No. 92210-1

IN THE WASHINGTON STATE SUPREME COURT

IN THE COURT OF APPEALS FOR
THE STATE OF WASHINGTON
DIVISION II

No. 45052-6-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,

Appellants,

v.

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

Respondent.

PETITION FOR REVIEW

MASTERS LAW GROUP, P.L.L.C.
Kenneth W. Masters, WSBA 22278
Shelby R. Lemmel, WSBA 33099
241 Madison Ave. North
Bainbridge Island, WA 98110
(206) 780-5033
Attorney for Appellant

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INTRODUCTION

Division Two held (2-1) that a manufacturer need not warn the purchasing hospital about the dangers of a complex surgical robot, even though the hospital must make the credentialing decision allowing a surgeon to use the robot on its patients. ***Taylor v. Intuitive Surgical, Inc.***, Washington State Court of Appeals No. 45052-6-II (July 7, 2015), *recon. denied* (Aug. 10, 2015) (copies attached). This holding contradicts Washington's Products Liability Act, requiring manufacturers to provide adequate warnings *with the product*. RCW 7.72.030(1)(b). The only way to provide adequate warnings with this product was to provide them to the purchasing hospital, which communicated directly with the manufacturer (not through a doctor) and which owns this unavoidably unsafe medical device. Hospitals owe an independent duty of care to their patients to credential doctors safely. This Opinion is incorrect and dangerous to patients.

Whether negligence or strict liability applies to inadequate-warnings claims is also an open question, where the leading Opinion from this Court was 4-4. Any decision permitting an exception to strict liability in this context is incorrect and harmful: the Court should grant review to overrule it. This Court should also address other issues that Division two failed to address. *See* Mot. for Recon. (attached).

ISSUES PRESENTED FOR REVIEW

1. Did ISI have a duty to warn and instruct Harrison Hospital, the purchaser of the unavoidably unsafe da Vinici robot, where Harrison was solely responsible for credentialing doctors to use it?

2. Did the trial court erroneously instruct the jury on negligence, rather than strict liability, for ISI's failures to warn and instruct?

3. Did the trial court erroneously instruct the jury to determine whether Dr. Bildsten's negligence was a superseding cause, where his negligence was a reasonably foreseeable consequence of ISI's failure to properly warn and instruct as a matter of law, and where the resulting harm was not different or independent?

4. Were the court's failure-to-mitigate instructions improper, where they instructed the jury: (a) not to include damages that could have been avoided, but also (b) to reduce damages by a percentage reflecting the failure to mitigate?

5. After an ISI employee testified that, aside from Taylor's surgery, the robotics program at Harrison was successful and that Harrison was purchasing a second robot, did the trial court err in refusing to allow Taylor to cross-examine witnesses on whether the robotics program was replete with problems?

STATEMENT OF THE CASE

A. Overview.

After discovering that he had prostate cancer in August 2008, Fred Taylor opted to have his prostate removed in a robotic laparoscopic procedure. RP 1067-68, 1145-48, 1916. Fred's surgeon, Dr. Scott Bildsten, had only recently completed robotics training, and was newly credentialed at Harrison Medical Center when he performed the surgery. RP 1060, 1662, 1664; CP 2309-2310. Harrison's robotics program was in its infancy. RP 1160.

Fred's procedure went horribly wrong, and it is undisputed that he suffered life-altering injuries as a result. *See* BA 29-34. As one friend succinctly put it, the operation "destroyed [Fred's] quality of life." RP 2093. The parties dispute whether the surgery hastened his death four years later. RP 1451.

Fred's widow asserted that Intuitive Surgical, Inc. ("ISI"), the manufacturer of the "da Vinci" robot used on Fred, misinformed and failed to adequately warn and instruct Harrison, which purchased the robot and credentialed Bildsten based on ISI's inaccurate and incomplete information. The Brief of Appellant fully explains how this tragedy came to pass. BA 5-34. A brief summary follows here.

B. The da Vinci robot is an unavoidably unsafe product that was never approved by the FDA.

ISI agrees that its robot is an "unavoidably unsafe product" under the WPLA. CP 110. And the FDA has never "approved" a da Vinci robot. RP 2709, 2712, 2723, 2741. In 1997, the FDA "cleared" the first da Vinci robot to hold certain instruments because it was "substantially equivalent to other types of products that held [such] instruments." RP 467-68. Obtaining clearance is far simpler, faster, and cheaper than obtaining approval. RP 491.

C. ISI obtained FDA "clearance" for prostatectomies by promising a four-phase comprehensive training program for surgeons wishing to operate using the robot.

ISI obtained 14 related FDA "clearances," including one for prostatectomies, by telling the FDA that it would provide a four-phase, comprehensive training program to surgeons wishing to use the device. RP 469, 1913; Ex 24, p.30. The specific phases were (1) a 70-question written test (RP 2625; CP 4631, 4634; Ex 10, p. 30; Ex 24, p. 31; (2) on-site and off-site training (RP 2625; Ex 10, p.31; Ex 24, p.31); (3) a series of drills using metrics to certify mastery (Ex 10, p. 31; Ex 24 p. 31-32); and (4) a self-directed learning curriculum using ISI's "standardized series of exercises" focusing on "surgical tasks" (Ex 10, p. 31; Ex 24, p. 32).

