IN THE COURT OF APPEALS OF THE STATE OF WASHINGTON

DIVISION II

JOSETTE TAYLOR, as Personal representative of the Estate of FRED E. TAYLOR, deceased; and on behalf of the Estate of FRED E. TAYLOR; and JOSETTE TAYLOR, Individually,

Appellant,

v.

INTUITIVE SURGICAL, INC., a foreign corporation doing business in Washington,

Respondent.

No. 45052-6-II

PUBLISHED IN PART OPINION

MELNICK, J. — Josette Taylor, individually and in her capacity as the personal representative of the estate of her husband Fred E. Taylor,[1] appeals from a jury verdict finding no liability by Intuitive Surgical, Inc. (ISI) under the Washington Tort Reform and Product Liability Act (WPLA),[2] for Taylor's injuries resulting from complications during a robotically assisted prostatectomy.[3] Taylor argues that the trial court erred by not instructing the jury that (1) ISI, manufacturer of the system used to perform the surgery, owed a duty to warn the hospital in addition to the surgeon, and (2) strict liability governed the duty to warn. In the published portion of this opinion, we hold that under the learned intermediary doctrine, ISI only had a duty to warn

[1] Josette Taylor was not involved in the events at issue. For the purpose of simplicity, we refer to the appellants collectively as "Taylor," and we will refer to Fred Taylor individually as the same. We intend no disrespect.

[2] Chapter 7.72 RCW.

[3] A prostatectomy is a surgery in which the patient's prostate gland is removed.

the surgeon and not the hospital. We further hold that a negligence standard governs the duty to warn a learned intermediary about a medical product.

Taylor further argues that the trial court abused its discretion by refusing to allow Taylor to introduce evidence of other incidents concerning ISI's product. In the unpublished portion of this opinion, we hold that the trial court did not abuse its discretion by excluding Taylor's evidence of other incidents with ISI's product. Accordingly, we affirm the trial court.[4]

FACTS

I. BACKGROUND

ISI designs, manufactures, and markets the da Vinci System. The da Vinci System facilitates minimally invasive robotic surgery by allowing a surgeon to remotely operate very small instruments that are inserted inside the patient's body through incisions much smaller than those used in traditional (open-patient) surgery. The use of small incisions often results in shorter recovery times, fewer complications, and reduced hospital costs. A robotic surgery may not, however, remove as much cancer as an equivalent open procedure. Despite these shortcomings, the da Vinci System is now used in approximately 84 percent of prostatectomy surgeries in the United States.

The da Vinci System is a fairly new technology, having been used for the first time on humans in 1997. In 2001, the Food and Drug Administration (FDA) cleared ISI to market the da

[4] Taylor requests that we reach two additional assignments of error: challenges to the trial court instructing the jury on superseding cause and failure to mitigate. Taylor concedes that the challenged instructions do not constitute reversible error because the jury did not reach either issue. However, Taylor requests that if we reverse the trial court and remand for a new trial, we address the additional instructional challenges to avoid repetition of the trial court's alleged errors on remand. Because we affirm the trial court, we do not reach Taylor's additional assignments of error.

Vinci System for prostatectomy surgery, finding that the da Vinci System was "substantially equivalent" to devices that the FDA had cleared in the past.[5] Clerk's Papers (CP) at 344; *see* Federal Food, Drug, and Cosmetic Act, § 510(k), 21 U.S.C. § 360(k). The da Vinci System is restricted "to sale by or on the order of a physician." CP at 364.

The da Vinci System is a highly complex medical device. While the learning curve varies from surgeon to surgeon, ISI estimates that between 20 and 30 da Vinci System surgeries are needed before a surgeon will be comfortable with the system. Although ISI's learning curve estimation is consistent with some scholarly research, other researchers believe that "[s]urgeon comfort and confidence" is not attained until a surgeon has performed between 150 and 250 robotic procedures. Report of Proceedings (RP) (May 1, 2013) at 1948.

As part of their training, ISI requires surgeons who are just beginning with the da Vinci System to undergo either two proctored cases or an amount set by hospital protocol. Following that, ISI requires surgeons to choose simple cases for their first four to six unproctored procedures and to "slowly progress in case complexity." Supp. CP at 6029. During their first surgeries with the da Vinci System, surgeons performing prostatectomies are advised to choose patients with a body mass index (BMI) of less than 30 and no prior history of lower abdominal surgery. ISI specifically warns surgeons not to use the da Vinci System if a patient exhibits "morbid obesity." CP at 159. Furthermore, ISI recommends that da Vinci System operators place their patients in a steep Trendelenburg position, which means an incline of greater than 20 degrees. This position is recommended to make it easier for the surgeon to see what he or she is doing.

Before a doctor may perform a procedure at a hospital or medical institution, he or she must be credentialed by the institution. Each institution determines its own credentialing process.

