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Washington Supreme Court Extends Medical-Device Manufacturers' Duty to Warn

by Eric D. Miller

Earlier this year, the Washington Supreme Court decided *Taylor v. Intuitive Surgical, Inc.*, 389 P.3d 517 (Wash. 2017), holding that the manufacturer of a medical device has a duty to warn hospitals, not just physicians, about the potential dangers of the device. The decision represents a significant and unwarranted expansion of the duty to warn under Washington's product-liability law.

Intuitive Surgical Inc. (ISI) manufactured a robotic surgical device for use in laparoscopic surgery, a surgical technique in which operations are performed through small incisions distant from the site of the operation. ISI provided doctors with a user's manual that contained warnings about its device. Among the warnings were (1) that the device should not be used to perform prostate surgery on obese patients, (2) that it should not be used to perform prostate surgery on patients who had previously undergone lower abdominal surgery, and (3) that patients should be tilted with their head downward during the procedure.

Dr. Scott Bildsten, a surgeon in Bremerton, Washington, used an ISI device to perform prostate surgery on Fred Taylor. Dr. Bildsten acknowledged that Taylor was not, as he put it, "an optimal candidate" for use of the device. In fact, using the device on Taylor implicated ISI's warnings: Taylor weighed 280 pounds; he had had three prior lower abdominal surgeries; and because of Taylor's weight, Dr. Bildsten did not position Taylor with his head down. During the surgery, Taylor suffered serious complications, including neuromuscular damage that prevented him from walking without assistance. He died four years later, partly as a result of those complications.

Taylor sued several entities involved in the surgery, including Dr. Bildsten, the hospital where the surgery was performed, and ISI. He later settled with all defendants except ISI. The trial court granted summary judgment in favor of ISI on all claims except Taylor's claim that ISI had violated the Washington Product Liability Act by failing to give an adequate warning of the risks of its device. That claim proceeded to trial, and the jury returned a verdict in favor of ISI. A divided panel of the Washington Court of Appeals affirmed, and the Washington Supreme Court granted Taylor's petition for review.

In a 6–3 decision, the Washington Supreme Court reversed. The court held that the trial court erred in failing to instruct the jury that ISI had a duty to warn the hospital, not just Dr. Bildsten, of the risks associated with the surgical device. In the court's view, a "manufacturer's duty to warn purchasing hospitals is not excused when a manufacturer warns doctors who use the devices because hospitals need to know the dangers of their own products, which cannot be accomplished simply by the manufacturer's warnings to the doctor who uses the product." 389 P.3d at 522.

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The court noted that Washington's product-liability statute tracks Section 402A of the *Restatement (Second) of Torts* and permits plaintiffs to recover when a product is "not reasonably safe because adequate warnings or instructions were not provided." *Id*. at 523. Recognizing that the statute is silent on who should receive such warnings, the court reasoned that "where the product is an extremely complex and inherently dangerous medical device, it is logical that hospitals would need warnings" because they "have an independent duty of care to their patients" and must "adopt credentialing requirements regarding staffing." *Ibid*.

The court acknowledged that, under the learned-intermediary doctrine, "manufacturers of medical products can satisfy their duty to warn patients of the risk of their products by providing those warnings to the doctors prescribing the products." *Id*. at 524. But it deemed that doctrine to be inapplicable here because "the manufacturer has an independent duty to warn the purchaser of the product and because physicians do not function in the same intermediary capacity between the manufacturer and purchaser" when the purchaser is a hospital. *Ibid*. The court further held that the failure-to-warn claim is governed by a strict-liability standard, not a negligence standard.

Justice Madsen dissented. In her view, a manufacturer does have a duty to warn the hospital that purchases its device, but that duty can support a claim only by the hospital, not by a patient. Taylor, she reasoned, "has no claim to enforce a duty owed to another" and therefore "cannot invoke a duty owed to [the hospital] to recover damages from ISI." *Id*. at 531 (Madsen, J. dissenting).

The majority opinion does not explain how providing a warning to the hospital could realistically have helped Taylor. The purpose of a warning, after all, is to make sure that the product is "reasonably safe" when used. Providing a warning to the product's users helps to promote safety; however, giving a warning to others in the chain of distribution does not. In the case of medical devices, the user is the physician employing (or prescribing) the device.

The learned-intermediary doctrine takes account of that reality. As the Washington Supreme Court previously explained, if a product is properly labeled, "the manufacturer may reasonably assume that the *physician* will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient." *Terhune v. A.H. Robins Co.*, 577 P.2d 975, 978 (Wash. 1978) (emphasis added). It would not make sense to require a manufacturer to give warnings directly to patients because an adequate warning would have to contain detailed technical information that would not be meaningful to laypeople.

Warning hospitals makes little more sense. The court in *Taylor* emphasized that hospitals make decisions about what products to purchase and about which physicians should have privileges to perform procedures. However, hospitals do not have the same role as physicians in treating patients. For example, they do not know which kind of surgery might be appropriate for a given patient or when it might be appropriate to use a specific medical device. Moreover, a hospital's decision to credential a physician is based on an assessment of that physician's education, experience, licensure, and abilities—not on an *ex ante* determination as to whether a physician should perform a particular procedure on a particular patient.

It is difficult to see how patients will benefit from thrusting hospitals into a more intrusive supervisory role. To the contrary, the rule adopted in *Taylor* may harm patients in the long run by discouraging the development and use of new medical devices that are beneficial despite their inherent risks. More broadly, the logic of *Taylor* suggests that manufacturers may have a duty to warn intermediate purchasers of other inherently dangerous products, not just medical devices. It remains to be seen how far the Washington Supreme Court will extend the decision, but it portends an overly broad expansion of product-liability law.

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