IN THE SUPREME COURT OF THE STATE OF WASHINGTON

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, Petitioner, v. INTUITIVE SURGICAL, INC., a foreign corporation doing business in Washington, Respondent.	No. 92210-1 En Banc Filed FEB 09 2017

OWENS, J. — Manufacturers have a duty to provide warnings to consumers about the risks of their products pursuant to the Washington product liability act (WPLA), chapter 7.72 RCW. In this case, a manufacturer sold a surgical device to a hospital, which credentialed some of its physicians to perform surgery with the device. The manufacturer's warnings regarding that device are at the heart of this case. We are asked to decide whether the manufacturer owed a duty to warn the hospital that purchased the device. The

manufacturer argues that since it warned the physician who performed the surgery, it had no duty to warn any other party. We disagree because the doctor is often not the product purchaser. We find that the WPLA requires manufacturers to warn purchasers about their dangerous medical devices. Hospitals need these warnings to credential the operating physicians and to provide optimal care for patients. In this case, the trial court did not instruct the jury that the manufacturer had a duty to warn the hospital that purchased the device. Consequently, we find that the trial court erred. We vacate the defense verdict and remand for retrial.

FACTS

Intuitive Surgical Inc. (ISI) is the manufacturer of a robotic surgical device called the "da Vinci System," which surgeons use to perform laparoscopic surgeries. ISI manufactures and markets the da Vinci System robotic device to medical centers, including Harrison Medical Center, which purchased the device. The device is used for robotic laparoscopic surgeries, which are minimally invasive because surgeons remotely operate on the person by inserting the robotic instruments into the patient through small incisions. Since laparoscopic procedures use small incisions through the skin, the recovery times are much shorter and the surgeries result in fewer complications

than alternative methods. Presently, the da Vinci System is used in about 84 percent of prostatectomies in the United States.

The da Vinci System was used for the first time in 1997. In 2000, the United States Food and Drug Administration cleared the da Vinci System for certain surgeries, and it was cleared for prostatectomies in 2001. The da Vinci System is not used on a patient unless a physician allows for its use. An expert urologist testified that surgeons must be credentialed in order to use the da Vinci System because it is one of the "most complex medical devices" surgeons use. 11 Verbatim Report of Proceedings (VRP) (May 1, 2013) at 1912. Even with expertise in open surgery, a skilled surgeon would still need training and experience to operate the da Vinci System successfully. Experts testified at trial that "confidence" with the device is not achieved until a surgeon has completed 150 to 250 procedures. *Id.* at 1948.

As part of its training, ISI requires that surgeons perform two proctored surgeries, but hospitals enforce their own requirements for credentialing surgeons to use the da Vinci System. Harrison Medical Center provided credentials after those two proctored procedures. Other hospitals in Washington provided credentials after three or four proctored surgeries. *See* 6 VRP (Apr. 22, 2013) at 774-75 (Tacoma General Hospital requiring three); 14 VRP (May 7, 2013) at 2408 (Swedish Medical Center requiring four). ISI

recommends that surgeons choose "simple cases" for initial unproctored procedures. Clerk's Papers (CP) at 6029. ISI provided a user's manual to doctors, containing various warnings related to the device. Three warnings are particularly relevant to this case. First, as part of its training, ISI advised surgeons not to perform prostatectomies on obese persons. ISI provided body mass index (BMI) guidelines stating patients should have a BMI of less than 30. Second, ISI advised not to perform prostate procedures on persons who previously underwent lower abdominal surgeries. Third, ISI warned that it was unsafe for the patient not to be in a steep Trendelenburg position (tilted with head downward) during the procedure.

Dr. Scott Bildsten had 15 years of experience performing open prostatectomies, having performed between 80 and 100 such procedures prior to Fred Taylor's surgery. He was also experienced with hand-assisted laparoscopic procedures, in which the surgeon operates with one hand outside of the patient's body and the other hand assisting the instruments inside of the body. Dr. Bildsten had performed two proctored prostatectomies before performing his first unproctored procedure on Taylor.

After receiving informed consent, Dr. Bildsten performed a robotic prostatectomy on Taylor to treat his prostate cancer using the da Vinci System on September 9, 2008. At the time of surgery, Taylor weighed 280 pounds and

had a BMI of 39 (contrary to ISI's advice to choose a patient with a BMI of less than 30). Dr. Bildsten testified that he considered Taylor to be "severely obese." 7 VRP (Apr. 23, 2013) at 1140. Furthermore, Taylor had three prior lower abdominal surgeries (which went against ISI's advice to avoid patients with prior lower abdominal surgeries). During the surgery, Dr. Bildsten did not position Taylor in the steep Trendelenburg position due to his weight (in spite of ISI's advice to conduct the procedure in that position). Although Dr. Bildsten knew that Taylor "was not an optimal candidate," he performed the prostatectomy as his first unproctored procedure using the robotic system. *Id.* at 1063.