ISI told the FDA that each of its training centers would "follow a standard curriculum and utilize standard performance assessment" before moving a surgeon through a phase, and that "[d]eficiencies [would] be identified and remediated." Ex 10 p. 30; RP 1923-25, 1928-29. ISI stated that it would "quantitatively asses[]" the surgical team's ability to use the robot using a Likert-type scale of one to five, and a "standard training checklist." RP 1924-25; Ex 13, p. 15.

ISI also told the FDA that surgeons should "meet basic and advanced laparoscopic requirements as outlined by private and/or academic organizations." RP 1915; Ex 20, p. 55. This was important, where robotic surgery is an extension of traditional laparoscopic surgery. RP 1915-16. A surgeon needs to have laparoscopic training in order to do robotic procedures. *Id.* Even a surgeon who is very experienced and confident in open procedures is not qualified to sit down and start doing a robotic procedure. RP 1911.

D. But ISI never delivered the promised training program.

By the time ISI was trying to sell Harrison a robot in 2008, it had abandoned the 70-question test for a 10-question test. CP 335, 4631. The entire Phase 1 distance-learning module took only one hour to complete. RP 2939-40. Although ISI told the FDA that "[c]ontinuation to Phase 2 is dependent upon successful completion

of Phase 1," ISI is not aware of anyone having ever failed the Phase 1 test. *Id.*; Ex 24 p. 31. It is impossible to fail. CP 4608-10.

ISI had also shortened off-site training to only one day, if (as here) only one member of the surgical team was training on the console. RP 2625-26; CP 4613, 4634-35. Despite its promise to use a "standardized Training Assessment tool," ISI had no "objective standard" to evaluate surgical duration. *Compare* Ex 24, p. 31, *with* RP 2627-28. ISI had dropped even a 1-to-5 scale, using no "standard performance assessment" in any Phase. CP 4652-54. It is unclear what, if anything, ISI did to evaluate the surgical team in Phase 3. *Id.* And despite its promise to provide a "standardized series of exercises" focusing on "surgical tasks," ISI had nothing to do with Phase 4, other than possibly referring a surgeon to an advanced training program. CP 4619-20; Ex 24, p.32.

By the time ISI sold a robot to Harrison, it used no standard performance assessment on any phase. CP 4621-22. Removing these assessments "made it dangerous" for patients. RP 1934-35. "[T]he foreseeable consequences of changing the program in this way" is that "[y]ou have surgeons who have not been adequately assessed if they could do the job." RP 1935. Regardless of any argument about surgical abilities, this is not sufficient training. *Id.*

E. ISI put its people on Harrison's credentialing committee, and advised it to allow surgeons to operate unsupervised after performing only two proctored procedures.

Although ISI maintained that credentialing is entirely up to hospitals, three of its employees sat on Harrison's steering committee – the group that recommended the credentialing requirements that Harrison adopted. RP 720. These included ISI's Clinical Sales Manager, Sean O'Connor, and ISI's Clinical Sales Representative, Damon Daniels. RP 720, 1640. ISI admitted that new purchasers depend on ISI's credentialing expertise. RP 714-15.

Indeed, ISI employees who worked directly with Harrison (and other customers) agreed that part of their job was to present themselves as partners in building a successful robotics program. RP 550, 657, 679-80, 1669, 1694; CP 4587-88; Ex 281, p. 5. Marketing materials extolled the virtues of partnering with ISI. CP 4584, 4587; Ex 48, p.2. And Daniels encouraged hospitals and surgeons to see him as a "leader" and an "expert." RP 1688.

Harrison asked for credentialing examples, and ISI provided some from local hospitals, claiming that the area average is to credential after only two proctored cases.[1] RP 714-16. Of course,

[1] ISI led Bildsten to believe that two proctored cases and ISI training would adequately prepare him to use the robot without supervision. RP 1036-37.

ISI also sold its robots to those hospitals. *See* RP 775-76, CP 4677-78. O'Connor gave Harrison ISI's "Clinical Pathway and Training Protocol For da Vinci Prostatectomy," purporting to lay out the steps to "ensure success in becoming a proficient robotic surgeon." Ex 511; RP 716, 840, 1036.[2] He agreed that Harrison would have understood this Clinical Pathway to recommend only two proctored procedures. Ex 511; RP 716. But O'Connor was unaware of any medical literature supporting that claim. RP 711-12.

F. Despite positioning itself on Harrison's credentialing committee," ISI misled Harrison about the learning curve.

An internal ISI document instructed sales reps to tell potential purchasers that "[t]here is a fairly short learning curve . . . ." RP 546; Ex 14, p. 2. The "learning curve" is the number of surgeries required to achieve "basic competency" on the robot. CP 5364-65. Put another way, "learning curve" refers to the time it takes a surgeon to gain the experience necessary to perform an "adequate robotic prostatectomy." RP 960.

In 2005, Drs. Herrell and Smith published an article titled "Robotic-Assisted Laparoscopic Prostatectomy: What Is The Learn

[2] This particular clinical pathway is for Bildsten's partner, Dr. Hedges. Bildsten's clinical pathway could not be found, but was the same. RP 1036.