[5] The training program for new operators of the da Vinci System is not FDA approved.

ISI recommends to hospitals that surgeons credentialed to use the da Vinci System "meet basic and advanced laparoscopic requirements."[6] CP at 5798.

II. TAYLOR'S SURGERY

Dr. Scott Bildsten, who performed Taylor's surgery, took an early interest in the da Vinci System. At the time of Taylor's surgery, Dr. Bildsten had extensive experience in traditional open surgery and had performed between 80 and 100 open prostatectomies. He also had experience in performing hand-assisted laparoscopic procedures, meaning he operated with one hand outside of the patient's body.

Dr. Bildsten received training from ISI and Harrison Medical Center credentialed him in operating the da Vinci System. As part of his training, Dr. Bildsten observed more than ten surgeries involving the da Vinci System, and he performed two proctored surgeries using the da Vinci System. Although the proctored surgeries were "fairly long," Dr. Bildsten thought he had done "really well" and felt encouraged to continue using the da Vinci System. RP (Apr. 23, 2013) at 1067, 1071. Dr. Bildsten denied that ISI ever pressured him into performing robotic surgery.

In 2008, Dr. Bildsten treated Taylor for prostate cancer. They discussed various courses of treatment, but Taylor insisted on a prostatectomy. They also discussed the possibility of a robotic procedure, and Dr. Bildsten advised Taylor that he was "just starting with the robotic technique." RP (Apr. 23, 2013) at 1067. Taylor agreed to start with a robotic surgery and to convert to an open procedure in the event of "any potential unsafe situations." RP (Apr. 23, 2013) at 1067.

[6] A laparoscopic procedure is any procedure in which the surgeon inserts tools through small incisions.

By Dr. Bildsten's own admission, because of Taylor's morbid obesity,[7] he was not an optimal candidate for a prostatectomy. Dr. Bildsten understood that he should only operate on thin patients while he was still new to the da Vinci System. Taylor had received numerous surgeries in the past, including three abdominal surgeries. He also suffered from "uncontrolled" diabetes, coronary artery disease, hypertension, and high cholesterol. RP (Apr. 24, 2013) at 1346. Doctors prescribed cholesterol medications for Taylor, but he did not consistently take them.

Nevertheless, in his first non-proctored surgery with the Da Vinci system, Dr. Bildsten operated on Taylor. Dr. Bildsten could not put Taylor in the steep Trendelenburg position because of Taylor's "abdominal girth." CP at 253. As a result, Dr. Bildsten had no choice but to flatten out Taylor to a slighter incline, which made it difficult to see what he was doing "due to the intestinal contents continually getting into the visual field." CP at 253. After "several hours of trying to get better visualization," Dr. Bildsten gave up on the da Vinci System and converted the procedure to an open prostatectomy. CP at 253. At some point during the open procedure, Dr. Bildsten tore Taylor's rectal wall with his finger. Fecal matter escaped Taylor's rectum and caused a blood infection.

Taylor remained in the operating room for approximately 15 hours. He suffered various complications from being under anesthesia for too long. He experienced a massive breakdown of muscle and kidney failure because he was not moving and his blood was not circulating properly. He also experienced brain swelling because his head was tilted down for an extended time during surgery.

[7] Taylor weighed 280 pounds and had a BMI of approximately 39. ISI advises beginner da Vinci System operators to choose patients with a BMI of less than 30.

Following the surgery, Taylor spent 20 days in the intensive care unit. He needed a mechanical ventilator to help him breathe for much of this time. Taylor had nerve and muscle damage, which may have been caused by his protracted stay in the intensive care unit. He also suffered a stroke during his stay in the intensive care unit.

III. AFTERMATH

Taylor's quality of life diminished following his prostatectomy. He suffered weakness in his shoulders, back, hip, and left arm; an atrophied right thigh; incontinence; and cognitive deficits including poor memory, depression, and anxiety. He needed a cane to walk most of the time. Losing his independence caused Taylor a great deal of frustration.

Taylor died in 2012, four years after his prostatectomy. The cause of death was preexisting "hypertensive cardiovascular disease." RP (May 6, 2013) at 2200-01. The parties dispute whether the prostatectomy hastened Taylor's death.

PROCEDURAL HISTORY

Based on various legal theories, Taylor sued Dr. Bildsten, Dr. Bildsten's partner and medical practice, Harrison Medical Center, and ISI. In an amended complaint, Taylor dropped Harrison Medical Center as a defendant. Taylor also settled with the doctors and their medical practice, leaving ISI as the only defendant for trial. The trial court granted ISI's summary judgment motion on all of Taylor's claims, except for the WPLA claim. Taylor does not assign error on appeal to this order granting summary judgment and dismissal.