During the surgery, Taylor suffered complications. Dr. Bildsten became aware that Taylor's rectal wall was lacerated. He converted the procedure to an open surgery, and another surgeon came in to fix the rectal tear. Taylor's quality of life was poor after the surgery. He suffered respiratory failure requiring ventilation, renal failure (that ultimately resolved itself), and infection. He was incontinent and had to wear a colostomy bag. He also suffered neuromuscular damage and could no longer walk without assistance. Roughly four years after the surgery, Taylor passed away. A doctor testified that the prostatectomy's complications hastened his death.

A year after the surgery, Taylor filed suit against Dr. Bildsten, his partner (Dr. John Hedges), their medical practice, and Harrison Medical Center. He later added ISI. After he died, his wife, Josette Taylor, proceeded with the lawsuit as personal representative of his estate. Before trial, Taylor[1] settled with Drs. Bildsten and Hedges, their private practice, and Harrison Medical Center. ISI was the only remaining defendant. Taylor proceeded against ISI for claims of product defect, breach of warranty, breach of contract, violation of Washington's Consumer Protection Act (ch. 19.86 RCW), negligence, and product liability under the WPLA. The trial court granted summary judgment in favor of ISI on all claims, except for Taylor's failure to warn claim under the WPLA.

At trial, ISI presented expert testimony that described the ISI training process. Dr. Joel Lilly, a urologist with significant robotic surgical experience, discussed the ISI training course. ISI trained surgeons on "how to select your best candidates for starting your experience," such as choosing "thin patients" and those with no prior abdominal surgery. 14 VRP (May 7, 2013) at 2405. Dr. Lilly told the jury that in his opinion, Dr. Bildsten was negligent in performing Taylor's surgery.

[1] We refer to both plaintiffs, Fred and Josette Taylor, as "Taylor" for convenience.

The jury returned a verdict in favor of ISI. It found specifically that ISI was not negligent in providing warnings or instruction to Dr. Bildsten. Taylor appealed, raising several assignments of error. First, Taylor claimed that the trial court erred by declining to instruct the jury that ISI had a duty to warn Harrison Medical Center. The Court of Appeals found by a 2-1 decision that the trial court did not err because ISI fulfilled its duty to warn by warning Dr. Bildsten. *Taylor v. Intuitive Surgical, Inc.*, 188 Wn. App. 776, 792, 797-98, 355 P.3d 309 (2015) (published in part). Second, Taylor claimed that the trial court erred by applying a negligence standard instead of a strict liability standard. The Court of Appeals unanimously found that the trial court properly applied a negligence standard to the inadequate warning claim. *Id.* at 794. Third, Taylor claimed that the trial court erred by excluding Taylor's evidence to rebut ISI's testimony that Harrison Medical Center's robotic surgery program was successful overall. In the unpublished portion of its opinion, the Court of Appeals unanimously agreed that the trial court did not abuse its discretion by excluding this evidence as confusing and prejudicial. *Taylor*, slip op. (unpublished portion) at 16-18, http://www.courts.wa.gov/Opinions. Finally, Taylor challenged jury instructions on superseding cause and failure to mitigate. Since the jury did not reach these issues and the Court of Appeals affirmed the trial court, it did not reach these additional assignments of error.

Taylor, 188 Wn. App. at 780 n.4. Here, Taylor seeks review of these assignments of error. We granted review. *Taylor v. Intuitive Surgical, Inc.*, 184 Wn.2d 1033, 379 P.3d 957 (2016).

Four amici have filed briefs in this case. The Washington State Association for Justice Foundation filed a brief in support of Taylor. The Medical Device Manufacturers Association and National Association of Manufacturers, the Washington State Hospital Association, and Product Liability Advisory Council Inc. filed briefs in support of ISI.

ISSUES

1. Did ISI have a duty to warn Harrison Medical Center as the purchasing hospital of the da Vinci System?

2. Did the trial court properly apply a negligence standard, as opposed to strict liability, to Taylor's inadequate warnings claim?

3. Did the trial court err when it excluded Taylor's proposed rebuttal evidence to testimony that Harrison Medical Center's robotics program was successful overall?

4. Did the trial court err by instructing the jury on superseding cause or failure to mitigate?

ANALYSIS

Taylor claims the trial court erred in four ways. First, Taylor claims the trial court erred by not instructing the jury on ISI's duty to warn Harrison Medical Center as the purchasing hospital. Second, Taylor claims the trial court erred in its application of the negligence standard rather than strict liability. Third, Taylor claims the trial court erred by excluding Taylor's rebuttal evidence to ISI's testimony that Harrison Medical Center's robotics surgery program was successful overall. Fourth, Taylor claims the trial court erred by instructing the jury on superseding cause and failure to mitigate. As explained below, we find that the trial court erred by not instructing the jury on ISI's duty to warn the purchasing hospital. Accordingly, we vacate the defense verdict and remand for retrial. Although we need not reach Taylor's additional claims, we reach them to provide guidance for the trial court should these issues arise on retrial.