Curve?" RP 803. Herrell was fellowship-trained in laparoscopic surgery, and Smith was well-recognized and highly-skilled in open prostatectomy. RP 1948-50. Herrell and Smith concluded that their robotic-surgery results were not comparable to routine open-surgery results until their team had completed 150 robotic prostatectomies. RP 804, 1948. "Surgeon comfort and confidence" was not comparable "until 250 robotic procedures." *Id.*

The article continues that hospitals considering a robotics program must consider that most surgeons "may never overcome the learning curve," where the median number of prostatectomies a urologist performs annually in the United States is only seven. RP 805-06, 1949. This is the only article that uses margin rates – cancer removal – as a basis for measuring the learning curve. RP 1949-50. This is, perhaps, the most important measure of a successful prostatectomy – "making sure you get all the cancer out. That's the number one thing the patient wants." RP 1949.

The Herrell and Smith article is consistent with a 2010 article published in the New England Journal of Medicine, considered to be the most prestigious medical journal. RP 984-85. The article concludes that it took between 150 and 250 robotic procedures to become "adept." RP 985. Although this article post-dates Fred's

procedure, there were many similar articles in 2008 talking about the steep learning curve in robotic procedures. *Id.*

In 2006, former ISI consultant Dr. Vip Patel reported that the learning curve for his surgical team was 20 to 25 cases. RP 567-69, 628, 1947. Patel is a highly respected leader in minimally invasive robotic surgery. RP 1947. Patel's "learning curve" is defined by good surgical times, low blood loss and transfusions, and few complications. RP 1947. Despite extensive laparoscopic training, Patel's team had a 1% complication rate, with two rectal injuries in his first 15 cases. RP 2004, 2060.

Defining "learning curve" solely as the number of surgeries necessary to complete a robotic prostatectomy in four hours, ISI consultant Dr. Ahlering reported that his team's learning curve was 8 to 12 cases. RP 557, 565, 630-32. Ahlering is a prolific expert in robotic prostatectomy and an accomplished open surgeon, but he was assisted by a "very accomplished" laparoscopic surgeon. CP 1942-43. But it took Ahlering's team 12 cases to perform a robotic prostatectomy in 4 hours. RP 1943-44.

And speed is not everything. RP 1944. Ahlering's team had one surgical complication in the first three procedures and two complications in the first nine procedures, a 22% complication rate.

RP 2052-53. And the team's margin rate (where cancer remained) was 30% to 35%. RP 1966, 2054.

But no one from ISI ever provided any of above information to Harrison. *See* BA 24-25.

G. Per ISI's recommendation, Harrison credentialed Dr. Bildsten after ISI training and two proctored procedures – Fred Taylor was his first unproctored robotic operation.

Bildsten completed ISI's reduced Phase 2 on July 17, 2008, and its reduced Phase 3 twelve days later. RP 1662. His two proctored procedures on July 28th and 29th lasted 10 hours and 7.5 hours. RP 1662-63; Ex 216. Although ISI thought these operative times were "long," it gave Bildsten only positive feedback. RP 1059.

Fred's procedure was five to six weeks later. RP 1060. This was Bildsten's first unproctored procedure. RP 1059-60. It took Bildsten and Daniels almost 1.5 hours to dock the robot, 2-to-3 times longer than it should take. RP 1074-75, 2357-58. After almost 8 hours, Bildsten could no longer proceed robotically, converting to an open procedure. RP 1079, 1287. Fred was in surgery for another 5 hours, totaling 13 hours in surgery. RP 1287. The surgery essentially destroyed Fred's quality of life. *See, e.g.*, BA 28-34.

REASONS TO GRANT REVIEW

A. The Court of Appeals dissent is correct on an issue of substantial importance to Washington citizens that substantially affects the interpretation of the WPLA.

Misinterpreting the WPLA presents an issue of substantial pubic interest that should be determined by this Court. RAP 13.4(b)(4). Judge Worswick's dissent captures the heart of Taylor's argument, which the majority failed to address. *See* Motion for Recon. at 5-8. Put simply, since ISI admits that its robot is not reasonably safe (CP 110) it had to provide "adequate warnings or instructions" "with the product" (here, the robot sold to Harrison):

> A product is not reasonably safe because **adequate warnings or instructions were not provided with the product**, 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) (emphasis added). The only way for ISI to provide adequate warnings with the robot was to provide them *to the purchaser* – Harrison – with the product. Yet the trial court refused to instruct the jury that ISI had to provide adequate warnings and instructions to Harrison. BA 37-38. Under the WPLA's plain

language, this was clear error. BA 40-42. This Court should grant review to consider this important issue.

Instead of following this straightforward statutory analysis, ISI, the trial court, and the appellate majority, each improperly applied the learned intermediary doctrine to obviate ISI's duty to warn Harrison. BA 42-45. That doctrine states that when a patient can obtain a product or service only from a physician, "the physician acts as a 'learned intermediary' ***between the manufacturer or seller and the patient***." ***Terhune v. A. H. Robins Co.***, 90 Wn.2d 9, 12-14, 577 P.2d 975 (1978) (emphasis added) (discussing RESTATEMENT (SECOND) OF TORTS § 402A, hereinafter "§ 402A"). Therefore, the manufacturer or seller does not have a duty to warn the patient, but rather the doctor. *Id.* The doctor then has the duty – and is the only entity that has the duty – to warn the patient. *Id.*

But this doctrine says nothing about the statutory duty to provide necessary warnings and instructions "with the product" to the purchaser. RCW 7.72.030(1)(b). This case shows why these warnings are so important: Harrison is responsible for credentialing doctors, which is crucial to keeping patients safe. Harrison sets the floor – the minimum requirements to permit surgeons to use the

dangerous medical device. If the hospital is not adequately warned and instructed, it cannot safely set those requirements.

