SECOND DIVISION

June 6, 2006

No. 1-04-1621

SHARON KENNEDY, as Administrator of the Estate of Ralph G. Studzinski,

Plaintiff-Appellant,

v.

MEDTRONIC, INC.,

Defendant-Appellee.

Appeal from the Circuit Court of Cook County.

Honorable David G. Lichtenstein, Judge Presiding.

JUSTICE SOUTH delivered the opinion of the court:

Plaintiff, Sharon Kennedy, as administrator of the estate of her father, Ralph G. Studzinski, brought this negligence action seeking damages for the alleged injury and wrongful death of her father following the implantation of a cardiac pacemaker and lead manufactured by defendant, Medtronic, Inc. The trial court granted Medtronic's motion for summary judgment.

The following facts are taken from the pleadings, depositions, affidavits, and exhibits contained in the record on appeal: On July 16, 1999, Dr. Joshua Salvador, a medical doctor licensed to practice medicine in Illinois, surgically implanted a Medtronic pacemaker and lead into the aorta and left ventricle of decedent's heart. Mr. Studzinski was 75 years old at the time of the procedure. Various witnesses provided deposition testimony, including Dr. Salvador, who testified that Mr. Studzinski had been his patient for over 15 years and had various health problems. Mr. Studzinski was afraid of hospitals and refused to have the implantation procedure

performed unless it was done on an outpatient basis. Dr. Salvador had inserted hundreds of pacemakers during the course of his career but had retired from hospital surgery and given up his surgical privileges at Thorek Hospital in 1995. The procedure performed on Mr. Studzinski occurred in an outpatient setting at Dr. Salvador's clinic, the Heart, Lung, and Vascular Institute (HLVI), which had just opened. It was the first such procedure Dr. Salvador had performed at HLVI, and he released Mr. Studzinski on the same day.

Dr. Salvador testified that Mr. Studzinski was provided local anesthesia with intravenous sedation, and his blood pressure, heart, and respiratory rates were monitored. Dr. Isham Afifi, a dentist who worked with Dr. Salvador at HLVI, monitored Mr. Studzinski during the surgery. A record of the monitoring of the patient's vital signs was not maintained. A clinical specialist provided by Medtronic was handed the wires from the pacemaker and checked them. Two registered nurses were also present, one of whom was the doctor's wife and one who was provided by a local agency.

Following the surgery, Mr. Studzinski continued to experience various health problems. In December 1999, he was taken to Oak Park Hospital after he was found in bed unresponsive. Dr. Balasubramaniam Iyer testified he discovered the electrode to the pacemaker had been placed in the left ventricle of the heart and determined it would need to be relocated to the right ventricle. On December 26, 1999, Dr. Iyer removed the device and implanted a new pacemaker and lead into the right ventricle. On April 24, 2000, Mr. Studzinski died of acute renal failure and congestive heart failure. Dr. Salvador subsequently admitted he deviated from the standard of care by inserting the pacemaker lead into the left ventricle and not identifying that the

pacemaker lead was left there.

Medtronic is a medical device manufacturer that makes a variety of implantable cardiac devices, including cardiac pacemakers and leads. These products are prescription medical devices which Medtronic sells only to licensed physicians. The safety of the device implanted into the decedent was not an issue, and there was no evidence of a defect. Heather Friedman, who had worked as a clinical specialist for Medtronic for approximately eight years, was present during the surgery. She provided technical support to ensure the lead parameters were correctly calibrated and the lead was functioning properly.

Friedman testified she is a registered nurse and while working for Medtronic she has provided technical support for one to three pacemaker insertion procedures per day, five days a week. Friedman was trained as a clinical specialist by Medtronic and was certified by the National Association of Pacing Electrophysiology (NASPE). Friedman's primary responsibility was to make sure that when the doctor puts the lead into the ventricle, she paces the heart and determines whether it is capturing or sensing appropriately. Friedman did not assist the doctor in inserting the pacemaker and lead and could not make a judgment as to whether the lead was placed in the appropriate ventricle. During Mr. Studzinski's surgery, in addition to herself and Dr. Salvador, she recalled a man, referred to as a doctor, stood at the head of the table and took the patient's blood pressure, and he had difficulty inserting the patient's IV. There was also a woman present who was responsible for "the sterile field."

Friedman further testified there was a continuous cardiac monitor on the patient and a portable X-ray machine which was used during the surgery which enabled her to see the lead.

