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PRODUCT LIABILITY

Washington Product Liability Act requires device manufacturers to provide warnings to hospital purchasers

The Washington State Supreme Court has ruled that manufacturers of prescription devices have a duty under the state's Product Liability Act (PLA) to provide warnings to hospital purchasers of their devices if they are to avoid strict liability under the PLA. The case at bar involved injuries to the decedent patient from alleged improper patient selection and use of the da Vinci System robotic surgery device. The manufacturer provided training for the surgeon, which included selection of patients with a BMI less than 30, with no prior abdominal surgery, and the need for placing the patient in a "steep Trendelenburg position," all of which precautions were violated by the surgeon in the instant case. The hospital chose to specify only 2 proctored operations with the device prior to credentialing the surgeon, where other hospitals in the region required 3 or 4 proctored procedures. It was conceded that the manufacturer did not provide specific warnings to the hospital that accompanied the device, and the estate alleged that therefore the manufacturer was strictly liable for injuries caused by the device under the PLA, and under Washington's adoption of the learned intermediary doctrine and comment k to the Restatement of Torts.

The estate sued the surgeon, the hospital, and the manufacturer, the latter under claims for product defect, breach of warranty, breach of contract, violation of the state Consumer Protection Act, negligence, and product liability under the PLA. The physician and hospital settled and the a jury returned a verdict for the manufacturer on the plaintiff's failure to warn claim. On appeal, the plaintiffs argued that the trial court erred by failing to instruct the jury on the manufacturer's duty to warn the hospital under a strict liability standard, and a divided appellate panel held that a negligence standard was appropriate. The estate appealed to the Supreme Court.

The Court agreed with the estate, holding that hospitals who purchase complex devices retain responsibility for their use, and that hospitals are "purchasers" for the purposes of the PLA, which explicitly requires provision of warnings "with the product." Because the PLA imposes a separate and distinct duty to provide warnings to purchasers, its failure to warn the hospital precluded application of the learned intermediary doctrine to find that in warning the physician it satisfied its duty to warn the hospital purchaser. Rather, the Court noted, the learned intermediary doctrine operates to allow warnings to the prescriber to satisfy a need to warn the patient. The hospital was able to purchase the da Vinci System without any intervening action by a prescriber. Or, as the dissenting

appeals court judge was quoted, "While a physician is the gatekeeper between the manufacturer and the unwarned patient, a physician is not a gatekeeper between the manufacturer and the unwarned *hospital* ..."

Finally, the Court clarified that its adoption of the Restatement of Torts §402A requires it to hold that in this instance, the Restatement's plain language augurs for application of the usual strict liability standard to failure to warn claims. It explained that comment k on unavoidably unsafe products confers a lack of unreasonable danger or defect on such products only when the product is "accompanied by proper directions and warning," and therefore proper warnings are a prerequisite to analyzing exemption from strict liability under comment k. Furthermore, comment k does not address the adequacy of the warnings, which must be determined by the trier of fact prior to applying comment k. Three justices dissented in part, agreeing that a duty is owed by a manufacturer to provide warnings to a hospital purchaser of a prescription device; however, they disagreed that such a duty extends to the patient. Rather, the dissent argued, only the hospital should be allowed to assert a claim against the manufacturer; the hospital's unwarned actions that failed to protect the patient were addressed in the plaintiff's claim against the hospital which was settled by the parties. [Taylor v. Intuitive Surgical, Inc., No. 92210-1, S.Ct. Wash., February 9, 2017]