At trial, Taylor proposed jury instructions stating that ISI had a duty to warn not only Dr. Bildsten, but also Harrison Medical Center. The trial court declined to do so and instructed the

jury that ISI's duty to adequately warn ran solely to Dr. Bildsten.[8] Furthermore, the trial court instructed the jury to apply a negligence standard in deciding ISI's liability for failure to adequately warn Dr. Bildsten. Taylor objected.

The jury returned a verdict in favor of ISI, with 10 of the 12 jurors concluding that ISI was not negligent in warning and training Dr. Bildsten. Taylor appeals.

ANALYSIS

I. STANDARD OF REVIEW

We review a jury instruction de novo if the challenge is based on a matter of law, or for abuse of discretion if based on a matter of fact. *Kappelman v. Lutz*, 167 Wn.2d 1, 6, 217 P.3d 286 (2009). "'Jury instructions are sufficient if they allow the parties to argue their theories of the case, do not mislead the jury and, when taken as a whole, properly inform the jury of the law to be applied.'" *Joyce v. Dep't of Corr.*, 155 Wn.2d 306, 323, 119 P.3d 825 (2005) (quoting *Hue v. Farmboy Spray Co.*, 127 Wn.2d 67, 92, 896 P.2d 682 (1995)). Even if erroneous, a jury instruction is reversible error only if it prejudices a party. *Anfinson v. FedEx Ground Package Sys., Inc.*, 174 Wn.2d 851, 860, 281 P.3d 289 (2012).

II. LEARNED INTERMEDIARY DOCTRINE

This case concerns the scope of a medical device manufacturer's duty to provide adequate warnings. In Washington, our learned intermediary doctrine treats manufacturers of prescription-only medical products differently from manufacturers of other products. *McKee v. Am. Home Products, Corp.*, 113 Wn.2d 701, 709, 782 P.2d 1045 (1989); *Terhune v. A.H. Robins Co.*, 90 Wn.2d 9, 12-13, 577 P.2d 975 (1978). The learned intermediary doctrine affects *who* must receive

[8] The court instructed the jury that a medical device manufacture's duty is to adequately warn or instruct/train the patient's doctor. For simplicity, we refer to the manufacture's duty simply as the duty to warn.

the manufacturer's warning and *how* the adequacy of the warning is to be measured. *See Ruiz-Guzman v. Amvac Chem. Corp.*, 141 Wn.2d 493, 506-08, 7 P.3d 795 (2000); *Rogers v. Miles Labs., Inc.*, 116 Wn.2d 195, 197, 207, 802 P.2d 1346 (1991); *Terhune*, 90 Wn.2d at 12-13; *McKee*, 113 Wn.2d at 709, 711. The doctor acts as a gatekeeper between the manufacturer and the patient. *See Terhune*, 90 Wn.2d at 14; *McKee*, 113 Wn.2d at 711. Therefore, both the challenged "failure-to-warn instruction" and the challenged "negligence instruction" involve the same issue: whether the learned intermediary doctrine is applicable in this situation.

In the following analysis, we explain the learned intermediary doctrine and its underlying policy rationale. We then apply the learned intermediary doctrine to the facts of this case and reject Taylor's challenges to the "failure-to-warn instruction" and the "negligence instruction."

A. WPLA Duty to Warn

The WPLA preempts common law and governs all claims for product-related harm in Washington. *Wash. Water Power Co. v. Graybar Elec. Co.*, 112 Wn.2d 847, 851, 853, -856, 774 P.2d 1199, 779 P.2d 697 (1989); *see* RCW 7.72.010(4). Under the WPLA, a product manufacturer is liable if a claimant's harm is "proximately caused by the negligence of the manufacturer in that the product was not reasonably safe as designed or not reasonably safe because adequate warnings or instructions were not provided." RCW 7.72.030(1). Warnings or instructions are inadequate if:

> at the time of manufacture, the likelihood that the product would cause the claimant's harm or similar harms, and the seriousness of those harms, rendered the warnings or instructions of the manufacturer inadequate and the manufacturer could have provided the warnings or instructions which the claimant alleges would have been adequate.

RCW 7.72.030(1)(b).

Despite the use of the term "negligence" in the statute, a manufacturer's failure to warn is generally governed by a strict liability test. *Macias v. Saberhagen Holdings, Inc.*, 175 Wn.2d 402, 409-10, 282 P.3d 1069 (2012); *Ayers v. Johnson & Johnson Baby Products Co.*, 117 Wn.2d 747, 762-63, 818 P.2d 1337 (1991). This interpretation mirrors the rule of the RESTATEMENT (SECOND) OF TORTS § 402A (1965), which "embodies a doctrine of strict liability with respect to products which are introduced into the stream of commerce." *Terhune*, 90 Wn.2d at 12. The standard is strict liability because "even where a product is faultlessly designed, it may be considered unreasonably unsafe if it is placed in the hands of the ultimate consumer unaccompanied by adequate warning of dangers necessarily involved in its use." *Terhune*, 90 Wn.2d at 12.

