COURT OF APPEALS, DIVISION II,
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, Appellants, vs. INTUITIVE SURGICAL, INC., a foreign corporation doing business in Washington, Respondent.	No. 45052-6-II MOTION FOR LEAVE TO SUBMIT OVER-LENGTH BRIEF OF RESPONDENT

COMES NOW respondent Intuitive Surgical, Inc. and requests that this Court grant it leave to file a 59-page brief pursuant to RAP 10.4(b). This motion is based on the annexed declaration of Philip A. Talmadge.

DATED this 9th day of May, 2014.

Respectfully Submitted,

Philip A. Talmadge

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DECLARATION

I, Philip A. Talmadge, declare as follows:

1. I am over the age of 18, competent to be a witness, and personally knowledgeable about the facts in this declaration.

2. Intuitive Surgical has endeavored to limit the length of its brief wherever possible, but a respondent brief of 59 pages is necessary to permit Intuitive to fully answer the arguments in appellants' opening brief and to advance its position in this case on the applicable facts and law. Intuitive notes that the appellants' opening brief was over-length, 71 pages.

I swear the foregoing to be true under penalty of perjury under the laws of the State of Washington. Executed at Tukwila, Washington, this 9th day of May, 2014.

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No. 45052-6-II

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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,

vs.

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

Respondent.

BRIEF OF RESPONDENT INTUITIVE SURGICAL

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A. INTRODUCTION

This is a product liability action arising out of the surgery performed by Dr. Scott Bildsten using a robotic surgical system ("da Vinci System") manufactured by Intuitive Surgical, Inc. ("Intuitive").

Intuitive specifically warned Dr. Bildsten not to perform da Vinci robotic surgery on obese patients with a high body mass index ("BMI"). Nevertheless, Dr. Bildsten performed a da Vinci prostatectomy[1] on Fred Taylor at Harrison Medical Center ("Harrison") in Bremerton when Taylor had been diagnosed with morbid obesity, diabetes, coronary artery disease, hypertension, and high cholesterol before the surgery. Taylor received treatment for these conditions, including a quintuple bypass heart surgery, years before his prostate cancer diagnosis. Although his doctors prescribed blood pressure, cholesterol, and diabetes medications for him, Taylor did not regularly take them.

Prior to the surgery, Dr. Bildsten specifically disclosed to Taylor, and discussed with him, the possible risks of his surgical procedure, including risks specific to robotic surgeries with the da Vinci System. After this discussion, Taylor signed a consent form stating that he understood that surgery could entail "serious complications" and "significant risks," including the risks of death, "[d]amage to [the] rectal

[1] A prostatectomy is a removal of the patient's prostate gland.

wall," and incontinence. During his surgery, Taylor sustained a rectal tear, and other complications. Fred Taylor passed away from unrelated heart failure four years post-surgery.

Josette Taylor, Fred Taylor's wife and personal representative ("Taylor")[2] sued several individuals and entities, including Intuitive. After various settlements, a jury trial took place with Intuitive as the last remaining defendant. Taylor obtained jury instructions on a "duty to train" that are not supported by Washington law, was given every possible opportunity by the trial court to introduce evidence vilifying Intuitive's marketing of the da Vinci System, and also secured an instruction allowing the jury to consider that marketing in assessing Intuitive's duty to warn Dr. Bildsten as the learned intermediary. Nevertheless, the jury exonerated Intuitive from liability, specifically finding that Intuitive was not negligent.

Taylor's present appeal now largely turns on claims of instructional error. Taylor asserts it is legally insufficient for Intuitive to have warned Dr. Bildsten. Taylor argues Harrison was an additional "learned intermediary" that Intuitive had a duty to warn under the Washington Products Liability Act, RCW 7.72 ("WPLA"). Taylor also

[2] Hereafter, Josette Taylor and the Estate of Fred Taylor will be referenced as Taylor, unless the context requires a reference to "Fred Taylor."

contends that a strict liability standard governs the duty to warn learned intermediaries.

This Court should reject Taylor's bid to create an appellate issue where none exists. Harrison is not a learned intermediary under the WPLA because it did not prescribe or operate the da Vinci System for Fred Taylor's surgery. Controlling precedent applies a negligence standard to the duty to warn learned intermediaries under the WPLA. Taylor had a fair trial and lost. This Court should affirm the judgment on the jury's verdict.

