First District Refuses to Find Exception to Learned Intermediary Doctrine

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The Illinois Appellate Court, First District, recently applied the learned intermediary doctrine in *Kennedy v. Medtronic, Inc.*, No. 1-04-1621, 2006 WL 1542598, at *9 (1st Dist. June 6, 2006). It held that a medical device manufacturer whose representative provided technical support during a pacemaker implantation procedure in an outpatient setting had no duty (1) to warn the patient of the dangers inherent in having the surgery in an outpatient clinic, (2) to refrain from providing a pacemaker or assisting in the procedure, or (3) to assist with the insertion.

On July 16, 1999, Dr. Joshua Salvador surgically implanted a Medtronic pacemaker and lead into the plaintiff’s father’s heart. The procedure was performed at Dr. Salvador’s clinic, the Heart, Lung and Vascular Institute (“HLVI”), because the plaintiff’s father was afraid of hospitals and insisted on having the procedure done on an outpatient basis. The pacemaker’s manufacturer provided a clinical specialist to ensure the lead parameters were correctly calibrated and the lead was properly functioning. The cardiac pacemaker and lead are prescription medical devices that the manufacturer sells only to licensed physicians.

The plaintiff’s father was released the same day of the procedure. He continued to experience various heart problems that year, and was hospitalized in December of 1999. His treating physician, Dr. Iyer, determined that the pacemaker’s electrode had been mistakenly placed into the left ventricle rather than the right ventricle. Dr. Iyer properly inserted a new pacemaker. Five months afterwards, the plaintiff’s father died of acute renal and congestive heart failure. Dr. Salvador admitted later that he had deviated from the standard of care by placing the pacemaker lead into the left ventricle.

The plaintiff, as executor of her father’s estate, filed a wrongful death action against Dr. Salvador, HLVI and the manufacturer because of the improperly inserted pacemaker. The plaintiff also alleged that the manufacturer was negligent in selling the pacemaker to Dr. Salvador and in participating and assisting in the implantation procedure.

The trial court granted the manufacturer’s motion for summary judgment. Two months later, the plaintiff’s complaints against Dr. Salvador and his clinic were dismissed following settlement. The plaintiff appealed the summary judgment order.

On appeal, the plaintiff alleged that the manufacturer owed the decedent three duties: 1) to refrain from providing a pacemaker to Dr. Salvador and participating in the procedure when the company knew the procedure was going to be done in an inadequate facility without qualified personnel present and without monitoring the patient’s vital signs; 2) to warn of the dangers inherent in proceeding with
the surgery under those conditions; and 3) to assist with the insertion in a reasonable manner once it voluntarily undertook to participate.

The manufacturer argued that it owed no duty to the decedent, particularly a duty to prevent physician malpractice. The manufacturer also stated that under the learned intermediary doctrine, the company was not required to warn the decedent of any dangers that accompanied the pacemaker surgery.

The manufacturer relied on *Kirk v. Michael Reese Hospital & Medical Center*, 117 Ill. 2d 507, 513 N.E.2d 387 (1987), the Illinois Supreme Court case which adopted the learned intermediary doctrine. The doctrine states that “manufacturers of prescription drugs have a duty to warn prescribing physicians of a drug’s known dangerous propensities, and the physicians, in turn, using their medical judgment, have a duty to convey the warnings to their patients.” *Id.* at 517, 513 N.E.2d at 392. The manufacturer also relied on *Hansen v. Baxter Healthcare Corp.*, 309 Ill. App. 3d 869, 723 N.E.2d 302 (1st Dist. 1999), which held that a medical device manufacturer has no duty to warn doctors of a device’s dangers that are generally appreciated by the medical community. The manufacturer also cited to *Fakhouri v. Taylor*, 248 Ill. App. 3d 328, 618 N.E.2d 518 (1st Dist. 1993), in which the court held that pharmacists have no duty to warn customers of a drug’s potential harm when the pharmacist simply fills a prescription written by a doctor. The *Fakhouri* court stated that a duty should not be imposed on a pharmacist that would place the pharmacist in the middle of the doctor-patient relationship.