Importantly, the Restatement makes an exception to the strict liability rule for products that are "incapable of being made safe for their intended and ordinary use" but nevertheless are "fully justified, notwithstanding the unavoidable high degree of risk."[9] RESTATEMENT (SECOND) § 402A cmt. k. Prime examples of such products are "drugs, vaccines, and the like, many of which for this very reason *cannot legally be sold except to physicians, or under the prescription of a physician.*" RESTATEMENT (SECOND) § 402A cmt. k (emphasis added). Similarly, the exception applies to

> new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk.

RESTATEMENT (SECOND) § 402A cmt. k.

[9] ISI admits that the da Vinci System is an "unavoidably unsafe" product, as that term is used in RESTATEMENT (SECOND) § 402A cmt. k. CP at 110.

Our Supreme Court adopted comment k in *Terhune*, 90 Wn.2d at 14-15, and has consistently held that it applied in cases involving medical products available only through a physician, including WPLA actions.[10] *Ruiz-Guzman*, 141 Wn.2d at 506-08 (citing *Young v. Key Pharms., Inc.*, 130 Wn.2d 160, 167-68, 922 P.2d 59 (1996) (plurality opinion); *Rogers*, 116 Wn.2d at 197, 202-04).

B. Who the Manufacturer Must Warn

The WPLA does not expressly specify *who* must receive the manufacturer's warnings. *See* RCW 7.72.030 (1)(b), (c) (referring to warnings provided "with the product" and warnings issued after a product was manufactured to "inform product users"). However, the learned intermediary doctrine directs that for certain medical products that are unavoidably unsafe, the "manufacturer's duty to warn of dangers associated with its product runs *only* to the physician; it is the physician's duty to warn the ultimate consumer." *McKee*, 113 Wn.2d at 709 (emphasis added). The reason for this doctrine is that when a medical product is available only by prescription (as is the da Vinci System), the physician acts as a gatekeeper who stands in the place of the manufacturer in relation to the patient. That is, the physician acts as a "'learned intermediary'" who undertakes the duty to "inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product." *Terhune*, 90 Wn.2d at 14. The patient places "primary reliance" on the physician's informed judgment, rather than whatever warnings the *manufacturer* may have included. *Terhune*, 90 Wn.2d at 14. Therefore, the physician is in a

[10] Taylor argues that the learned intermediary doctrine may excuse a manufacturer from the *common law* duty to warn a purchaser, but *not* the statutory duty to warn under RCW 7.72.030(1)(b). But the WPLA preempts all common law products liability causes of action. *Wash. Water Power Co.*, 112 Wn.2d at 853, 856. This preemption means that there is only *one* duty to warn in products liability law. We address that duty in the foregoing analysis.

superior position to warn the patient and the courts should not interfere with the physician-patient relationship.

Taylor argues that ISI's duty to warn also runs to Harrison Medical Center as the purchaser of the da Vinci System and that the learned intermediary doctrine is inapplicable here; i.e, the doctrine has no bearing on whether ISI has a duty to warn Harrison Medical Center. We disagree.

The fact that Harrison Medical Center purchased the product rather than Taylor arguably distinguishes our Supreme Court's medical products cases, where the patient actually purchased the product at issue. *See, e.g.*, *Terhune*, 90 Wn.2d at 10-11 (intrauterine contraceptive device); *McKee*, 113 Wn.2d at 703-04 (prescription drug); *Rogers*, 116 Wn.2d at 198-99 (blood products administered intravenously); *Young*, 130 Wn.2d at 162-63 (prescription drug). However, this distinction is immaterial because the da Vinci System was used on Taylor and he suffered the harm caused by that surgery. The learned intermediary doctrine is not concerned with who pays for the product or who retains possession of the product. Rather, its rationale is based on the physician's role as gatekeeper who stands in the place of the manufacturer in relation to the patient to provide warnings about unavoidably unsafe products accessible only by prescription. Here, Dr. Bildsten acted as the gatekeeper; *i.e.* the learned intermediary similar to the doctors who acted as gatekeepers in *Terhune*, *McKee*, *Rogers*, and *Young*.

The dissent would hold that the learned intermediary doctrine does not apply to ISI's duty to warn Harrison Medical Center. The dissent's analysis is premised on the idea that ISI had a duty to warn Harrison Medical Center about the da Vinci System because Harrison Medical Center purchased the product. Dissent at 2 ("I would hold that the learned intermediary doctrine does not remove a manufacturer's duty to warn a hospital about medical equipment purchased by that hospital."). We disagree with the dissent that the learned intermediary doctrine operates by

removing a manufacturer's duty to warn. Rather, we understand the doctrine as directing that manufacturers of "unavoidably unsafe products" satisfy their duties under the WPLA by providing warnings solely to learned intermediaries.