She did not have the medical expertise, however, to tell whether the lead was in one place or another. Friedman recalled the patient screamed somewhat loudly that he was in pain several times during the beginning of the procedure. At the completion of the surgery, she interrogated the device and made sure the lead was capturing appropriately and that there was an adequate amount of energy to pace it. Friedman testified that a pacemaker should be placed in the right ventricle and was not made aware that it had been placed in Mr. Studzinski's left ventricle until the date of her deposition. The procedure involving Mr. Studzinski was the first time ever she had participated in a setting outside of a hospital. The only experiences she had in 1998 and 1999 involving same-day surgeries were battery or generator replacements.

Plaintiff testified that she accompanied her father to Dr. Salvador's office on the day of the surgery. The surgical room was located downstairs from the office, and although she was unhappy with her father's decision to have the procedure performed there, it was what he wanted. Prior to the procedure, Friedman, the representative from the pacemaker manufacturer, told her, " 'Don't worry about anything. Dr. Salvador has put in thousands of these. He's very qualified and everything is going to be fine. ' " Plaintiff took her father home that same evening, although he was very groggy when he left the clinic.

Dr. Kathleen Ward testified that she has participated in many invasive surgical procedures, including pacemaker implants, and is familiar with the role of the technical representative. Dr. Ward opined that Friedman should have refused to participate in the insertion of the decedent's pacemaker. Her opinion was based on the fact that the procedure was not done in a hospital but in an office structure, and that she should have noticed there were no recovery

room facilities and personnel to supervise the patient after the surgery. Dr. Ward testified the procedure could not have gone forward or been completed without Friedman.

Dr. Harvey Alpern, a cardiologist with a background in pacemaker implant procedures, testified in his deposition that a reasonable standard of care would require the doctor to monitor and record the various vital signs during the pacemaker implant surgery. The implantation of a single lead pacemaker, such as the one in this case, also requires monitoring for at least part of a day in order to make sure that any changes in the body do not dislodge the newly placed device. Dr. Alpern opined that "an inpatient admission to a monitored bed, whether it be in the hospital or as part of the hospital complex, is necessary." When asked what criticisms he had of Friedman, he replied:

> "[S]he went to a facility that was not a full-fledged medical center or associated with any major hospital and it was an outpatient facility and since she testified that she had never seen this before, my criticism is that she should have called - either left or called her superiors to find out what to do."

Dr. Alpern testified that one of the choices available to Friedman was to leave and not provide the equipment until she received approval from one of her superiors.

On April 18, 2002, the trial court granted plaintiff leave to file her second amended complaint in which she added Medtronic as a party. In her wrongful death and survival cause of action against them, plaintiff alleged that her father suffered severe complications due to the improperly inserted pacemaker lead which resulted in his death. Plaintiff also alleged, in

relevant part, that Medtronic was negligent in selling the pacemaker to Dr. Salvador and through its participation and assistance in the pacemaker implant procedure.

On March 9, 2004, the trial court granted Medtronic's motion for summary judgment. On May 12, 2004, plaintiff's complaint against defendants Dr. Salvador, Holistic and Anti-Aging Institute, and HLVI was dismissed with prejudice following resolution, compromise, and/or settlement. On June 2, 2004, the trial court granted plaintiff's motion for Rule 304(a) (155 Ill. 2d R. 304(a)) findings in her cause against Medtronic, the sole remaining defendant, and this appealed followed. *Amicus curiae* briefs have been filed by St. Jude Medical, Inc., and Product Liability Advisory Council, Inc., in support of Medtronic.

Plaintiff contends the trial court erred by granting Medtronic's motion for summary judgment because it owed the decedent a duty of care and because genuine issues of material fact exist with respect to breach and proximate causation. Specifically, plaintiff contends Medtronic owed decedent, under the unique circumstances of this case, the following three duties: (1) to refrain from providing a pacemaker to Dr. Salvador and from participating in the insertion of the pacemaker when she knew he intended to proceed in an inadequate facility without qualified personnel present and without monitoring any of the patient's vital signs; (2) to warn of the dangers inherent in proceeding with the surgery under the conditions present; and (3) to assist with the insertion in a reasonable manner once it voluntarily undertook to participate. Medtronic responds there is no legal basis to support any of plaintiff 's claims of duty and, in particular, that it had no duty to prevent physician malpractice or to guarantee against it. Medtronic also asserts that under the learned intermediary doctrine it was exempt from having to warn decedent or his

family of any dangers in proceeding with the surgery.