Judge Worswick (like Taylor) correctly asserts that the learned intermediary doctrine cannot apply here because the physician does not stand between the manufacturer and the hospital:

> 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. [Emphasis in original.]

Dissent at 21. Inserting a learned intermediary between a manufacturer and a purchasing hospital has no sound basis in law. And even if the doctrine could apply here, the hospital itself (not a doctor) would be the learned intermediary. *See* BA 46-48.

It also puts patients at risk. That is, if ISI has no duty to warn the hospital about the risks of using its robot, and about the learning curve necessary before doctors should be credentialed to use that device, untrained doctors anxious to gain experience on the machine may obtain unfettered access to the hospital's patients. This Court should grant review to determine whether manufacturers still have a duty under the WPLA to warn product purchasers, where (as here) those warnings are the *only* means to ensure that hospitals can make

sound, independent judgments about which doctors should be permitted to use the devices they purchase in providing quality care to their patients.

There is no question under Washington law that hospitals owe an independent duty of care to their patients.[3] But hospitals cannot meet this duty to their patients if they are not properly warned about cutting-edge technologies so that they can properly credential their doctors on them. This Court should grant review to consider this important issue.

B. This Court should accept review to finally resolve whether and how comment *k* applies to § 402A inadequate-warning claims and to overrule incorrect and harmful precedents.

The trial and appellate courts erred in ruling that negligence, rather than strict liability, governs Taylor's inadequate-warnings claim. This turns on (1) whether RESTATEMENT OF TORTS (SECOND) § 402A, comment *k*, applies at all to inadequate-warning claims,

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[3] *See, e.g.*, ***Douglas v. Freeman***, 117 Wn.2d 242, 248, 814 P.2d 1160 (1991) ("The doctrine of corporate negligence . . . is based on a nondelegable duty that a hospital owes directly to its patients. One commentary finds four such duties owed by a hospital under the doctrine of corporate negligence: . . . (2) to furnish the patient . . . equipment free of defects; [and] (3) to select its employees with reasonable care") (citations omitted)); ***Pedroza v. Bryant***, 101 Wn.2d 226, 236, 677 P.2d 166 (1984) ("'The hospital's liability is based on a duty of care owed by the institution directly to patients to ensure their safety and welfare while within its confines'" (citation omitted)).

despite its language requiring that proper directions and warnings are provided; and if not, (2) whether courts should apply a product-by-product inquiry to determine whether a particular prescription drug or medical device should be exempt from strict liability. The Court should accept review to resolve these important questions.

In ***Falk v. Keene***, the Court held that under RCW 7.72.030(1)(a), strict liability, not ordinary negligence, is the standard for design-defect claims. 113 Wn.2d 645, 654, 782 P.2d 974 (1989). Following ***Falk*** in ***Ayers v. Johnson & Johnson Baby Prods. Co.***, the Court held that strict liability is also the standard in subsection (b) governing inadequate-warning claims. 117 Wn.2d 747, 762-63, 818 P.2d 1337 (1991). And in ***Anderson v. Weslo, Inc.***, this Court held that "[t]he standard for allegations of defective design and of inadequate warnings is one of strict liability." 79 Wn. App. 829, 836, 906 P.2d 336 (1995)). This is consistent with § 402A, which imposes strict liability on manufacturers and sellers of defective products. Strict liability is the correct standard.

By its express terms, comment *k*'s exemption from strict liability applies only when the seller has satisfied a very important predicate – the product was "properly prepared and marketed" and "accompanied by proper directions and warning." § 402A, cmt *k*.

Thus, comment *k* simply cannot apply to inadequate-warning claims. None of this Court's decisions compels a different result.

There are four major Washington Supreme Court cases addressing comment *k*, beginning with ***Terhune***, *supra*. This Court held that the manufacturer of the Dalkon Shield, a contraceptive device, would not be liable for injuries caused by its product if it gave adequate warnings to the prescribing physician. 90 Wn.2d at 9, 13-14. In other words, ***Terhune*** adopted the learned intermediary doctrine. *Id.* at 14.

The second case addressing comment *k*, ***Rogers v. Miles Labs., Inc.***, involved a blood product supplied to hemophiliacs. 116 Wn.2d 195, 198, 802 P.2d 1346 (1991). The Court held that blood and blood products fall under comment *k*'s exemption from strict-liability. *Id.* at 204.

The third major case is a 4-4 plurality decision affirming (for lack of a constitutional majority) summary judgment dismissing plaintiff Young's strict-liability claims, holding that Young's inadequate-warning claims were governed by a negligence standard under comment *k*. ***Young v. Key Pharmaceuticals, Inc.***, 130 Wn.2d 160, 168-71, 922 P.2d 59 (1996). The plurality adopted an

unpublished holding that comment *k* applies to all prescription drugs, rejecting a product-by-product determination. *Id.* at 170.