1. Manufacturers Have a Duty To Warn Hospitals That Purchase Medical Products

We find that the WPLA imposes a duty on manufacturers of medical products to warn hospitals of the products' dangers when they purchase them. The 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. Thus, we conclude that the trial court erred by failing to instruct the jury there was a duty to warn Harrison Medical Center of the da Vinci System's risks.

A. Manufacturers Have a Duty under the WPLA To Warn Purchasing Hospitals of Product Dangers with the Product

For the reasons explained below, we find that the WPLA provides a statutory duty that manufacturers must warn purchasers of its dangerous products.[2] Although the duty is not explicitly stated in the text of the statute, the WPLA requires that warnings be provided with products. Since warnings must be provided "with" products, manufacturers like ISI have a duty to provide warnings to the purchaser of the product—in this case, Harrison Medical Center.

The WPLA governs product-related harm claims based on a manufacturer's failure to warn. *Macias v. Saberhagen Holdings, Inc.*, 175 Wn.2d 402, 409, 282 P.3d 1069 (2012); RCW 7.72.010(4), .030. We have held that the "WPLA is the exclusive remedy for product liability claims," including claims for inadequate warnings. *Macias*, 175 Wn.2d at 409.

The WPLA was enacted in 1981 and closely mirrors the *Restatement (Second) of Torts* § 402A (Am. Law. Inst. 1965), which we adopted in a series

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[2] ISI dedicated several pages of its briefing to defend against a "duty to train" standard. While Taylor argued that ISI had a duty to train to the trial court, Taylor does not raise that claim to this court.

of cases prior to the enactment of the WPLA. *See* LAWS OF 1981, ch. 27; *Terhune v. A.H. Robins Co.*, 90 Wn.2d 9, 12, 577 P.2d 975 (1978); *see also Ulmer v. Ford Motor Co.*, 75 Wn.2d 522, 531-32, 452 P.2d 729 (1969) (adopting the *Restatement*'s liability standard for a manufacturer case). Thus, although the WPLA governs product harm claims, some case law regarding product harm cases comes from *Restatement* principles.

Here, Taylor argues that the manufacturer's duty to warn exists in the plain text of the WPLA. Taylor is correct. The WPLA provides standards for product manufacturers and the basis for claims where "the claimant's harm was 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). A product is not reasonably safe due to inadequate warnings where the likelihood and seriousness of the harms the product could cause "rendered the warnings or instructions of the manufacturer inadequate" and could have been provided. *Id.* at (1)(b).

The WPLA does not specify who should receive these warnings. However, it states that "[a] product is not reasonably safe because adequate warnings or instructions were not provided *with the product* . . . ." *Id.* (emphasis added). On one hand, the statute discusses inadequate 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. *Id.* On the other hand, it discusses that warnings provided *after* the product was manufactured be given to "product users." *Id.* at (1)(c). Since the product is owned and maintained by the purchasing hospital, it follows from the text of the statute that the purchaser is owed product warnings *with the product* it purchases.

Especially here, where the product is an extremely complex and inherently dangerous medical device, it is logical that hospitals would need warnings. We have held that hospitals have an independent duty of care to their patients. *Pedroza v. Bryant*, 101 Wn.2d 226, 232-33, 677 P.2d 166 (1984). Both parties recognize this. During summary judgment argument, ISI's counsel acknowledged that "Harrison Medical Center had an independent, nondelegable duty to credential and to perform a due-diligence evaluation to determine whether Dr. Bildsten was competent to perform surgery with the da Vinci [System] without supervision." VRP (Feb. 26, 2013) at 37. Although we have recognized that hospitals do not have a duty to intervene in the doctor-patient relationship, *Howell v. Spokane & Inland Empire Blood Bank*, 114 Wn.2d 42, 55, 785 P.2d 815 (1990), hospitals are required by law to adopt credentialing requirements regarding staffing. *See* RCW 70.41.230; WAC 246-320-161; 42 C.F.R. § 422.204. Harrison Medical Center has a credentialing

process and it cleared Dr. Bildsten to use the da Vinci System for the prostatectomy here. Thus, it follows that hospitals need product warnings to design a credentialing process that will keep patients as safe as possible.