We apply a *de novo* standard of review in appeals from summary judgment rulings. Williams v. Covenant Medical Center, 316 Ill. App. 3d 682, 688 (2000). Summary judgment is appropriate when the pleadings, depositions, and admissions, together with any affidavits, show that there is no genuine issue of material fact. 735 ILCS 5/2-1005(c) (West 2002); Gilbert v. Sycamore Municipal Hospital, 156 Ill. 2d 511, 517-18 (1993). Accordingly, the party moving for summary judgment must show, as a matter of law, that it is entitled to judgment. Wright v. St. John's Hospital of the Sisters of the Third Order of St. Francis , 229 Ill. App. 3d 680, 682 (1992).

When ruling on a motion for summary judgment, the evidence must be viewed in the light most favorable to the nonmovant. Williams, 316 Ill. App. 3d at 687-88. Where a reasonable person could draw divergent inferences from the undisputed facts, summary judgment should be denied. Outboard Marine Corp. v. Liberty Mutual Insurance Co, 154 Ill. 2d 90, 102 (1992); Loyola Academy v. S & S Roof Maintenance, Inc., 146 Ill. 2d 263, 272 (1992). The purpose of summary judgment is not to try a question of fact but to determine whether one exists. Golla v. General Motors Corp., 167 Ill. 2d 353, 358 (1995). "Summary judgment is a drastic measure and should only be granted if the movant's right to judgment is clear and free from doubt." Outboard Marine Corp., 154 Ill. 2d at 102. In deciding a motion for summary judgment, however, inferences may be drawn from the undisputed facts. Loyola Academy, 146 Ill. 2d at 272. "If what is contained in the papers on file would constitute all of the evidence before a court and would be insufficient to go to a jury but would require a court to direct a

verdict, summary judgment should be entered." Pyne v. Witmer, 129 Ill. 2d 351, 358 (1989).

The essential elements of a cause of action based on common law negligence are the existence of a duty owed by the defendant to the plaintiff, a breach of that duty, and an injury proximately caused by that breach. Kirk v. Michael Reese Hospital & Medical Center, 117 Ill. 2d 507, 525 (1987). The issue before us concerns the existence of a duty, *i.e.*, whether defendant and plaintiff stood in such a relationship to one another that the law imposed upon defendant an obligation of reasonable conduct for the benefit of plaintiff that would support this cause of action. Ward v. K mart Corporation, 136 Ill. 2d 132, 140 (1990). "Four factors are relevant to deciding whether a duty of care exists: (1) the reasonable foreseeability of injury; (2) the likelihood of injury; (3) the burden of guarding against injury; and (4) the consequences of placing that burden on the defendant." Brewster v. Rush-Presbyterian-St. Luke's Medical Center, 361 Ill. App. 3d 32, 35-36 (2005), citing City of Chicago v. Beretta U.S.A. Corp., 213 Ill. 2d 351, 391 (2004). A duty to warn exists where there is unequal knowledge, actual or constructive of a dangerous condition, and the defendant, possessed of such information, knows or should know that harm might or could occur if no warning is given. Happel v. Wal-Mart Stores, Inc., 199 Ill. 2d 179, 186 (2002).

" 'Whether a duty of care exists is a question of law to be determined by the court.' [Citation.]" Beretta, 213 Ill. 2d at 391. However, the question of whether the defendant breached its duty and whether the breach was the proximate cause of the decedent's injuries are factual matters for the jury to decide. Bajwa v. Metropolitan Life Insurance Co., 208 Ill. 2d 414, 422 (2004).

In Kirk, cited by Medtronic, the learned intermediary doctrine was adopted by our supreme court. Under that doctrine, "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, 117 Ill. 2d at 517. The doctrine's rationale is that a doctor is considered in the best position to prescribe drugs and monitor their use because he is knowledgeable of the propensities of the drugs he is prescribing and the susceptibilities of his patient. Kirk, 117 Ill. 2d at 518. Consequently, in selling prescription drugs, the manufacturer is only required to warn the prescribing doctor, who then acts as a "learned intermediary" between the manufacturer and the consumer. Kirk, 117 Ill. 2d at 518. The learned intermediary doctrine was considered by this court in relation to a medical device manufacturer in Hansen v. Baxter Heathcare Corp., 309 Ill. App. 3d 869 (1999). There, in the context of the doctrine, we found that a medical device manufacturer has no duty to warn physicians of the device's dangers which the medical community generally appreciates. Hansen, 309 Ill. App. 3d at 881.