We now address Taylor's instructional challenges.

C. Harrison Medical Center Is Not a Second Learned Intermediary

Taylor argues that the trial court erred by failing to instruct the jury that ISI had a duty to warn Harrison Medical Center. ISI argues that the court correctly instructed the jury that ISI's duty to warn ran only to Dr. Bildsten. We agree with ISI and affirm the trial court.

No one disputes that as the prescribing physician, Dr. Bildsten is a learned intermediary. Further, no one disputes that under the learned intermediary doctrine, ISI had a duty to provide warnings to Dr. Bildsten. The issue Taylor raised is, if the learned intermediary doctrine applies, whether the hospital acted as a second learned intermediary, meaning that ISI also had a duty to provide warnings to Harrison Medical Center.

We review this question of first impression in Washington by reviewing the policies behind the learned intermediary doctrine as noted above. Those policies convince us that the hospital does not share in the physician's role as a learned intermediary. The learned intermediary doctrine singles out the physician "because it is he who finally controls the dispensing of the product." *Terhune*, 90 Wn.2d at 16. Here, Dr. Bildsten held final control over the use of the da Vinci System. Dr. Bildsten examined Taylor, took his individualized circumstances into account, discussed several potential courses of treatment with Taylor, warned him of the risks, and made the ultimate decision to employ the da Vinci System.

Taylor argues that if Harrison Medical Center had not purchased the da Vinci System, Taylor would not have received a da Vinci System surgery. But a third party that facilitates the

distribution of a medical product, yet does not exercise its own individualized medical judgment, is not a learned intermediary. In *McKee*, our Supreme Court considering a closely related issue held that a pharmacist owed no duty to warn the patient because

> [n]either manufacturer nor pharmacist has the medical education or knowledge of the medical history of the patient which would justify a judicial imposition of a duty to intrude into the physician-patient relationship. In deciding whether to use a prescription drug, the patient relies primarily on the expertise and judgment of the physician. . . . Requiring the pharmacist to warn of potential risks associated with a drug would interject the pharmacist into the physician-patient relationship and interfere with ongoing treatment. We believe that duty, and any liability arising therefrom, is best left with the physician.

113 Wn.2d at 711-712.

Like the pharmacist in *McKee*, Harrison Medical Center did not take Taylor's individualized circumstances or medical history into account. Nothing in the record indicates that Harrison Medical Center played any role in deciding whether Taylor should receive a da Vinci System surgery. Harrison Medical Center did not and could not exercise independent medical judgment in Taylor's specific case. It merely made the da Vinci System available for physicians, like Dr. Bildsten, and credentialed them. But as *McKee* demonstrates, a party that simply *enables* a medical product to get to a patient does not share the special type of relationship with the patient as does the prescribing physician.

Our Supreme Court's policy of deferring to the physician-patient relationship applies in full to this case. *See, e.g.*, *McKee*, 113 Wn.2d at 711-12; *Terhune,* 90 Wn.2d at 14-15. Dr. Bildsten, the prescribing physician, bore the ultimate decision-making responsibility, and under the learned intermediary doctrine ISI fully complied with its duty to warn by warning Dr. Bildsten. We reject Taylor's invitation to extend the learned intermediary rule to a hospital that does not exercise patient-specific medical judgment. The trial court did not err by instructing the jury that

ISI's duty to warn ran to Dr. Bildsten. And the trial court did not err by refusing to instruct the jury that ISI's duty to warn also ran to Harrison Medical Center.

D. Standard of Liability for Duty to Warn

Having established *who* must receive warnings (the physician), we now turn to *what* kind of warning must be given. Taylor argues that the trial court improperly applied a negligence standard based on its erroneous application of comment k to the RESTATEMENT (SECOND) § 402A. Taylor argues that the proper standard for its failure-to-warn claim is strict liability. We disagree and hold that a negligence standard governs the duty to warn a learned intermediary about a medical product.

In *Rogers*, our Supreme Court held that comment k applies to blood and blood products, and that a manufacturer of such products is "liable in negligence and not in strict liability" if it fails to provide adequate warnings. 116 Wn.2d at 207. This rule came about because a manufacturer of an unavoidably unsafe product is liable for failure to warn *only* if it knew or should have known of the defect. *Rogers*, 116 Wn.2d at 207 (citing *Brown v. Superior Court*, 44 Cal.3d 1049, 1059, 751 P.2d 470, 245 Cal.Rptr. 412 (1988)). This knowledge requirement is "an idea which 'rings of negligence.'" *Rogers*, 116 Wn.2d at 207 (internal quotation marks omitted) (quoting *Brown*, 44 Cal.3d at 1059).