The Washington State Hospital Association argues in its amicus brief in support of ISI that the hospital is not in the best position to determine what procedure should be performed. Br. of Amicus Curiae Wash. State Hosp. Ass'n at 13. However, just because the physician is in the best position to make a decision regarding a patient's treatment, the hospital is not completely absent from the process. In *Pedroza*, we adopted the doctrine of corporate negligence to address negligence beyond that of the physician, to recognize the onus on the hospital itself for the competency of the hospital's medical staff. 101 Wn.2d at 231-33. There, we observed that in addition to the physicians themselves, "[h]ospitals are also in a superior position to monitor and control physician performance." *Id.* at 231. In adopting that doctrine, we recognized the "public's perception of the modern hospital as a multifaceted health care facility responsible for the quality of medical care and treatment rendered." *Id.* We reasoned that imposing the doctrine of corporate negligence on hospitals and requiring them to assume responsibility would provide "hospitals a financial incentive to insure the competency of their medical staffs." *Id.* at 232.

It is true that the hospital, as an entity, did not have a one-on-one relationship with Taylor—Dr. Bildsten did. However, as we have appreciated, hospitals must maintain a high standard of care for the benefit of their patients. As it pertains to the da Vinci System, hospital personnel are actively involved in credentialing doctors to use the device. The hospital simply cannot maintain the high standard that the law requires by excusing manufacturers from the duty to provide them information about devices that they own. Knowing the risks of the da Vinci System is necessary in order to allow hospitals to impose stricter credentialing processes as needed. Certainly an airplane manufacturer does not only supply a user's manual to the pilots—the airline owner needs a copy as well. It is in the best interest of all parties for warnings to be provided, but particularly for patients, who trust that their safety is a priority. The WPLA is concerned with the safety of product users, which is why it explains what makes a product unsafe. It requires warnings for these dangerous products in order to make them safe. Thus, the manufacturer's duty to warn hospitals is embedded in the text of the WPLA itself.

Prior to the adoption of the WPLA, we adopted the learned intermediary doctrine, which flowed from a comment to the *Restatement* that discussed the interpretation of products liability principles to dangerous medical products. The applicability of that doctrine is discussed in the next section.

B. The Learned Intermediary Doctrine Does Not Apply to This Case

Under the learned intermediary doctrine, manufacturers of medical products can satisfy their duty to warn patients of the risks of their products by providing those warnings to the doctors prescribing the products. The manufacturer's duty to provide warnings to patients transfers to the doctor, who is in a better position to communicate them to the patient. In this case, ISI contends that the manufacturer's duty to warn the hospital, which buys the product, is similarly met by providing those warnings to the doctor using the product. We reject this reasoning because the WPLA imposes a separate and distinct duty for the manufacturer to provide warnings to the purchaser of the product. Hospitals cannot meet their own duty to patients without knowing the risks of the dangerous medical products they own.

i. Background on the Learned Intermediary Doctrine

We have found that under the learned intermediary doctrine, the manufacturer satisfies its duty to warn the patient of the risks of its product where it properly warns the prescribing physician. *Terhune*, 90 Wn.2d at 14. We have explained the policy behind the doctrine as follows:

> 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.

Id. (footnote omitted). Thus, although the manufacturer has a duty to warn patients of product risks, it can satisfy this duty by warning the doctor (the learned intermediary), who then takes on the responsibility of communicating those warnings to the patient. *Id.* at 17.

Here, we are asked the novel question of whether the manufacturer's duty to warn the hospital also can be satisfied by warning the doctor. However, as explained below, the doctor is not a learned intermediary between the manufacturer and the hospital, and thus the doctrine does not apply here.

ii. The Learned Intermediary Doctrine Does Not Apply To Excuse the Manufacturer's Duty To Warn the Purchasing Hospital

As stated above, the learned intermediary doctrine's focus is on the warnings to the patient and the doctrine releases the manufacturer's duty to warn the patient where it provides warnings to the learned intermediary physician. Here, ISI argues that a manufacturer need not warn *any other party* where it has warned the prescribing physician. As explained below, this argument fails 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.

The dissenting judge for the Court of Appeals explained why the learned intermediary doctrine does not apply in this case: the "doctrine does not remove a manufacturer's duty to warn hospitals about medical equipment purchased by that hospital." *Taylor*, 188 Wn. App. at 795 (Worswick, J., dissenting in part). That duty to warn the purchaser is independent of the duty to warn the patient. The judge explained, "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* . . . ." *Id.* at 796 (Worswick, J., dissenting in part). Hospitals have an independent duty to ensure a device is used safely. They can meet that duty only if they are informed of the risks of using a device. Physicians do not function as an intermediary with a duty to warn the hospital of the risks of a device, so nothing about the learned intermediary doctrine applies here.