In Fakhouri v. Taylor, 248 Ill. App. 3d 328 (1993), also cited by Medtronic, the plaintiff, as administrator of the decedent's estate, filed a wrongful death claim against the defendant pharmacists who filled the prescriptions on which the decedent allegedly overdosed. The plaintiff claimed the pharmacists had a duty to warn either the decedent or his doctor that the prescribed dosage of medication was for an excessive and unsafe quantity. We found that pharmacists, like drug manufacturers, do not have a duty to warn customers of a drug's potential adverse effects where the pharmacists did nothing more than fill the prescriptions as ordered by the doctor. We noted, to hold otherwise would be to place the pharmacist in the middle of the

doctor-patient relationship. Fakhouri, 248 Ill. App. 3d at 332-33.

In Happel, relied upon by plaintiff, a regular customer of the defendant's pharmacy was injured when she was prescribed a medication that was related to the one she was allergic to. Happel, 199 Ill. 2d at 181. The pharmacy regularly asked customers about their known drug allergies and the plaintiff's allergy information was in the pharmacy's computer and available to it when it filled her prescription. Happel, 199 Ill. 2d at 181-83. The pharmacy's computer system was designed to notify the pharmacist of a contraindication and the pharmacist would have to override the system by entering a special code before dispensing the medication. Happel, 199 Ill. 2d at 182-83. The defendant's pharmacy's failure to adhere to its own policy caused the plaintiff's injury. Happel, 199 Ill. 2d at 183-84.

The supreme court concluded that the scope of protection provided to pharmacists by the learned intermediary doctrine is limited, particularly in situations where a pharmacy has knowledge that a prescribed medication is contraindicated for a specific customer. Happel, 199 Ill. 2d at 195. The learned intermediary doctrine, therefore, did not relieve defendant's pharmacy of a duty to warn either the customer or her doctor that the prescribed drug was contraindicated because the pharmacy knew of the customer's allergies and knew that she was placed at risk of serious injury or death by taking the medicine. Happel, 199 Ill. 2d at 197. The supreme court found that imposing the duty to warn would not require the pharmacist to learn the customer's condition and monitor her drug use because it already had all the knowledge it needed. Happel, 199 Ill. 2d at 187. Also, imposing a duty on the defendant's pharmacy to warn would not intrude into the doctor-patient relationship, forcing it to practice medicine without a license, because the

plaintiff was not asking the pharmacist to exercise any medical judgment or interject himself into the customer's relationship with her doctor. Happel, 199 Ill. 2d at 187-88. Finally, by asking customers about their drug allergies, the pharmacy was found to engender reliance in the customer that it would take steps to ensure the customer did not receive a drug which she was allergic to. Happel, 199 Ill. 2d at 188.

While we find the cases relied upon by the parties to be instructive, the situation here differs, and no Illinois case has addressed plaintiff's specific claim. She advances a theory that Medtronic owed her father a duty to refrain from providing a pacemaker to Dr. Salvador, and participating in the insertion of the device, once Medtronic's clinical specialist discovered the procedure was being performed in a setting that was not part of a hospital with adequate qualified personnel, and which lacked proper monitoring devices to check the patient's vital signs. Plaintiff also claims Medtronic owed her father a duty to warn of the dangers inherent in proceeding with the surgery under the conditions present at Dr. Salvador's clinic.

We reject plaintiff's claim and find the four factors in determining whether a duty exists do not weigh in her favor. Dr. Salvador admitted that he deviated from the standard of care by inserting the pacemaker lead, which was free from defects, into the left ventricle of Mr. Studzinski's heart. Friedman was not responsible for the insertion of the pacemaker and lead and testified that she could not make a judgment as to where a lead was placed. Plaintiff alleged in her second amended complaint that her father suffered severe complications due to Dr. Salvador's error which resulted in his death. These alleged injuries, however, unlike those experienced by the plaintiff in Happel, were not reasonably foreseeable to Medtronic or likely based upon the

surgery being performed at a clinic such as Dr. Salvador's. The implant surgery could have been performed by Dr. Salvador at a full-fledged hospital, and the same error could have occurred. Moreover, in Happel, in stark contrast to this case, the defendant had all of the knowledge it needed that plaintiff was allergic to the medication which had been prescribed and would be placed at risk of serious injury if she took the prescription.