B. RESTATEMENT OF ASSIGNMENTS OF ERROR

Intuitive acknowledges the assignments of error in Taylor's brief at 2, but for the Court's consideration offers the following alternate formulations of the issues on appeal:

1. Does the duty to warn about the dangers of a product also encompass a duty to train learned intermediaries in the product's use?

2. When a manufacturer fulfills its duty to warn a learned intermediary surgeon about the dangers associated with use of its product, and also its duty to warn the surgeon about how to use the product safely, can that manufacturer nonetheless be held liable for a failure to warn the hospital that allowed the surgeon to work at its premises?

3. When a learned intermediary receives a product warning, is the claim for failure to warn properly analyzed as one in negligence?

4. Is a superseding cause instruction appropriate in a product liability case where the user of the product received adequate warnings, but ignored them and used the product inappropriately in an unforeseeable manner?

5. Does a verdict form that asks the jury to allocate a percentage of fault to the plaintiff somehow shift the burden of proof for failure to mitigate or suggest that the jury should twice reduce the plaintiff's damages?

6. Can this Court affirm a defense verdict on the grounds that superseding cause was present as a matter of law, when the facts show that a surgeon, a learned intermediary, was warned not to perform a robotic surgery on precisely the kind of patient who was injured here, and the surgeon performed the surgery anyway?

C. STATEMENT OF THE CASE

(1) History and Background of Intuitive Surgical and the da Vinci System

Intuitive was founded in 1995. It designs, manufacturers, and markets the da Vinci System, which is an advanced robotically-assisted surgical system designed to support minimally invasive surgery. CP 139.

Open surgical procedures are still commonly used by surgeons, but the large incisions required for open surgery create trauma to the patient, resulting in longer recovery time, increased chance of blood loss, increased hospitalization time, and increased pain and suffering. CP 335. Over the past two decades, minimally invasive robotic surgery has reduced this patient trauma by allowing selected surgeries to be performed through small ports rather than large incisions, often resulting in shorter

recovery times, fewer complications, and reduced hospitalization time. *Id.*

The da Vinci System translates the surgeon's natural hand movements, which are performed on instrument controls at a surgeon's console, into corresponding micro-movements of instruments positioned inside the patient through small incisions, or ports. CP 335. The da Vinci System provides the surgeon with intuitive control, range of motion, fine tissue manipulation capability, and high definition 3-D vision.[3] *Id.* The da Vinci System is used to perform surgery across multiple surgical specialties. *Id.*

The da Vinci System is a medical device that may only be used by medical professionals upon a physician's order or prescription for its use. CP 364. There are three generations of da Vinci systems currently in use. The system used in Fred Taylor's surgery was a da Vinci S Surgical System. CP 335.

In March 1997, surgeons using an early prototype of the technology performed the first da Vinci surgery on humans. Before being sold in the United States, the da Vinci System was cleared for marketing by the United States Food and Drug Administration ("FDA") pursuant to its so-called 510(k) process. CP 334. In July 2000, Intuitive obtained

[3] This vision system is designed to give surgeons the perception that their hands are immersed in the surgical field even though they are outside the patient's body. The image emulates the focal distance to the surgeon's hands so that the surgeon perceives that the tools are in his or her own hands. CP 335.

clearance from the FDA to market its products in the United States for use in general laparoscopic procedures. *Id.*; CP 338. In May 2001, the FDA granted clearance to Intuitive to use the da Vinci System in prostatectomy procedures. CP 334, 344.[4] Since its introduction, the da Vinci System has gained wide acceptance among surgeons. It is currently used, for example, in approximately 84% of prostatectomy surgeries in the United States. CP 334.