Both parties point to one case for support, in which we relied on the learned intermediary doctrine to hold that pharmacists do not have a duty to warn patients about prescription drugs they provide patients. *McKee v. Am. Home Prods. Corp.*, 113 Wn.2d 701, 720, 782 P.2d 1045 (1989). However, *McKee* is not helpful to this case. *McKee* presented the question of whether the

pharmacist had a duty to warn the patient about a medication in addition to the physician who prescribed the medication. *Id.* at 707. In that case, we compared the pharmacist to the manufacturer and found that the pharmacist did not have to separately warn the patient because the doctor, as learned intermediary, had already done so. *Id.* at 711. That analysis has no bearing here because this case involves a separate duty that flows from the manufacturer to the purchaser and is not about whether a learned intermediary cuts off the duty to warn patients.

This doctrine should not serve to excuse the manufacturer's duties to warn other entities to ensure the safety of persons its product will be used on. Since the learned intermediary doctrine underscores the importance of patient safety, it would be illogical if the doctrine was used to excuse another avenue to achieve that goal. If patient safety is the goal, then it requires all hands on deck. While doctors are recognized as the gatekeepers between the manufacturer and the patient, the hospital is the gatekeeper between the physician and the use of the da Vinci System since the hospital clears surgeons to use it. Thus, the hospital must have warnings about its risks and no tort doctrine should excuse the manufacturer from providing them.

Thus, the learned intermediary doctrine does not excuse the manufacturer's WPLA duty to warn the hospital because it pertains to the

manufacturer's duty to warn only the patient, not the product purchaser. Consequently, we find that the trial court erred by declining to give the jury an instruction on ISI's duty to warn Harrison Medical Center. Based on that error, we vacate the defense verdict and remand for retrial. To provide guidance to the parties on retrial, we address Taylor's other arguments below.

2. The Strict Liability Standard Governs Inadequate Warning Claims on Dangerous Medical Products Like the da Vinci System

Taylor argues that the trial court erred by applying a negligence standard to her WPLA failure to warn claim because strict liability governs such claims. In this instance, we agree. Our case law on this issue is unsettled, and there is no binding precedent that requires adoption of a negligence standard when inadequate warnings are given. We instead follow the plain language of *Restatement* § 402A and hold that the usual strict liability standard applies to failure to warn claims.

Under the WPLA, a manufacturer is liable where the plaintiff's harm was "proximately caused by the negligence of the manufacturer" as to design or inadequate warning. RCW 7.72.030(1). However, strict liability generally governs product liability claims because of the common law foundation of the WPLA. *Macias*, 175 Wn.2d at 409-10. A strict liability standard is also used in *Restatement* § 402A, which this state adopted. One comment to § 402A, which we have likewise adopted, provides an exception to the application of

strict liability for "unavoidably unsafe products." RESTATEMENT (SECOND) OF TORTS: SPECIAL LIABILITY OF SELLER OF PRODUCT FOR PHYSICAL HARM TO USER OR CONSUMER § 402A cmt. k. (AM. LAW INST. 1965). Comment *k* states:

> *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other 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. It is also true in particular of many 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. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Thus, where a product is inherently dangerous by nature but is still desirable because of its public benefit, it is an "unavoidably unsafe product" under

comment k. Comment k exempts such products from strict liability under § 402A.

But comment k specifies that the exception is not available to a manufacturer who fails to adequately warn. Comment k states that "[t]he seller of such products, again *with the qualification that they are properly prepared and marketed, and proper warning is given,* where the situation calls for it, is not to be held to strict liability." *Id.* (emphasis added). Thus, by its express terms, proper preparation, marketing, and warnings are prerequisites to a manufacturer being able to qualify for this exception to strict liability.

It should be noted that although proper warnings are a prerequisite to application of the exception, comment k does not govern the adequacy of those warnings. However, one thing is clear: comment *k* is an *exception* to § 402A strict liability. It thus applies only after the trier of fact determines the prerequisites have been met. Comment k exempts a manufacturer from § 402A's strict liability standard only if proper warnings accompanied the product, and we must measure the adequacy of those warnings under § 402A *before* applying the exception. To apply the standard of the exception before its prerequisites have been met would allow the exception to swallow the rule.

Intuitive asserts that negligence, not strict liability, governs duty to warn claims, arguing that "Washington and federal courts have had little difficulty in

holding a negligence standard applies to comment k cases." Revised Suppl. Br. of Resp't at 16. However, this is not the case in Washington when a manufacturer fails to provide adequate warnings. While this court has been divided on this issue, there is no binding precedent that requires us to hold that a negligence standard applies when determining whether comment k applies to failure to warn claims. We instead follow the language of the comment itself and hold that the usual strict liability standard applies here.

In *Terhune*, 90 Wn.2d at 12-13, we applied the comment k exception to an intrauterine contraceptive device. However, in that case the evidence was undisputed that the defendant warned the plaintiff's physician of the danger of perforation of the uterus upon insertion of the device. The court rejected an argument that the defendant owed a duty to warn the plaintiff patient directly. While the court acknowledged that comment k "does not purport to state what is 'proper warning' where [an unavoidably unsafe] product is involved," *id.* at 13, the court clarified that the warning was proper in that case, stating that a manufacturer "fulfills its duty if it warns the physician of the dangers attendant upon its use, and need not warn the patient as well." *Id.* at 17.