The ***Young*** dissent, authored by Chief Justice Madsen, disagreed with the plurality's application of a negligence standard to inadequate-warning claims, stating that strict liability applies and that the contrary suggestion in ***Rogers*** is *dicta* based on a California case that had since been clarified as inconsistent with ***Rogers***. *Id.* at 179 (Madsen, J., dissenting). The dissent also distinguished ***Rogers*** on the ground that it involved a product-defect claim, not a failure-to-warn claim. *Id.* at 182. The dissent is correct on all counts.

After ***Young***, the Court again revisited comment *k* in ***Ruiz-Guzman***, addressing a question certified by the Ninth Circuit: whether a pesticide can be "an 'unavoidably unsafe product' as described in comment *k*?" 141 Wn.2d 493, 495, 7 P.3d 795 (2000). The Court was also asked to revisit the ***Young*** plurality decision that all prescription drugs are governed by a negligence standard under comment *k*. *Id.* at 508. But the Court held only that whether a pesticide is governed by comment *k* "is to be determined on a product-by-product basis, as opposed to a blanket exemption like that for medical products," with the jury determining the products' "value to society relative to the harm it causes." *Id.* at 511.

This Court should accept review to clarify the law and to overrule Division One's ***Estate of LaMontagne v. Bristol Meyers Squibb***, which held that under comment *k*, a negligence standard governs inadequate-warning claims. 127 Wn. App. 335, 343, 111 P.3d 857 (2005). ***LaMontagne*** is both incorrect and harmful. *See, e.g.*, ***In re Rights to Waters of Stranger Creek***, 77 Wn.2d 649, 653, 466 P.2d 508 (1970). ***LaMontagne*** provides no analysis, and ignores ***Young*** and ***Rogers***. It mistakenly relies on ***Ruiz-Guzman***, which does not address this issue or even involve a negligent-warning claim. It badly undermines the safety regime of the WPLA concerning negligent-warning claims. This Court should grant review, adopt the ***Young*** dissent's reasoning, and overrule ***LaMontagne***.

Alternatively, this Court should accept review to hold that comment *k* does not apply unless and until the jury concludes that the da Vinci robot's social utility greatly outweighs its inherent risk. In ***Ruiz-Guzman***, the Supreme Court adopted a "product-by-product approach" for pesticides, holding that "the defendant manufacturer of a challenged product would have to demonstrate that an inherently dangerous product is also 'necessary regardless of the risks involved to the user.'" 141 Wn.2d at 509-10 (quoting ***Rogers***, 116 Wn.2d at

204). This approach is consistent "with the social utility reasoning of ***Rogers***," focusing "on the product and its *relative value to society* . . . ." *Id.* (emphasis in original).

C. The Court should also review the remaining issues.

The remaining issues do not independently require this Court to grant review. *See* BA 60-71. But the Court should consider them if, as requested, it reverses and remands for trial on either of the above issues.

CONCLUSION

For the reasons stated above, this Court should grant review.

RESPECTFULLY SUBMITTED this 9th day of September 2015.

MASTERS LAW GROUP, P.L.L.C.

Kenneth W. Masters, WSBA 22278
Shelby R. Frost Lemmel, WSBA 33099
241 Madison Ave. North
Bainbridge Island, WA 98110
(206) 780-5033

CERTIFICATE OF SERVICE BY MAIL AND/OR EMAIL

I certify that I caused to be mailed, postage prepaid, via U.S. mail, and/or emailed a copy of the foregoing **PETITION FOR REVIEW** on the 9th day of September 2015, to the following counsel of record at the following addresses:

Carol Nofziger Johnston
Jane Morrow
Otorowski Johnston Morrow & Golden PLLC
298 Winslow Way West
Bainbridge Island, WA 98110

___ U.S. Mail
_✓_ E-Mail
___ Facsimile

Richard Friedman
William Siemon Cummings
Friedman Rubin
1126 Highland Ave
Bremerton, WA 98337-1828

___ U.S. Mail
_✓_ E-Mail
___ Facsimile

Peter J. Mullenix
Friedman Rubin
51 University St Ste 201
Seattle, WA 98101-3614

___ U.S. Mail
_✓_ E-Mail
___ Facsimile

Philip Talmadge
Talmadge/Fitzpatrick
2775 Harbor Ave SW
Third Floor, Suite C
Seattle, WA 98126-2138

___ U.S. Mail
_✓_ E-Mail
___ Facsimile

Jeffrey Royal Johnson
Scheer & Zehnder
701 Pike Street, Suite 2200
Seattle, WA 98101-2358

✓ U.S. Mail
___ E-Mail
___ Facsimile

Allen J. Ruby
Skadden, Arps, Slate,
Meagher & Flom
525 University Ave.
Palo Alto, CA 94301

✓ U.S. Mail
___ E-Mail
___ Facsimile

Catherine B. Stevens
Quinn Emanuel
51 Madison Avenue
New York, N.Y. 10010

✓ U.S. Mail
___ E-Mail
___ Facsimile

Karen M. Firstenberg
Morris Polich & Purdy LLP
1055 W. 7th Street, Suite 2400
Los Angeles, CA 90017

✓ U.S. Mail
___ E-Mail
___ Facsimile

Kenneth W. Masters, WSBA 22278
Attorney for Appellants

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.

