

What The Intuitive Ruling Means For Medical Device Makers

Law360, New York (March 1, 2017, 10:59 AM EST) -- Last month, in *Taylor v. Intuitive Surgical Inc.*, the Washington Supreme Court saddled medical device manufacturers with a new duty to warn under Washington law — the duty to warn hospitals about potential risks their products may pose — and eroded exemptions from strict liability afforded to manufacturers of certain “unavoidably unsafe” products.[1]

This decision comes as a surprise, and represents an unexpected shift in the law with regard to medical device manufacturers.

Background

Intuitive Surgical Inc. (Intuitive) manufactures and markets the da Vinci System robotic device — a device that has been used for robotic laparoscopic surgeries for nearly two decades. Due to its complexity, the da Vinci System may only be used by credentialed surgeons.

In this case, Intuitive sold the da Vinci System to a hospital in Washington state. Separately, Intuitive provided a user’s manual with warnings to the doctors that would use the device. A credentialed doctor used the da Vinci System to treat the plaintiff’s prostate cancer in September 2008.

According to the opinion, the doctor did not follow all of the warnings, and the plaintiff experienced complications during the procedure. As a result, the plaintiff alleged that his quality of life was reduced.

The plaintiff sued the doctor who performed his surgery, his partner and their medical practice, the hospital that purchased the da Vinci Robot, and Intuitive. The plaintiff settled with the medical provider defendants before trial, leaving Intuitive as the only defendant.

The trial court granted summary judgment in Intuitive’s favor on all claims except the plaintiff’s failure-to-warn claim under the Washington Product Liability Act (WPLA). The case went to trial. The jury returned a verdict for Intuitive, specifically finding it was not negligent in providing warnings or instructions to the doctor who performed the surgery.



Erin Bosman



Julie Park



Austin Marsh

On appeal, the plaintiff pursued a number of arguments, including that the trial court (1) erred in declining to instruct the jury that Intuitive had a duty to warn the hospital and (2) improperly applied a negligence standard to the plaintiff's failure-to-warn claims (rather than strict liability).

The case was affirmed on appeal and the Washington Supreme Court granted review.

Evolving Law

The Washington Supreme Court made two significant holdings, finding the trial court erred by: (1) not instructing the jury on Intuitive's duty to warn the purchasing hospital; and (2) improperly applying the negligence standard, rather than strict liability, to the plaintiff's failure to warn claim.

A New Duty to Warn Hospitals

The court created a new duty to warn hospitals. The court reasoned that this duty arises from the WPLA, which requires manufacturers to warn of risks to "purchasers" of dangerous products. But even the court could not decide whether the text of the statute supports this duty.

At one point the court admits that "the duty [to warn hospitals] is not explicitly stated in the text of the [WPLA]." Yet in another part of the opinion the court agrees with plaintiff's argument "that the manufacturer's duty to warn exists in the plain text of the WPLA."^[2]

Ultimately, the court reasoned that the text of the WPLA requires manufacturers to provide warnings "with" products and therefore the purchaser (here, the hospital) is owed product warnings "with" the product. The court conceded that the "physician is in the best position to make a decision regarding the patient's treatment," but noted that "the hospital is not completely absent from the process."^[3]

Following this unprecedented path, the court held that the warnings provided to the credentialed doctor should also have been given to the hospital. Rather than rely on legal precedent, however, the court leaned on policy and logic arguments, as well as dicta from other cases.

The result opens a Pandora's Box of questions for manufacturers seeking to warn end users and learned intermediaries about its products. For example, what entities or individuals in various distribution chains require warnings? And who qualifies as a purchaser?

In fashioning this new duty, the court held that the learned intermediary doctrine did not apply here because the manufacturer's duty ran to the hospital. By contrast, the learned intermediary doctrine allows manufacturers to discharge their duty to warn the patient by warning the doctors prescribing the products.

The dissenting justice noted that the court lost sight of how the duty to warn translates to liability. Specifically, this unprecedented duty to warn the hospital, even if supported in law, is only a duty owed to the hospital and should not form the basis for recovery by the plaintiff/patient. *Id.* at *37 ("[The plaintiff] cannot invoke a duty owed to [the hospital] to recover damages from Intuitive.")

Comment k Protections Inapplicable

Unfortunately, the court also reinterpreted and limited the protections provided to certain manufacturers of unavoidably unsafe products.

Comment k to the Restatement (Second) of Torts, § 402A concerns unavoidably unsafe products (products incapable of being made safe that are not unreasonably dangerous given the public benefit they offer). Recognizing the public policy benefits of keeping such products on the market, Comment k exempts manufacturers from strict liability if they produce unavoidably unsafe products so long as the products are “properly prepared and marketed, and proper warning is given.”[4]

In short, manufacturers of unavoidably unsafe products are held to negligence, not strict liability standards. Ignoring cases that applied this negligence standard, and finding “no binding precedent in Washington” on the issue, the court determined that “proper warnings are a prerequisite to application of the exception” provided by Comment k.[5]

The court reasoned that because Intuitive did not provide warnings to the hospital, application of the Comment k protection was improper and Intuitive should be judged on a strict liability basis.

Conclusion

In sum, the Washington Supreme court (1) expanded medical device manufacturers’ duty to warn to hospitals, and (2) stripped away a layer of protection offered to manufacturers of unavoidably unsafe products.

Fortunately, this case appears to be an outlier, and is unlikely to be followed in other jurisdictions that adhere to traditional principles of product liability law.

—By Erin Bosman, Julie Park and Austin Marsh, Morrison & Foerster LLP

Erin M. Bosman and Julie Y. Park are partners, and Austin James Marsh is an associate, at Morrison & Foerster LLP in San Diego.

The opinions expressed are those of the author(s) and do not necessarily reflect the views of the firm, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.

[1] Taylor v. Intuitive Surgical Inc., No. 92210-1, 2017 Wash. LEXIS 200, at *2 (Feb. 9, 2017)

[2] Id. at *11-12

[3] Id. at *14-15

[4] Restatement 2d of Torts, § 402A (2nd 1979)

[5] Taylor, No. 92210-1, 2017 Wash. LEXIS 200, at *25, 28