Here, Taylor alleges that ISI failed to warn physicians of dangers that it *knew or should have known about* based on both the medical literature and the studies that indicate the da Vinci System has a high learning curve. Like the failure-to-warn issue in *Rogers*, this question "rings of negligence." 116 Wn.2d at 207 (internal quotation marks omitted) (citation omitted). Therefore, whether ISI failed to warn physicians of *known* dangers raises an issue of negligence. *Rogers*, 116 Wn.2d at 207.

Taylor argues that *Rogers* is distinguishable and the da Vinci System is not entitled to the blanket exemption from strict liability for medical products that the Court acknowledged in *Ruiz-Guzman*, 141 Wn.2d at 511. Rather, Taylor argues that the da Vinci System should be treated like a pesticide, and the applicability of comment k should be conditioned on a factual analysis of whether the product's value to society exceeds the harm it causes. *See Ruiz-Guzman*, 141 Wn.2d at 511 (rejecting a blanket application of comment k to pesticides and opting instead for a product-by-product approach). Taylor's argument is unsupported by any Washington authority.

The presence of the physician as learned intermediary places medical products in a class of their own, and justifies the "blanket exemption" referenced in *Ruiz-Guzman.* 141 Wn.2d at 511, 508-09. Unlike the pesticide in *Ruiz-Guzman*, the da Vinci System is a prescription product with access strictly controlled by a physician. This fact is relevant because in a strict liability case, "the reason why the warning was not issued is irrelevant, and the manufacturer is liable even if it neither knew nor could have known of the defect." *Brown*, 44 Cal.3d at 1059 n.4. That is, ordinarily a manufacturer's failure to warn will never be reasonable, and thus strict liability is warranted. But when the manufacturer is required to utilize a trained, credentialed physician to get the product to the consumer, the reason *why* a manufacturer fails to give a warning becomes relevant.

With medical products, the risks depend as much on the patient's individual circumstances, as assessed by a qualified physician, as the qualities of the product itself. The manufacturer has no way of knowing at the outset what an individual patient's needs will be. A manufacturer may reasonably choose to defer to the treating physician's medical judgment rather than attempting to impose blanket warnings that may not apply in an individual patient's case. Hence, the blanket exemption for medical products discussed in *Ruiz-Guzman* makes sense. The trial court did not err by instructing the jury on the negligence standard.

D. Conclusion

We hold that the court properly instructed the jury with the "duty-to-warn" and negligence instructions under the learned intermediary doctrine, as articulated in controlling medical products cases. Accordingly, we affirm.

A majority of the panel has determined that the remainder of this opinion lacks precedential value and will not be printed in the Washington Appellate Reports. The remainder of this opinion will be filed for public record in accord with RCW 2.06.040, it is so ordered.

I. EVIDENCE OF OTHER INCIDENTS

Taylor argues that the trial court abused its discretion when it excluded Taylor's rebuttal evidence concerning the overall success of Harrison Medical Center's robotics program. ISI argues that the court properly excluded this rebuttal evidence under ER 403. ISI further argues that the trial court's curative instruction mitigated any prejudice to Taylor. We agree with ISI.

A. Additional Facts

Before trial on Taylor's WPLA claim, Taylor moved to exclude evidence "related to the absence of subsequent injuries, accidents, or bad outcomes at the hands of surgeons other than Dr. Scott Bildsten at Harrison Medical Center using the da Vinci robot." CP at 2626. The trial court reserved its ruling.

During Taylor's recross-examination, he asked ISI representative Sean O'Connor whether he had expressed doubts about the quality of the da Vinci System program at Harrison Medical Center. O'Connor said that he had not. When Taylor asked why, O'Connor responded that:

> outside of this incident we're talking about, [the da Vinci System has] been a very successful program. The surgeons that were involved from the beginning are still involved today. The hospital made the decision to buy [ISI] technology this past December. They're currently talking to our clinical team to buy another one. These are all the same doctors that were involved in 2008 minus Dr. Bildsten. So if they

> were concerned about the quality the technology was providing to the patient care, they wouldn't be reinvesting in the program.

RP (Apr. 22, 2013) at 855.

Taylor requested a sidebar and argued that O'Connor's testimony improperly implied that Taylor's surgery was "the only incident with the da Vinci" and, thus, opened the door to evidence of other mishaps with the da Vinci System. RP (Apr. 24, 2013) at 1229-30. As such, Taylor offered proposed exhibit 304, a record of the first 233 robotic procedures at Harrison Medical Center.

The trial court refused to admit exhibit 304, ruling that it had "very little probative value" because there was "no indication of who the surgeons were, their experience, patient outcomes," and "no comparison of complication rates with nonrobotic surgeries." RP (Apr. 29, 2013) at 1428. But the court did read a curative instruction to the jury stating:

> Each side has its own view as to whether there were other incidents at Harrison [Medical Center] after Mr. Taylor's incident. I have ruled that neither side should present that evidence, and accordingly, I am instructing you to disregard Mr. O'Connor's testimony regarding whether or not there were other incidents in the Harrison [Medical Center] da Vinci program.