As part of the FDA clearance process, Intuitive stated to the FDA in 2000 that doctors would be trained on the use of the system in twenty-three phases. RP 2606-2618. Doctors in Harrison's credentialing program were trained on all twenty-three phases when Harrison acquired the system in 2008. *Id.*

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[4] Taylor's statement of the case goes to great lengths to suggest that Intuitive was somehow deceptive in its representations to the FDA regarding how it would go about warning physicians about the use of its product. It appears to be an attempt to vilify Intuitive. However, the FDA clearance process is apparently not material to any of the legal issues on appeal, as there is little mention of it in the argument section of the Brief of Appellants. Also, an FDA witness clarified to the trial court that surgeon training was the practice of medicine and was not regulated by the FDA. CP 2738. Finally, the FDA continued to grant clearances for use of the da Vinci System long after granting clearance for prostatectomies:

- May 2001 — Prostatectomy procedures
- November 2002 — Cardiotomy procedures
- July 2004 — Cardiac revascularization procedures
- April 2005 — Gynecologic surgical procedures
- June 2005 — Pediatric surgical procedures
- December 2009 — Transoral Otolaryngologic surgical procedures.

CP 334.

The User Manual for the da Vinci System, which was submitted to the FDA, contained a number of instructions, warnings, contraindications,[5] and precautions, including:

> 1.5 General Precautions, Warnings, and Contraindications
>
> Failure to properly follow instructions, notes, cautions, warnings and danger messages associated with this equipment may lead to serious injury or surgical complications for the patient. ...Generally, non-procedure specific, contraindications to endoscopic surgery include bleeding diathesis, *morbid obesity* and pregnancy.

CP 159, 366 (emphasis added).

In addition to this Manual, Intuitive makes available to surgeons the "da Vinci Prostatectomy Procedure Guide." Ex. 509. The guide cautioned that "[u]seful guidelines for early patient selection are: Thin patient: BMI <30." *Id.* at 4. Intuitive also provides "The Clinical Pathway and Training Protocol for da Vinci Prostatectomy," which advised surgeons to "pick simple cases" for their "[f]irst 4-6 cases" and to choose patients with a "[l]ow BMI." Ex. 511. Intuitive also recommends that surgeons choose patients with no prior abdominal surgery. Ex. 509 at 4.

Intuitive also warns that patients should be placed in the "steep

[5] According to the FDA regulations, "contraindications" refers to "situations in which the drug *should not be used* because the risk of use clearly outweighs any possible benefit." 21 C.F.R. § 201.57(d) (emphasis added).

Trendlenberg position" during robotic surgery, which is where the operating table is inclined sharply. *Id.* at 5. Intuitive further warned and instructed surgeons in the "Intraoperative Patient Preparation" section of the da Vinci Prostatectomy Guide that "the extreme Trendelenburg position (>30° and reflexed)" is to be "used for much" of the prostatectomy. Ex. 509 at 5.

Intuitive told surgeons that the learning curve for the da Vinci System is "highly variable" and "differs from surgeon to surgeon." RP 1983. When pressed for a number of cases in the learning curve, Intuitive told surgeons it was "probably between 20 and 30." RP 779.

(2) Fred Taylor's Medical History and Diagnosis, and Dr. Bildsten's Decision to Conduct a Robotically-Assisted Prostatectomy

Fred Taylor was "severely obese" according to Bildsten. CP 173-74; RP 1140. His treating physician called him "morbidly obese" in clinical terms. RP 1359. He had a history of multiple surgeries, including three abdominal surgeries (appendectomy, gall bladder removal, hernia surgery with mesh), which complicated his suitability for prostate surgery. CP 178. Fred Taylor had been diagnosed with diabetes, coronary artery disease, hypertension, and high cholesterol. RP 1348-50, 1370. He had received treatment for those conditions, including a quintuple bypass heart surgery in 2002. RP 1348-57. Fred Taylor's physicians prescribed blood

pressure, cholesterol, and diabetes medications, which he did not regularly take. *Id.* The medical records show that Taylor's diabetes and high blood pressure were out of control for many years before his death. RP 1376.

In June 2008, Fred Taylor was diagnosed with prostate cancer. CP 176. He sought treatment for that condition from Dr. Bildsten, a board-certified urologist. RP 1017-18. Dr. Bildsten presented him with several cancer treatment options, one of which was a robotic prostatectomy using the da Vinci System. CP 180-81. Dr. Bildsten had 15 years of experience in urology and urologic surgery and had performed more than one hundred open prostatectomy procedures; he had received training on how to use the da Vinci System from Intuitive, observed more than ten surgeries involving the da Vinci System, and had performed two proctored surgeries using the da Vinci System. CP 218. Intuitive provided Dr. Bildsten with training on how to operate the da Vinci System both at Intuitive headquarters and at Harrison. CP 217.