Melnick, J.

I concur:

Sutton, J.

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.

[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.

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

ORDER DENYING MOTION FOR RECONSIDERATION

The Appellant filed a motion for reconsideration of the Court's July 7, 2015 published in part opinion (Worswick, J. dissenting). After review of the files and records herein, we deny the motion.

Dated this 10th day of August, 2015.

Melnick, J.

Sutton, J.

Based on my dissent to the majority opinion, I would grant the motion for reconsideration. Therefore, I dissent to the denial of this motion.

Worswick, J.

No. 45052-6-II

IN THE COURT OF APPEALS FOR
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,

Appellants,

v.

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

Respondent.

MOTION FOR RECONSIDERATION

MASTERS LAW GROUP, P.L.L.C.
Kenneth W. Masters, WSBA 22278
Shelby Lemmel, WSBA 33099
7241 Madison Ave. North
Bainbridge Island, WA 98110
(206) 780-5033
Attorney for Appellant

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INTRODUCTION

This case perfectly illustrates why ISI is required to warn hospitals *before* they warn and train physicians. Despite strong warnings directly to a surgeon who was much too quick to use this dangerous device on patients, he used it on Taylor anyway. Had Harrison been properly warned about the true learning curve – which this Court acknowledges is at least 20 to 30 procedures – the hospital never could have credentialed this surgeon to conduct an unproctored procedure on this terribly unsuited patient after training and only two proctored procedures. Without that credential, the surgeon could not have used this device on Taylor.

In short, it is good public policy to require manufacturers to warn purchasers like Harrison. While the Court appears to see this issue, it never answers the key question: does the WPLA require manufacturers to warn purchasers? Since it does, the next question is whether the learned intermediary doctrine (LID) somehow obviates ISI's duty to warn Harrison. This Court holds that ISI may discharge its duty to warn Harrison by warning the surgeon, removing a layer of patient protection. This contradicts both the WPLA and the LID.

The majority has misapprehended several key points of fact and law. The Court should reconsider. The Dissent has it right.

POINTS OF FACT THE COURT HAS OVERLOOKED OR MISAPPREHENDED

The Court has overlooked or misapprehended two key facts that support Taylor's leading argument on appeal that ISI owed Harrison a warning. When the Court comes to understand the true record, it should reconsider and join the Dissent's cogent analysis.

A. Contrary to the Opinion, and despite telling the FDA that it would do so, ISI never recommended basic or advanced laparoscopic skills to Harrison or to any other hospital.

The Court incorrectly states that "ISI recommends to hospitals that surgeons credentialed to use the da Vinci System 'meet basic and advanced laparoscopic requirements.'" Opinion at 4 (citing CP 5798). The document the Court cites is ISI's representations to the FDA (Ex 20); the very page the Court has cited is in ISI's "Training Program Overview" marked "**Not for External Distribution**." CP 5798. ISI represented to the FDA that it would make this recommendation to hospitals. *See* BA 12.

But the entire point of the next portion of the opening brief is that ***ISI utterly failed to deliver on this promised training***. BA 12-16. In other words, ISI told the FDA that it would recommend basic and advanced laparoscopic skills, but it never did so. *Id.* On the contrary, it instructed its sales reps to target doctors with only basic lap skills. *Id.* at 16.

This failure to recommend advanced lap skills lies at the heart of Taylor's claim that ISI breached its duty to adequately warn hospitals that credential doctors. In other words, the Court misapprehends a material fact, and so fails to recognize that it proves Taylor's claims. ISI never recommended basic and advanced lap skills to Harrison or to any other hospital. At the very least, the Court should correct this misstatement of fact.

B. Contrary to the Opinion, credentialing doctors *requires* an exercise of independent medical judgment.

Tied directly to its first error and to Taylor's leading argument, the Court also states that Harrison "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***." Opinion at 13 (emphasis added). But "credentialing them" ***requires*** independent medical judgment. *See, e.g.*, ***Douglas v. Freeman***, 117 Wn.2d 242, 248, 814 P.2d 1160 (1991) ("The doctrine of corporate negligence . . . is based on a nondelegable duty that a hospital owes directly to its patients. One commentary finds four such duties owed by a hospital under the doctrine of corporate negligence: . . . (2) to furnish the patient . . . equipment free of defects; [and] (3) to select its employees with

reasonable care") (citations omitted)); ***Pedroza v. Bryant***, 101 Wn.2d 226, 236, 677 P.2d 166 (1984) ("'The hospital's liability is based on a duty of care owed by the institution directly to patients to ensure their safety and welfare while within its confines'" (citation omitted)).

Simply put, Harrison decided whether this surgeon was qualified to perform this type of surgery. That required medical judgment. Harrison owed a direct duty to Taylor to exercise its judgment non-negligently. This is why ISI must give proper warnings to hospitals.

