claims*

¶ 38 "To recover in a products liability action, a plaintiff must plead and prove that the injury resulted from a condition of the product, that the condition was an unreasonably dangerous one, and that the condition existed at the time the product left the manufacturer's control." *Sollami v. Eaton*, 201 Ill. 2d 1, 7 (2002). A product may be unreasonably dangerous because of the manufacturer's "failure *** to warn of [a] danger or instruct on the proper use of the product as to which the average consumer would not be aware." *Sollami*, 201 Ill. 2d at 7.

¶ 39 The plaintiffs contend that the circuit court erred by finding as a matter of law that the warning provided by the defendants to Dr. Hindi was adequate. They maintain that a question of fact as to the adequacy of the warning precluded summary judgment.

¶ 40 In a strict liability case, the adequacy of the warning usually presents a jury question. *Palmer v. Avco Distributing Corp.*, 82 Ill. 2d 211, 221 (1980). The sufficiency of the warning can become a question of law where the warning is clear, accurate and unambiguous. *Upjohn*

Co. v. MacMurdo, 562 So. 2d 680 (Fla. 1990); see *Kelso v. Bayer Corp.*, 398 F.3d 640 (7th Cir. 2005) (applying Illinois law and holding summary judgment was proper where the warning was plain, clear and accurate).

¶ 41 In support of its motion for summary judgment on the product liability counts, Schering relied on the package insert which specifically warned of blindness. In response to the motion, the plaintiffs relied on the deposition testimony of Dr. Peter Rost. Dr. Rost testified that blindness was a serious side effect. In his opinion, the manufacturer should have drawn attention to the blindness side effect by placing the warning as to blindness in a "Black Box." Failure to do so rendered the warning inadequate. The circuit court noted that Dr. Rost was the only witness to offer an opinion on the adequacy of the warning. However, as Dr. Rost was not a licensed physician who could prescribe medication in Illinois, the court found that he was not competent to give an expert opinion on the adequacy of the warning.

¶ 42 The defendants maintain that the plaintiffs have forfeited the issue as to the competency of Dr. Rost's opinion testimony by failing to raise and argue the issue in their opening brief on appeal. See Ill. S. Ct. R. 341(h)(7) (eff. July 1, 2008). In their reply brief, the plaintiffs did respond to the defendants' discussion of the issue in their appellee's brief. Even if the issue was not forfeited, the plaintiffs failed to establish that Dr. Rost was competent to give an expert opinion on the adequacy of the warning as to the risk of blindness contained in the package insert.

¶ 43 The duty to warn of the dangers of prescription drugs is owed to the physician, and therefore, the adequacy of the warning must be judged by whether it sufficiently apprises

physicians of the risks associated with the use of the drug. *Northern Trust Co. v. Upjohn Co.*, 213 Ill. App. 3d 390, 401 (1991). "For that reason, only a physician or someone with specialized knowledge would be qualified to determine whether the warning was inadequate." *Northern Trust Co.*, 213 Ill. App. 3d at 398. The court in *Northern Trust Co.* further held that just as medical malpractice cases in Illinois required expert testimony, " expert testimony shall be necessary and proper *** where a drug manufacturer's liability for a prescription drug is based upon its failure to provide adequate warnings." *Northern Trust Co.*, 213 Ill. App. 3d at 399. The court limited the expert witness requirement to those situations where the adequacy of the label was not so obvious that a lay person could not readily understand the insufficiency of the warning. *Northern Trust Co.,* 213 Ill. App. 3d at 399.

¶ 44 In determining whether a witness is competent to render an expert opinion, the court considers whether the witness's education, training, knowledge and skill afford the witness knowledge and experience beyond that of the average citizen and whether that knowledge will assist the trier of fact. *Thompson v. Gordon*, 221 Ill. 2d 414, 429 (2006). A person's practical experience in a field may serve well enough to qualify him. *Thompson*, 221 Ill. 2d at 429. Whether to admit expert testimony is within the discretion of the trial court. *Thompson*, 221 Ill. 2d at 428.

¶ 45 The defendants maintain that Dr. Rost's competency to testify as an expert in this case must be determined by applying the three-part analysis set forth in *Purtill v. Hess*, 111 Ill. 2d 229 (1986). We disagree. That test is applicable to whether a medical expert is qualified to give an opinion on the standard of care applicable to a physician in a malpractice case. See *Alm v.*

Loyola University Medical Center, 373 Ill. App. 3d 1, 4-5 (2007). The adequacy of the warning, not the standard of care, is at issue in this case.

¶ *46* The plaintiffs maintain that Dr. Rost was qualified to give an expert opinion on the adequacy of the warning because of his "specialized knowledge." Dr. Rost graduated from medical school in Sweden, where he practiced as an anaesthesiologist for one year. He then worked in the areas of advertising, medical education and marketing for several drug companies. Between 2001 and 2005, he oversaw the creation, publication and distribution of marketing materials for drugs and medical devices for drug companies. He visited physicians' offices with the drug representatives and provided input as to packaging inserts, which eventually became part of the drug listing in the Physician's Desk Reference.

¶ 47 According to his deposition testimony, Dr. Rost was not an expert in pharmacology, ophthalmology or neurophthalmology and was not an expert in the side effects of interferons. He had no experience as a physician prescribing medication for a patient. Dr. Rost's experience was in marketing, and he acknowledged that his expert's report in this case was from the point of view of a pharmaceutical marketing expert. Dr. Rost had no knowledge gained by either education or experience as to what a practicing physician, as opposed to a marketing expert, would consider an adequate warning when determining whether to prescribe a particular medication for a patient. Therefore, Dr. Rost had no specialized knowledge to qualify him to testify as an expert on the adequacy of a side effects warning to prescribing physicians.

¶ 48 We conclude that the circuit court did not abuse its discretion when it found that Dr. Rost was not competent to render an expert opinion on the adequacy of the warning. Without the

expert testimony, the plaintiffs cannot prevail on their product liability claims. *Northern Trust Co.*, 213 Ill. App. 3d at 399. Therefore, summary judgment on counts I through IV was proper. Deciding this issue as we do, we need not address the defendants' alternative argument that an inadequate warning was not a proximate cause of the injury to Mr. Hernandez.

¶ 49 The order of the circuit court granting summary judgment to the defendants on counts I through VI of the fourth amended complaint is affirmed.

¶ 50 Affirmed.