In warning Dr. Bildsten about how to use the da Vinci System, Intuitive told Dr. Bildsten that for his early cases using the da Vinci System, he should choose simple cases and patients with a low BMI. RP 780, 1140. Dr. Bildsten was also reminded of these selection criteria by Intuitive's sales representative. RP 1067. In addition to Intuitive's general guide and the prostatectomy-specific guide, he was provided with

the Clinical Pathway guide, which again indicated that during his first four to six surgeries he should start with simple cases in patients with a low BMI, and that patients should be in the "steep Trendelenburg" position. Ex. 509.

Dr. Bildsten knew he was in the early learning curve for the device. RP 1133-34. He knew he should only perform surgery with the da Vinci System on thin patients during his early part of his learning curve. RP 1134.

Dr. Bildsten discussed the risks of robotic surgery with Fred Taylor. CP 243-48, 250. Dr. Bildsten warned him of the risks and complications including possible rectal injury, incontinence, and even more significant complications. *Id.* Indeed, Dr. Bildsten provided Fred Taylor with an informed consent form that identified the risks that Dr. Bildsten knew about robotic surgery, including serious complications associated with the surgery, including damage to the rectal wall. CP 243. *See* Appendix. *Id.* Dr. Bildsten testified that he told his patient of the risks, and that Fred Taylor insisted on surgery rather than radiation:

> Q: Now, Dr. Bildsten, ...[w]hy did you do this operation on Mr. Taylor, who clearly had a high BMI?
>
> A. ...He didn't even want to talk much about the other options. I actually encouraged him to consider the radiation because of his size and the amount of cancer we found there on the biopsies. He said he had a close relative that

> had problem with radiation and would never consider it. He wanted his prostate removed.

RP 1067.

Dr. Bildsten answered Fred Taylor's questions about the surgery and Dr. Bildsten ultimately determined – based upon his medical training, judgment, and experience – to proceed with robotic surgery, despite Intuitive's warnings, and despite Fred Taylor's complex medical history. RP 1134. With Dr. Bildsten's advice, Fred Taylor elected to proceed with surgery using the da Vinci System and signed the detailed consent form. CP 243-48. *See* Appendix.

At the time of his surgery, Fred Taylor weighed 280 pounds and had BMI of approximately 39. CP 926. Dr. Bildsten claimed that he thought Taylor's BMI was 34. CP 22. Dr. Bildsten admitted that "extreme obesity" was an "absolute contraindication" for the da Vinci surgery. RP 1138. He defined extreme obesity as a BMI of 40 or more. RP 1139.

Dr. Bildsten also warned Fred Taylor that the robotic surgery might need to be converted to an open surgical procedure if Taylor could not be positioned adequately, if the surgery was not progressing, if he became unstable, or if he had excessive blood loss. RP 1067. Fred Taylor told Dr. Bildsten that he consented to a conversion to open surgery if Dr. Bildsten deemed it to be necessary. *Id.*

(3) The Surgery and Dr. Bildsten's Decision to Switch from a Robotic to a Non-Robotic Procedure

The surgery took place at Harrison on September 9, 2008. CP 32. Dr. Bildsten stated that he attempted to put Fred Taylor in the steep Trendelenburg position, but had to abandon that position it because of Taylor's "abdominal girth." RP 1072. A number of hours into the surgery, Dr. Bildsten determined that the surgery was not progressing appropriately and made the decision to convert to an open surgery. RP 1082. The da Vinci System was then undocked, turned off, moved away from Fred Taylor. CP 1107. Dr. Bildsten testified that he believed that during the open procedure his finger caused a tear in the rectal wall. RP 1080-83, 1108.[6]

The rectal tear was eventually repaired and Dr. Bildsten completed the open procedure. RP 1108. Almost four years after his prostatectomy in 2012, Fred Taylor passed away. RP 2182. His death certificate stated the cause of death as "natural causes." RP 2202. Taylor's pathological expert, Dr. William Brady, performed an autopsy and concluded that the cause of Fred Taylor's death was "hypertensive cardiovascular disease." RP 2200. This heart disease had been ongoing long before Fred Taylor's

[6] The issue of when the tear occurred was disputed. An expert for Taylor opined that it was possible the tear occurred during the robotic portion of the procedure. CP 919.

prostatectomy in 2008. RP 2201. A board-certified cardiologist from the University of Washington Medical Center, Dr. Peter Kudenchuk, testified that Fred Taylor's non-compliance with health care recommendations contributed to and caused his death, and his death had "no relationship whatsoever to his prostate surgery." RP 2289.