Following *Terhune,* we answered a certified question asking whether comment k applied to blood products. *Rogers v. Miles Labs., Inc.,* 116 Wn.2d 195, 802 P.2d 1346 (1991). The court in *Rogers* held that the comment k

exception did apply. However, even though *Rogers* did not involve an inadequate warning claim, in dicta the court posed a hypothetical, stating,

> It might be argued that, in order fully to resolve the question whether strict liability applies, we must also resolve whether defendants met their duty to warn under comment *k*. The argument would be that if defendants did not qualify for the comment *k* exception, then the overall rule—strict liability—would apply.

Id. at 207. The court then expressed agreement with the reasoning of a California case applying a negligence standard. *Id.* (citing *Brown v. Superior Court*, 44 Cal.3d 1049, 1059, 751 P.2d 470 (1988)).

This passage was unnecessary to resolve the certified question at issue, and has never been applied by a majority of this court. In *Young v. Key Pharm., Inc.,* 130 Wn.2d 160, 167-69, 922 P.2d 59 (1996), a four-justice lead opinion relied on *Rogers,* requiring a negligence standard for failure to warn claims with respect to unavoidably unsafe products. However, the four-justice "dissent" concluded that *Rogers* was not binding authority on the standard for failure to warn claims, explaining, "*Rogers* wrongly applied comment *k* and Washington law. Exemption from strict liability under comment *k* is expressly limited to products accompanied by *adequate warnings.* Stated another way—adequate warnings are a predicate to application of comment *k* by the express terms of the comment." *Id.* at 184 (Madsen, J., dissenting).

Since *Young*, this court addressed comment k another time, but again not in the context of an inadequate warnings claim. In *Ruiz-Guzman v. Amvac Chem. Corp.*, 141 Wn.2d 493, 496, 7 P.3d 795 (2000), the sole question pertaining to comment k was whether a pesticide could qualify as an "unavoidably unsafe product" under *Restatement* § 402A. A failure to warn claim was not raised. The court noted, however, that "[b]ecause comment *k* was not expressly provided for in the WPLA, we must be sparing in its application lest we defeat the letter or policy of the WPLA." *Id.* at 506. Thus, the issue remains unresolved.

Because no binding precedent in Washington requires adoption of a negligence standard here, we follow the language of the Restatement itself and hold that the comment k exception is not available to a manufacturer who fails to adequately warn. Comment k provides that a product is "unavoidably unsafe" only when it is otherwise properly prepared and accompanied by adequate warnings; thus, the exception applies only *after* the trier of fact determines that the prerequisites have been met. The adequacy of a manufacturer's warnings are to be measured under Washington's strict liability test. Maintaining strict liability for these claims is essential to the purpose of comment, which is to safeguard the public to the greatest extent possible

without discouraging the development and marketing of unavoidably unsafe products. We reverse the trial court's application of negligence in this case.

3. The Trial Court Did Not Err in Prohibiting Taylor's Rebuttal Evidence

Taylor also argues that the trial court erred by excluding one exhibit that Taylor proposed to rebut one witness' testimony. We find that the trial court was within its discretion to exclude Taylor's proposed rebuttal evidence in response to an ISI witness' assertion that the robotics program at Harrison Medical Center was successful overall. The trial judge correctly recognized that the proffered evidence was complicated and might have confused the jury. More importantly, the trial court gave a curative instruction to limit any prejudice from the ISI witness' assertion.

First, some additional facts are necessary to evaluate this issue. Before trial, Taylor filed a motion in limine to exclude evidence of the absence of subsequent accidents using the da Vinci System at Harrison Medical Center. At trial, ISI put forth testimony from Sean O'Connor, the ISI representative who worked with Harrison Medical Center, who testified about Harrison's robotics program. When Taylor cross-examined O'Connor, Taylor asked O'Connor whether he had doubts about the success of the robotics program. When O'Connor said no, Taylor asked why. O'Connor responded that "outside of this incident we're talking about, it[']s been a very successful program."

6 VRP (Apr. 22, 2013) at 855. A few days later, Taylor offered exhibit 304, a record of 233 surgeries at Harrison Medical Center, to rebut the overall success of the program. The document listed all robotic procedures and notations about complications. Taylor argued that O'Connor's testimony opened the door to that list. The trial court excluded the evidence as confusing and prejudicial, but gave the following curative instruction:

> Each side has its own view as to whether there were other incidents at Harrison 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 da Vinci program.