Or as Harrison's website puts it:

> **Our promise to our patients is to strive to fulfill our quality vision**
>
> Harrison's commitment to provide patients with exceptional care and service begins with quality. From our caregivers at the bedside to our leaders and board of directors, quality is at the heart of everything we do.
>
> - We build systems to ensure that our patients are treated with world-class, evidenced-based medical care.
> - **We keep our patients completely safe from errors.**
> - ...
> - We work in an organization which regulatory and accreditation activities are routine and welcomed events, and seen as opportunities to improve care.
> - Every member of the Harrison team is committed to providing the very best care to our patients and excellent service to one another.

http://www.harrisonmedical.org/home/quality-safety/ (some formatting and emphasis altered).

POINTS OF LAW THE COURT HAS OVERLOOKED OR MISAPPREHENDED

A. The Court begs the primary legal question in this appeal.

Intending no disrespect, of course, the Court's analysis of Taylor's primary issue – the one on which the Dissent focuses in plain and convincing terms – is fatally circular. The Court begins its analysis of the WPLA duty to warn with a single-sentence: "the WPLA does not expressly provide *who* must receive the manufacturer's warnings." Opinion at 10 (emphasis original). But despite its parenthetical recognizing that manufacturers must provide warnings "with the product," the Court ignores that this plain language expressly creates a duty to warn purchasers. BA 40-42; RCW 7.72.030(1)(b). The only way to provide warnings "with the product" is to provide them to the purchaser.

The Court instead uses the LID – an exception to the WPLA – to determine whether the WPLA requires warnings to purchasers. Saying that manufacturers must warn "only" physicians (rather than patients) under the LID, the Court seems to hold that manufacturers may satisfy the duty to warn purchasing hospitals by warning physicians. Opinion at 10-11. The exception thus swallows the rule.

The Court subsequently correctly states Taylor's leading argument: "Taylor argues that ***ISI's duty to warn <u>also</u> runs to***

Harrison Medical Center as the purchaser of the da Vinci System and that the learned intermediary doctrine is inapplicable here." Opinion at 11 (emphasis added). That is, ISI owes two warnings, one to the doctor (to which the LID applies) and the other to the hospital (to which it does not).

The Court also acknowledges that each of the allegedly controlling precedents is "arguably" distinguishable because the patients in those cases directly "purchased the product," while Taylor did not. *Id.*[1] Rather, Harrison directly purchased this product.

But the Opinion then says this distinction is "immaterial" because the robot "was ***used on*** Taylor and he suffered the harm caused by that surgery." *Id.* (emphasis added). On the contrary, it is entirely material that no one could use this product on Taylor without Harrison's prior consent – without its credential. As explained above, that is the crucial difference between this case and the others. This distinction is dispositive, not immaterial.

---

[1] Distinguishing ***Terhune v. A.H. Robins Co.***, 90 Wn.2d 9, 12-13, 577 P.2d 975 (1978); ***McKee v. Am. Home Products, Corp.***, 113 Wn.2d 701, 709, 782 P.2d 1045 (1989); ***Rogers v. Miles Labs., Inc.***, 116 Wn.2d 195, 207, 802 P.2d 1346 (1991); and ***Young v. Key Pharms., Inc.***, 130 Wn.2d 160, 167-68, 922 P. 2d 59 (1996).

The Court's analysis again swallows its tail: "The ***learned intermediary doctrine*** is not concerned with who pays for the product or who retains possession of the product." Opinion at 11 (emphasis added). Perhaps, but that is irrelevant. The question is whether ***the WPLA*** is concerned with who pays for and owns the product. The WPLA requires manufacturers to give warnings *with the product*, so the WPLA is concerned with "who pays" (in a manner of speaking). And it is the Hospital who pays for and owns the product.

Put bluntly, the Opinion begs the question: it asserts that the LID controls the question whether the LID applies. There is no authority for this circular analysis. Rather, the first question is whether the WPLA requires manufacturers to give warnings to purchasers with their products. Since it expressly does so, the second question is whether the LID somehow obviates that legal duty. The Opinion fails to answer either of these key questions.

Instead, in addressing the Dissent, the Opinion simply "disagrees" that the LID "operates by removing a manufacturers' duty to warn." Opinion at 11-12. The Court apparently holds that the LID permits a manufacturer to meet its duty to warn a hospital by warning a doctor. *Id.* The exception thus swallows the rule.

As a result, the Opinion fails to address the primary legal issue that it correctly states on Opinion page 11: does ISI's WPLA duty to warn run to Harrison as the purchaser? That is a question under the WPLA, not under the LID, and its obvious answer is that ISI owed a direct duty to Harrison as the purchaser. Indeed, no doctor could or did stand as a "learned intermediary" between ISI and Harrison. The trial court therefore erred in failing to instruct the jury on ISI's duty to warn Harrison, as the Dissent correctly states.

As noted above, this Opinion is not good policy under the WPLA. But indeed, it is not good policy ***even under the LID***. The purpose of the LID is to ***increase*** patient safety, not to decrease it. By removing a layer of patient protection – a duty to warn the purchasing hospital so that it can protect its patients by properly credentialing surgeons – this Opinion decreases patient safety. The Court should reconsider, reverse, and remand for a new trial.

B. The Court should address the last two issues to avoid substantial delay.

The Court correctly notes that Taylor properly conceded that the last two issues (superseding cause and failure to mitigate) do not constitute ***reversible*** error because the trial court never reached them. Opinion 2 n.4. The problem, however, is that if this Court does

not resolve those issues now, and if the Supreme Court accepts review, reverses, and remands, this appeal likely will take a detour back to this Court to resolve those two issues. In the past, such remand detours have occasionally taken a year or more.