We also find the burden and consequences of imposing the duty proposed by plaintiff to be substantial. It would be a significant burden to require Medtronic to monitor the conditions under which a doctor performs surgery. In Happel, the defendant was not required to learn the customer's condition or monitor her drug use because it already had that necessary information. Moreover, a central aspect of the learned intermediary doctrine, as first adopted by our supreme court in Kirk, is that a licensed physician, such as Dr. Salvador, has the knowledge of his patient's medical history and background, and, therefore, he is in a better position, utilizing his medical judgment, to determine a patient's needs and what medical care should be provided. It would be unreasonable, and potentially harmful, to require a clinical specialist such as Friedman to delay or prevent a medical procedure simply because she believes the setting is not appropriate or the doctor is unqualified. To hold otherwise would place a medical device manufacturer, such as Medtronic, in the middle of the doctor-patient relationship. In Happel, unlike the case at hand, imposing the duty on the defendant's pharmacy to warn did not intrude upon the doctor-patient relationship because the pharmacy was not asked to exercise any modicum of medical judgment or interject itself into the customer's relationship with her doctor. Finally, as pointed out by *amicus*, the consequences of requiring such screening by Medtronic would run the risk of

imposing additional liability on the manufacturer in the event it determined a physician was not in a position to properly implant a device, refused to provide one, and the patient suffered adverse medical consequences because he did not have access to a needed device.

Plaintiff relies, in the alternative, upon section 324A of the Restatement (Second) of Torts in support of her claim that Medtronic owed a duty to assist in a reasonable manner with the surgery once it voluntarily undertook to participate. Plaintiff maintains that Medtronic also voluntarily assumed a duty because Friedman, prior to the surgery, reassured plaintiff about Dr. Salvador's qualification in performing the implant procedure.

"Like other issues of duty, whether a defendant has voluntarily undertaken a duty to a plaintiff is a question of law for the court that is properly addressed in a motion for summary judgment." Lange v. Fisher Real Estate Development Corp., 358 Ill. App. 3d 962, 973 (2005). "Under the voluntary undertaking theory of liability, the duty of care to be imposed on a defendant is limited to the extent of the undertaking." Lange, 358 Ill. App. 3d at 973. Section 324(A) of the Restatement (Second) of Torts has been adopted by courts in Illinois to analyze voluntary undertaking claims. See, *e.g.*, Bailey v. Edward Hines Lumber Co., 308 Ill. App. 3d 58, 65 (1999). Section 324(A) provides:

> "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

(a) his failure to exercise reasonable care increases the risk of such harm, or

(b) he has undertaken to perform a duty owed by the other to the third person, or

(c) the harm is suffered because of reliance of the other or the third person upon the undertaking." Restatement (Second) of Torts §324A (1965).

In the instant case, Medtronic's clinical specialist attended the surgery to provide technical support and ensure that the lead parameters were correctly calibrated and the lead was functioning properly. This limited role did not entail her voluntarily assuming a duty, under section 324A of the Restatement (Second) of Torts, for the placement of the lead into the correct ventricle of the patient's heart. Likewise, plaintiff has failed to demonstrate that Medtronic voluntarily assumed a duty based simply upon a brief conversation between Friedman and plaintiff during which she allegedly reassured plaintiff prior to her father's surgery. According to plaintiff's deposition testimony, Friedman told her not to worry, that Dr. Salvador had put in thousands of pacemakers, and everything would be fine. Plaintiff never alleged that Friedman made any representations about the conditions under which the surgery was being performed at the clinic. We find there is no basis for us to conclude that decedent would not have proceeded with the surgery without Friedman's alleged reassurance. On the contrary, plaintiff, herself, testified that her father insisted upon having the procedure performed at the clinic, despite her reservations, and that it was his decision. This was consistent with Dr. Salvador's testimony that Mr. Studzinski, who had

been his patient for over a decade, was afraid of hospitals and would not agree to have the surgery unless it was done on an outpatient basis. For the foregoing reasons, we reject plaintiff's claim that Medtronic voluntarily assumed a duty.

Inasmuch as Medtronic did not owe a legal duty to the decedent that would support plaintiff's negligence cause of action, we find the trial court properly granted the motion for summary judgment.

Accordingly, the judgment of the circuit court of Cook County is affirmed.

Affirmed.

WOLFSON and HALL, JJ., concur.