CP at 4693. The Court of Appeals affirmed. *Taylor*, slip op. (unpublished portion) at 16-18.

In general, when one party opens the door to a topic, the other party may also introduce evidence in order to establish the truth for the jury. *State v. Gefeller*, 76 Wn.2d 449, 455, 458 P.2d 17 (1969). However, all evidence must be relevant. ER 402. Even relevant evidence is limited where its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury. ER 403. We review evidentiary challenges for an abuse of discretion. *Kappelman v. Lutz,* 167 Wn.2d 1, 6, 217 P.3d 286 (2009). A trial court's decision on excluding evidence will be reversed only where it was based on untenable grounds or reasons. *Id.*

Here, excluding exhibit 304 was not an abuse of discretion because in the trial court's assessment, the exhibit was confusing and prejudicial. First, ISI did not open the door to this evidence since *Taylor* was questioning O'Connor—not ISI. Second, exhibit 304 likely would have confused the jury because it was not offered contemporaneously with O'Connor's testimony or with an expert who could explain the significance of the notations regarding the complications. The jury would not know whether the complications were minor or serious, or whether the various procedures were comparable to prostatectomies. Third, the judge issued a limiting instruction. As the Court of Appeals observed, if admitting O'Connor's testimony was problematic in the first instance, the proper remedy would not be to pile on confusing evidence. The proper remedy was to provide a limiting instruction, which the trial court did. Consequently, we find that the trial court did not abuse its discretion in excluding exhibit 304.

4. The Trial Court Did Not Err by Giving Jury Instructions on Superseding Cause or Failure To Mitigate

Taylor raises two additional alleged instructional errors. Taylor claims that the trial court erred by instructing the jury on Dr. Bildsten's negligence as a superseding cause and Taylor's own failure to mitigate. Since the jury did not reach these issues because it found in favor of the defendant and the Court of Appeals affirmed, the Court of Appeals declined to reach these issues.

However, we reach these issues to provide guidance to the parties should the issues come up again on remand. As explained below, since evidence supported the defendant's theories on these issues, the trial court acted within its discretion by providing these instructions.

In general, whether to give a particular instruction is within the trial court's discretion. *Stiley v. Block*, 130 Wn.2d 486, 498, 925 P.2d 194 (1996). Where substantial evidence supports a party's theory of the case, trial courts are required to instruct the jury on the theory. *Id.* We review a trial court's decision to give a jury instruction "de novo if based upon a matter of law, or for abuse of discretion if based upon a matter of fact." *Kappelman*, 167 Wn.2d at 6. That means that where the parties' disagreement about an instruction is based on a factual dispute, it is reviewed for an abuse of discretion. *State v. Walker*, 136 Wn.2d 767, 771-72, 966 P.2d 883 (1998). To determine whether to give an instruction, the trial judge "must merely decide whether the record contains the kind of facts to which the doctrine applies." *Kappelman*, 167 Wn.2d at 6.

a. Superseding Cause

The trial court instructed the jury on Dr. Bildsten's negligence as a superseding cause that cut off ISI's liability. Taylor objected to the instruction, arguing Dr. Bildsten's actions were not independent of ISI's duty to warn. In

general, we have agreed that the superseding cause theory applies to product liability actions. *Campbell v. ITE Imperial Corp.*, 107 Wn.2d 807, 814, 733 P.2d 969 (1987). Washington courts have found that superseding cause instructions are properly given in a failure to warn case where the manufacturer provided warnings, but the manufacturer did not foresee that the consumer would fail to heed that warning. *See, e.g.*, *Minert v. Harsco Corp.*, 26 Wn. App. 867, 874-75, 614 P.2d 686 (1980). Here, the facts adduced at trial show that Dr. Bildsten was negligent despite being given very specific warnings. He failed to heed warnings about not choosing patients with a BMI of over 30 and/or prior lower abdominal surgeries. Thus, the facts in the record indicate that his negligence may have been a superseding cause. The trial court was within its discretion to instruct the jury on superseding cause.

b. Failure To Mitigate

The trial court instructed the jury that it could consider Taylor's own alleged failure to mitigate. Taylor objected to the instruction, arguing that giving the instruction was inappropriate because the verdict form allowed the jury to deduct damages twice. Washington law states that the plaintiff's failure to mitigate can be considered under the comparative fault statute. RCW 4.22.005. The statute states that the conduct of both parties is considered when determining damages. RCW 4.22.015. We have held that a "plaintiff's

negligence directly reduces plaintiff's recovery by the percentage of negligence involved." *ESCA Corp. v. KPMG Peat Marwick*, 135 Wn.2d 820, 830, 959 P.2d 651 (1998). Here, it was appropriate for the trial court to include the instruction to consider any potential mitigation of other parties, as facts were adduced at trial about the fault of Dr. Bildsten and Taylor. The verdict form allowed a place for the jury to fill in percentages of fault and does not indicate double deduction, as Taylor contends. Thus, the trial court was within its discretion to provide the failure to mitigate instruction.

