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Washington Case Update

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Manufacturers of Medical Supplies Must Warn Purchasers of Potential Risks

From the desk of Kyle Riley: Washington's products liability act requires manufacturers to warn consumers about the risks of their products. But when the manufacturer of a medical device has provided warning to the product user—the physician—does it also have a duty to warn the hospital that purchased the product? Read on to find out.

Claims Pointer: In this case arising out of surgical complications that resulted in a loss of quality of life and ultimately the death of the patient, the Washington Supreme Court held that the manufacturer did have a duty to warn the hospital of risks associated with the product. This case provides important insight into the scope of the manufacturer's duty to warn, especially in the medical context.

Taylor v. Intuitive Surgical, Inc., No. 92210-1, Washington Supreme Court (February 9, 2017)

Intuitive Surgical, Inc. ("ISI") manufactures a robotic surgical device called the "da Vinci System." Surgeons use the device to perform minimally invasive robotic laparoscopic surgeries. The device requires training and experience to operate it correctly, even for surgeons with expertise in open surgery. ISI accordingly requires that surgeons perform two proctored surgeries, and hospitals also enforce their own requirements for credentialing surgeons to use the device. ISI also recommends that surgeons choose simple cases for initial unproctored procedures and ISI provides a user's manual to doctors containing various warnings related to the device. Three ISI warnings are particularly relevant: (1) not to perform prostatectomies on obese persons (guidelines stated that patients should have a body-mass index ("BMI") below 30; (2) not to perform prostate procedures on persons who previously underwent lower abdominal surgeries; and (3) that patients should be in a steep Trendelenburg position (tilted with head downward) during the procedure.

Dr. Scott Bildsten had 15 years of experience performing open prostatectomies, and he had performed between 80 and 100 such procedures prior to Fred Taylor's surgery. He had performed two proctored prostatectomies but no unproctored procedures before operating on Mr. Taylor for prostate cancer in September 2008. At the time of surgery, Mr. Taylor weighed 280 pounds and had a BMI of 39 (exceeding ISI's recommended maximum BMI of 30); he had three prior lower abdominal surgeries (contrary to ISI's advice to avoid patients with prior lower abdominal surgeries); and Dr. Bildsten did not position him in the steep Trendelenburg position due to his weight (contrary to ISI's advice to conduct the procedure in that position). Although Dr. Bildsten knew Mr. Taylor was not an optimal candidate, he performed the prostatectomy as his first unproctored procedure using the da Vinci System.

Mr. Taylor suffered complications that resulted in respiratory failure, renal failure, incontinence, and neuromuscular damage. A year later, Mr. Taylor filed suit against Dr. Bildsten, his partner, their medical practice, and Harrison Medical Center, later adding ISI as a defendant. Roughly four years after the surgery, he passed away, and his wife, Josette Taylor ("Taylor"), proceeded with the lawsuit as representative of his personal estate. Prior to trial, Taylor settled with the physicians, their practice, and the hospital. She proceeded against ISI on multiple theories, but the trial court granted summary judgment for ISI on all claims but one: failure to warn under the Washington Product Liability Act (WPLA). At trial, ISI presented expert testimony describing its training process, including training on "how

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to select the best candidates for starting your experience," such as choosing "thin patients" and those with no prior abdominal surgery. The jury returned a verdict in favor of ISI, finding that ISI was not negligent in providing warnings or instructions to Dr. Bildsten. Taylor appealed on several grounds, including that the trial court erred in declining to instruct the jury that ISI had a duty to warn Harrison Medical Center.

The WPLA governs product-related harms based on a manufacturer's failure to warn. It provides a basis for claims where a claimant's harm was caused a product that is "not reasonably safe because adequate warnings or instructions were not provided with the product." RCW 7.72.030(1) (emphasis added). Under the WPLA, a product is not reasonably safe if the likelihood and seriousness of potential harms rendered the warnings or instructions of the manufacturer inadequate. The Court noted that the WPLA discussed both (1) warnings owed "with the product" for products where at the time of manufacture, there was a likelihood the product would cause the plaintiff's harm, and (2) warnings provided to "product users" after the product was manufactured. Here, the product was owned and maintained by the purchasing hospital, and the Court reasoned that the purchaser was owed product warnings with the product it purchased.

For the Court, it was logical that hospitals would need warnings, particularly where the product is a complex and inherently dangerous device. Hospitals have an independent duty of care to their patients, and they are required by law to adopt credentialing requirements regarding staffing. Thus, the Court reasoned, it followed that all hospitals need product warnings to design a proper credentialing process. The Court explained that hospitals must maintain a high standard of care for the benefit of their patients, which they cannot do if manufacturers were excused from their duty to provide hospitals with information about devices they own. Thus, it was in the best interest of all parties for warnings to be provided, particularly patients, who trust that their safety is a priority. The Court therefore held that the WPLA requires manufacturers to warn purchasers—in this case, the hospital—about their dangerous medical devices. Because the trial court did not instruct the jury that the manufacturer had a duty to warn the hospital that purchased the device, the defense verdict was vacated, and the case was remanded for retrial.

View full opinion at: https://www.courts.wa.gov/opinions/pdf/922101.pdf

Case updates are intended to inform our clients and others about legal matters of current interest. They are not intended as legal advice. Readers should not act upon the information contained in this article without seeking professional counsel.

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