CP at 4693.

B. Trial Court's Ruling

We review an evidentiary challenge for abuse of discretion. *Kappelman*, 167 Wn.2d at 6. Similarly, a trial court has considerable discretion regarding whether the door is opened to a line of inquiry. *Burchfiel v. Boeing Corp.*, 149 Wn. App. 468, 490, 205 P.3d 145 (2009).

Here, Taylor sought to introduce evidence concerning 233 other surgeries utilizing the da Vinci System. The court disagreed, pointing out that:

> Aside from the other issues of hearsay and the business records, we don't have the ability and I'm not going to open the case up to inquire of the other surgeries, were the complications actual complications, were they really bad, some

> sound bad, or were they minor, were they typical things that occur during the course of regular surgeries.
>
> . . . .
>
> Each side indicates if we were to get involved in this, it would be necessary to question the doctors who performed the surgeries listed in the complications chart.

RP (Apr. 29, 2013) at 1428-29. For these reasons, the court ruled that "the admission of this evidence would be confusing and prejudicial." RP (Apr. 29, 2013) at 1429.

Here, the specific circumstances of Taylor's da Vinci System surgery—including his preexisting conditions, his suitability for a robotic prostatectomy, and the particular procedure Dr. Bildsten used in conducting the surgery—were crucial to the case. In contrast, Taylor did not (and could not reasonably) offer details regarding the 233 other surgeries. But without this context, the jury could not reasonably compare Taylor's outcome to the outcomes in other surgeries involving the da Vinci System. If O'Connor's testimony improperly invited the jury to consider the da Vinci System outside the specific context of Taylor's case, the proper remedy was not to exacerbate the error by introducing *more* evidence of outside matters. Rather, the proper remedy was to admonish the jury not to consider other incidents, as the trial court did. The trial court did not abuse its discretion, and we affirm.

Melnick, J.

I concur:

Sutton, J.

Worswick, P.J., (dissenting in part) — I agree with the majority that the trial court properly instructed the jury to apply a negligence standard to Fred E. Taylor's inadequate warning claims. In addition, I agree that the trial court did not abuse its discretion when it excluded rebuttal evidence concerning the overall success of Harrison Medical Center's robotics program. But I disagree with the majority's conclusion that the "learned intermediary"[11] doctrine applies to Intuitive Surgical Inc.'s (ISI) duty to warn Harrison.

While it is true that the rationale behind the learned intermediary doctrine is that the physician serves the role of a gatekeeper, I would hold that the physician serves this gatekeeper role only where the physician stands between a manufacturer and *the person who the manufacturer failed to warn.*

Because physicians are gatekeepers between manufacturers and unwarned *patients*, the physician protects the unwarned patients. Thus, the learned intermediary doctrine serves to remove a manufacturer's duty to warn the patient. But because the physician does not stand between manufacturers and unwarned *hospitals*, the physician does not protect the unwarned hospital. Thus, the learned intermediary doctrine does not remove a manufacturer's duty to warn hospitals about medical equipment purchased by that hospital. Because sufficient evidence supports Taylor's theory that ISI's negligent failure to warn Harrison caused Taylor's harm, I would hold that the trial court erred by failing to give an instruction on whether ISI negligently failed to warn Harrison and thereby caused Taylor's harm.

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[11] *Terhune v. A.H. Robins Co.*, 90 Wn.2d 9, 14, 577 P.2d 975 (1978) (internal quotation marks omitted).

I. LEARNED INTERMEDIARY DOCTRINE

I would hold that the learned intermediary doctrine does not remove a manufacturer's duty to warn a hospital about medical equipment purchased by that hospital. In *Terhune v. A.H. Robins Co.*, our Supreme Court held that under the learned intermediary doctrine, the manufacturer has no duty to warn a physician's patient because the physician stands as a "learned intermediary" between the manufacturer and the unwarned patient. 90 Wn.2d 9, 14, 577 P.2d 975 (1978) (internal quotation marks omitted). The court explained its reasoning for applying the learned intermediary doctrine:

> Where a product is available only on prescription or through the services of a physician, the physician acts as a "learned intermediary" *between* the manufacturer or seller and the patient. It is his duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and *to exercise an independent judgment*, taking into account his knowledge of the patient as well as the product. The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. *The physician decides what facts should be told to the patient.* Thus, if the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, 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.* It has also been suggested that the rule is made necessary by the fact that *it is ordinarily difficult for the manufacturer to communicate directly with the consumer.*

90 Wn.2d at 14 (emphasis added) (footnote omitted). Thus, a properly warned physician is a learned intermediary *between* the manufacturer and the unwarned patient because by using independent judgment to determine which medical products a patient should receive and what information a patient needs to know about those medical products, the physician serves as a gatekeeper *between* the manufacturer and the unwarned patient.