CONCLUSION

We find that pursuant to the WPLA, manufacturers have a duty to warn hospitals about the dangers of their products. The manufacturer's warnings to Dr. Bildsten did not excuse its duty to warn Harrison Medical Center. As such, we find that the trial court erred in failing to instruct the jury on this duty. We vacate the jury's defense verdict and remand for a new trial. Further, we hold that the comment k exception in *Restatement* § 402A is not available to a manufacturer who fails to adequately warn and reverse the trial court's application of negligence in this case.

WE CONCUR:

No. 92210-1

MADSEN, J. (dissenting)—I agree with the majority that strict liability governs inadequate warning claims on dangerous medical products because the exception found in comment k to section 402A of the *Restatement (Second) of Torts* (Am. Law. Inst. 1965) is predicated on adequate warnings being given. And I agree that Intuitive Surgical Inc. (ISI) had a duty to warn Harrison Medical Center of the dangers of the "da Vinci System" surgical device when Harrison purchased that product. I write separately, however, because even though this duty exists, it is not a duty that was owed to the petitioner in this case. Therefore, the trial court did not err by not instructing the jury on ISI's duty to warn Harrison.

Discussion

The majority holds that the Washington product liability act (WPLA), chapter 7.72 RCW, requires manufacturers to warn purchasers of the dangers of their products because the WPLA states that a product is not reasonably safe if adequate warnings are not provided with the product. *See* majority at 11 (citing RCW 7.72.030(1)(b)). Thus, because Harrison was the purchaser of the da Vinci System, ISI had a duty to provide warnings to Harrison. Although I concur with the majority's conclusion based on the text

of the WPLA that ISI owed a duty to Harrison, I cannot agree that Josette Taylor somehow has the ability to invoke this duty that was owed to Harrison.

Under the WPLA, a manufacturer must provide adequate warnings with its product. RCW 7.72.030(1)(b); *see* majority at 10-11. This duty, however, is one that the manufacturer owes the purchaser. The manufacturer must provide product warnings with the product that the purchaser purchases. *See* majority at 11. Here, ISI would owe this duty to Harrison. So if ISI breached this duty, Harrison would presumably have a claim against ISI. But Taylor has no claim to enforce a duty owed to another. Taylor cannot invoke a duty owed to Harrison to recover damages from ISI.

Taylor is not alleging that ISI breached a duty to warn her or her husband, Fred Taylor, nor could she. Any theoretical duty here is untenable. There are several steps between ISI and Taylor. ISI manufactured the product, ISI sold the product to Harrison, Harrison credentialed the doctor, and the doctor ultimately operated on Taylor's husband using the product. Although different duties exist in that chain of events, none supports this claim. First, a duty to Taylor from ISI does not pass through the doctor. As this court has said, it is a well-established rule that "the duty of the manufacturer to warn of dangers involved in use of a product is satisfied if he gives adequate warning to the physician who prescribes it." *Terhune v. A.H. Robins Co.*, 90 Wn.2d 9, 13, 577 P.2d 975 (1978). The duty to warn runs to the physician, not the patient. Thus this cannot be the basis for Taylor's claim against ISI.

Second, a duty to Taylor from ISI does not pass through the hospital. Harrison's potential liability to Taylor for credentialing Dr. Scott Bildsten does not save Taylor's claim because Taylor has already settled all claims against Harrison. Taylor suggests that she can bring this claim because ISI's failure to warn Harrison may have caused Harrison to credential doctors it would not have otherwise, which in turn caused the ultimate injury to her husband. But by rooting her claim in Harrison's credentialing, it appears that Taylor is really seeking recovery from ISI for a claim that she has already settled with Harrison. Seeking recovery from ISI for the failure of Harrison in credentialing its doctors is also improper because hospitals owe a nondelegable duty to their patients. *See Douglas v. Freeman*, 117 Wn.2d 242, 248, 814 P.2d 1160 (1991). Any duty that Harrison owed to Taylor could not have been delegated to ISI. Thus this also cannot be the basis for Taylor's claim against ISI. ISI simply owed no duty to warn—direct or indirect—to Taylor.

Taylor cannot recover for an alleged breach of a duty that was owed to another. She has no claim against ISI for a breach of its duty to Harrison. Because Harrison is not a party to this case and thus cannot assert a claim against ISI, the trial court did not err by not instructing the jury as to the duty that ISI owed Harrison. Even if the trial court erroneously believed that no such duty existed, remanding this case would not suddenly give Taylor a cause of action to invoke a duty owed to another.

Accordingly, I respectfully dissent.

Madsen, J.

Gonzalez, J.

Fairhurst, C.J.