The plaintiff argued, based on *Happel v. Wal-Mart Stores, Inc.*, 199 Ill. 2d 179, 766 N.E.2d 1118 (2002), that the manufacturer owed a duty to the decedent. In *Happel*, the Illinois Supreme Court found the learned intermediary doctrine inapplicable where a pharmacy had actual knowledge that a drug was contraindicated for a specific customer. The defendant pharmacy regularly asked customers about their drug allergies and entered the information into a computer system that was designed to notify the pharmacist of any conflict of medications. Despite this practice, the customer was given a medication to which she was allergic and suffered a subsequent injury. The court stated that when a pharmacist has knowledge of a patient’s allergies, the pharmacist has a duty to warn the patient of any contraindicated medications. Imposing such a duty would not further burden the pharmacist because the customer’s condition would already be known. Further, the pharmacist would not be inserted in the middle of the doctor-patient relationship because the pharmacist would not be exercising any independent medical judgment.

**Duty to Warn / Duty to Refrain from Providing Medical Device or Participate in Procedure**

The appellate court stated that the *Kirk*, *Fakhouri*, *Hansen*, and *Happel* cases were instructive but did not address the specific issue in the present case. In fact, no Illinois case had addressed the plaintiff’s claim: that the manufacturer owed her father a duty to refrain from providing the pacemaker to the doctor and from participating in its insertion once its specialist learned of the inadequate facility in which the procedure was to be performed.

The court rejected the plaintiff’s claim that the manufacturer was required to warn the decedent of the dangers in having the surgery at an outpatient clinic. The court distinguished the present case from *Happel*, where the plaintiff’s injuries were reasonably foreseeable. Here, the manufacturer could not have foreseen Dr. Salvador’s error of placing the device’s lead into the wrong ventricle. In addition, the physician’s error was not likely related to the procedure being performed in an outpatient clinic and could just as easily have happened in a hospital setting.

The court also stated that requiring companies like the manufacturer to warn customers of potential risks of surgery would impose substantial burdens. In contrast to *Happel*, where the defendant already had knowledge of the customer’s medical condition, here, manufacturers would be required to monitor
the conditions under which each surgery is performed. Under the learned intermediary doctrine, doctors such as Dr. Salvador with knowledge of their patient’s conditions are better positioned to make judgments regarding medical procedures. The court refused to require a manufacturer’s clinical specialist to delay or prevent a procedure because of a belief that the setting is inappropriate or the doctor is unqualified. To do so, the court stated, would insert a medical device manufacturer into the doctor-patient relationship. Additional liability could also result if a manufacturer refused to provide a device to an unqualified doctor and the patient suffered injury for lack of the needed device.

**Voluntary Assumption of Duty**

The plaintiff argued that under the Restatement (Second) of Torts § 324(A), Medtronic voluntarily undertook a duty to the decedent by having one of its specialists participate in the procedure. Section 324(A) states

> [o]ne 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 . . . .

The court rejected that argument and found that the specialist’s sole responsibility during the procedure was to provide technical support and to ensure the pacemaker’s lead parameters were correctly calibrated and properly functioning. The specialist could not judge whether or not the lead had been placed into the correct ventricle.

The court also dismissed the plaintiff’s argument that the manufacturer had voluntarily assumed a duty when the specialist made reassurances to the decedent prior to the surgery. The court further found that the decedent’s fear of hospitals would have compelled him to have the procedure done on an outpatient basis regardless of any assurances by the specialist. The court concluded that the manufacturer did not owe a duty to the decedent and, thus, upheld summary judgment.

**Conclusion**

The *Kennedy* case demonstrates that the learned intermediary doctrine remains an effective defense for medical products manufacturers. The First District Appellate Court was unwilling to find an exception to the longstanding doctrine and solidified the notion that physicians, not manufacturers, are solely responsible for warning patients of the dangers of a medical procedure. The Illinois Supreme Court’s failure to apply the learned intermediary doctrine in *Happel*, its most recent decision regarding the doctrine, could have emboldened an appellate court to further weaken the doctrine and craft additional exceptions. Nonetheless, the First District correctly recognized that *Happel* was an extremely narrow decision.
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