Taylor respectfully requests that this Court address these two issues now, while the case is fresh in the Court's mind, so to say. This is both so that the parties and this Court can avoid a time-consuming remand detour, and also so that Taylor can determine now whether to seek review of these two issues in the Supreme Court, or to simply let them go. Judicial economy likely will be served by considering them now.

CONCLUSION

For the reasons stated, this Court should reconsider its decision and adopt the reasoning of the Dissent on the leading issue in this appeal. It should reverse and remand for a new trial.

Alternatively, the Court should reconsider its analysis and clarify its position on that leading issue.

Either way, the Court should address the final two issues to avoid delay in the future.

RESPECTFULLY SUBMITTED this 27th day of July, 2015.

MASTERS LAW GROUP, P.L.L.C.

Kenneth W. Masters, WSBA 22278
Shelby Lemmel, WSBA 33099
241 Madison Ave. North
Bainbridge Island, WA 98110
(206) 780-5033

CERTIFICATE OF SERVICE BY MAIL AND/OR EMAIL

I certify that I caused to be mailed, a copy of the foregoing **MOTION FOR RECONSIDERATION** postage prepaid, via U.S. mail on the 27th day of July 2015, to the following counsel of record at the following addresses:

Carol Nofziger Johnston
Jane Morrow
Otorowski Johnston Morrow & Golden PLLC
298 Winslow Way West
Bainbridge Island, WA 98110

✓ U.S. Mail
___ E-Mail
___ Facsimile

Richard Friedman
William Siemon Cummings
Friedman Rubin
1126 Highland Ave
Bremerton, WA 98337-1828

✓ U.S. Mail
✓ E-Mail
___ Facsimile

Peter J. Mullenix
Friedman Rubin
51 University St Ste 201
Seattle, WA 98101-3614

✓ U.S. Mail
✓ E-Mail
___ Facsimile

Phillip Talmadge
Talmadge/Fitzpatrick
2775 Harbor Ave SW
Third Floor, Suite C
Seattle, WA 98126-2138

✓ U.S. Mail
✓ E-Mail
___ Facsimile

Jeffrey Royal Johnson Scheer & Zehnder 701 Pike Street, Suite 2200 Seattle, WA 98101-2358	✓ U.S. Mail ____ E-Mail ____ Facsimile
Allen J. Ruby Skadden, Arps, Slate, Meagher & Flom 525 University Ave. Palo Alto, CA 94301	✓ U.S. Mail ____ E-Mail ____ Facsimile
Catherine B. Stevens Quinn Emanuel 51 Madison Avenue New York, N.Y. 10010	✓ U.S. Mail ____ E-Mail ____ Facsimile
Karen M. Firstenberg Morris Polich & Purdy LLP 1055 W. 7th Street, Suite 2400 Los Angeles, CA 90017	✓ U.S. Mail ____ E-Mail ____ Facsimile

Kenneth W. Masters, WSBA 22278
Attorney for Appellants

RCW 7.72.030

Liability of manufacturer.

(1) A product manufacturer is subject to liability to a claimant if 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.

(a) A product is not reasonably safe as designed, 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, outweighed the burden on the manufacturer to design a product that would have prevented those harms and the adverse effect that an alternative design that was practical and feasible would have on the usefulness of the product: PROVIDED, That a firearm or ammunition shall not be deemed defective in design on the basis that the benefits of the product do not outweigh the risk of injury posed by its potential to cause serious injury, damage, or death when discharged.

(b) A product is not reasonably safe because adequate warnings or instructions were not provided with the product, 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.

(c) A product is not reasonably safe because adequate warnings or instructions were not provided after the product was manufactured where a manufacturer learned or where a reasonably prudent manufacturer should have learned about a danger connected with the product after it was manufactured. In such a case, the manufacturer is under a duty to act with regard to issuing warnings or instructions concerning the danger in the manner that a reasonably prudent manufacturer would act in the same or similar circumstances. This duty is satisfied if the manufacturer exercises reasonable care to inform product users.

(2) A product manufacturer is subject to strict liability to a claimant if the claimant's harm was proximately caused by the fact that the product was not reasonably safe in construction or not reasonably safe because it did not conform to the manufacturer's express warranty or to the implied warranties under Title 62A RCW.

(a) A product is not reasonably safe in construction if, when the product left the control of the manufacturer, the product deviated in some material way from the design specifications or performance standards of the manufacturer, or deviated in some material way from otherwise identical units of the same product line.

(b) A product does not conform to the express warranty of the manufacturer if it is made part of the basis of the bargain and relates to a material fact or facts concerning the product and the express warranty proved to be untrue.

(c) Whether or not a product conforms to an implied warranty created under Title 62A RCW shall be determined under that title.

(3) In determining whether a product was not reasonably safe under this section, the trier of fact shall consider whether the product was unsafe to an extent beyond that which would be contemplated by the ordinary consumer.

[1988 c 94 § 1; 1981 c 27 § 4.]

MASTERS LAW GROUP

September 09, 2015 - 11:58 AM

Transmittal Letter

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