In *McKee v. American Home Products Corp.*, the court held that pharmacists have no duty to warn patients because physicians, not pharmacists, serve as the gatekeepers between the

manufacturer and the unwarned patient. 113 Wn.2d 701, 711-12, 782 P.2d 1045 (1989). This is because it is physicians, not pharmacists, who exercise independent judgment to determine which medical products a patient should receive and what information a patient needs to know about those products. *See* 113 Wn.2d at 711-12.

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* because the physician does not use independent judgment to determine which medical products a hospital should receive and what information a hospital needs to know about those products. Rather, the hospital exercises independent judgment to determine which medical products it should purchase and receives information about those products directly from the manufacturer. Furthermore, unlike in the situation of a patient, it is not difficult for the manufacturer to communicate directly with the hospital.

This case illustrates why the learned intermediary doctrine should not apply to a manufacturer's failure to warn a hospital that has purchased a medical product. Here, Harrison purchased the "da Vinci System" and was responsible for credentialing physicians to use it. Clerk's Papers at 344. This required exercising independent judgment to determine which physicians had sufficient experience in laparoscopic surgery to use the da Vinci System, the amount and nature of training required of these physicians, and the number of proctored da Vinci System surgeries required of these physicians. ISI had influence over Harrison's independent determinations: three ISI employees sat on the steering committee that designed Harrison's credentialing requirements. These independent determinations by Harrison could affect the quality of the physicians' use of the da Vinci System, which could affect the patients. Therefore, ISI's failure to warn Harrison could harm Harrison, the physicians, and the patients. I would

hold that because the physician is not a learned intermediary between manufacturers and hospitals, the learned intermediary doctrine does not apply to a manufacturer's failure to warn a hospital that purchased a medical product.

II. Instruction On Failure To Warn Harrison

I would hold that the trial court erred by failing to give an instruction on whether ISI negligently failed to warn Harrison and thereby caused Taylor's harm. A trial court is obligated to provide a jury instruction on any theory of the case that is supported by substantial evidence. *Kelsey v. Pollock*, 59 Wn.2d 796, 798, 370 P.2d 598 (1962); *Estate of Dormaier v. Columbia Basin Anesthesia, PLLC*, 177 Wn. App. 828, 851, 313 P.3d 431 (2013). Substantial evidence is a "'sufficient quantum to persuade a fair-minded, rational person of the truth of a declared premise.'" 177 Wn. App. at 851 (quoting *Helman v. Sacred Heart Hosp.*, 62 Wn.2d 136, 147, 381 P.2d 605 (1963)). This requires more than speculation and conjecture. 177 Wn. App. at 852. An instructional error is not harmless if it prevents a party from arguing his or her theory of the case. *Chunyk & Conley/Quad-C v. Bray*, 156 Wn. App. 246, 255, 232 P.3d 564 (2010).

One of Taylor's theories of the case was that ISI's negligent failure to warn Harrison led Harrison to allow Dr. Scott Bildsten to use the da Vinci System on Taylor unsupervised despite Dr. Bildsten's inexperience, thus causing harm to Taylor. This theory was supported by testimony that (1) no physician at Harrison had any significant knowledge about the da Vinci System; (2) the medical research supported that physicians needed up to 250 surgeries with the da Vinci System to be comfortable with it; (3) after ISI gave Harrison information suggesting that two proctored surgeries was sufficient, Harrison required physicians to perform only two proctored surgeries; (4) Dr. Bildsten used the da Vinci System unsupervised on Taylor after only two proctored surgeries; (5) Dr. Bildsten needed far more than two proctored surgeries before

safely operating the da Vinci System unsupervised; and (6) use of the da Vinci System contributed to Taylor's harm. This is substantial evidence to support that ISI's negligent failure to warn Harrison led Harrison to allow Dr. Bildsten to use the da Vinci System on Taylor unsupervised despite Dr. Bildsten's inexperience, thereby causing harm to Taylor.

Allowing the learned intermediary doctrine to shield manufacturers in this instance creates an environment that encourages manufacturers to refrain from disclosing dangers or defects to the actual purchaser of the medical equipment. This skews the doctrine's purpose.

I would hold that the learned intermediary doctrine did not apply to eliminate ISI's duty to warn Harrison about the da Vinci System purchased by Harrison. Because sufficient evidence supports Taylor's theory that ISI's negligent failure to warn Harrison caused Taylor's harm, I would hold that the trial court erred by failing to give an instruction on that theory. Therefore, I respectfully dissent in part.

Worswick, P.J.