(4) Procedural History

On December 15, 2009, Taylor commenced the present action claiming professional negligence, medical malpractice, and corporate liability against Dr. Bildsten, Dr. Hedges, and their practice at Kitsap Urology Associates PC. CP 1-9. Taylor also sued Harrison. *Id.* Taylor amended the complaint to assert claims against Intuitive for negligence, breach of contract, product liability under the WPLA, violation of warranties, violation of the Consumer Protection Act, RCW 19.86, and punitive damages. CP 27-37. Taylor settled with Harrison and dropped claims against it in the third amended complaint. CP 749-63. Taylor settled with the doctors and their practice. CP 764-77.

Intuitive moved for summary judgment under the WPLA and to exclude any punitive damages claim. CP 66-133. The trial court denied the motions on those issues, but granted summary judgment on all non-WPLA claims. CP 2951-60.

At trial, Taylor's own urological expert, Dr. S. Adam Ramin,

testified that Dr. Bildsten was negligent:

> Q. All right. Now, were Taylor's injuries, in your opinion, a consequence of Dr. Bildsten's failure to live up to the standard of care as we have defined it here?
>
> A. Yes, sir.
>
> . . .
>
> Q. Dr. Ramin, were all of the injuries suffered by Taylor in the surgery of September 9, 2008, caused by the deviations from the standard of care by Dr. Bildsten that you explained earlier?
>
> A. Yes, sir.

RP 977.

Taylor argued at trial that Intuitive's marketing of the da Vinci System pressured Dr. Bildsten to use robotic surgery before he was sufficiently capable of doing so. *See, e.g.,* RP 3378. Taylor also suggests this in his opening brief. Br. of Appellants at 17. However, Taylor's claims, ultimately irrelevant to the legal issues on appeal, are contradicted by Dr. Bildsten's own testimony in response to a question from the jury:

> Q: Did you feel pressure by ISI to do surgery?
>
> Dr. Bildsten: No. No. Never. This was my choice.
>
> . . .
>
> Q: Was the ISI rep pushing you to do more operations with

the robot?

Dr. Bildsten: No. They were never pushy.

RP 1177, 1180.[7]

Taylor also wanted to argue to the jury that Intuitive failed to sufficiently warn Harrison about the learning curve for the da Vinci System. RP 1416. However, Taylor called no witnesses from Harrison at trial. There was no evidence that anyone aside from Dr. Bildsten met with Fred Taylor, had the authority to prescribe the use of the da Vinci System for him, discussed the risks of robotic surgery with him, or chose to conduct the robotic procedure on him. The jury instructions did permit such "learning curve" arguments with respect to Dr. Bildsten.

The jury exonerated Intuitive from any liability for a failure to warn or train Dr. Bildsten. CP 5628-30. The trial court entered a judgment on that verdict on June 28, 2013, CP 5631-39, from which Taylor appealed to this Court. CP 5640-64.

D. SUMMARY OF ARGUMENT

Despite benefitting from an incorrect jury instruction, particularly the court's Instruction 11, that claimed Intuitive had a "duty to train" Dr.

[7] In any event, the question of whether Intuitive's marketing materials were persuasive to Dr. Bildsten is irrelevant to the legal issues Taylor now raises. The trial court gave Taylor the opportunity to argue about Intuitive's marketing practices to the jury by issuing Instruction No. 12. CP 5399. The jury still exonerated Intuitive.

Bildsten under the WPLA, Taylor still did not prevail at trial. The trial court should have rejected Taylor's invitation to transform the duty to warn under RCW 7.72.030(1)(b) into a broad duty to train physicians on the use of its product, because the Legislature never created such a duty in the WPLA. Moreover, the trial court instructed the jury that it could consider Taylor's extensive evidence on Intuitive's marketing of the da Vinci System, evidence that had no relevance whatsoever to a duty to warn claim under the WPLA. However, despite these errors, Intuitive still prevailed.

Now, casting about for a viable appellate theory, Taylor claims that even if Intuitive adequately warned and trained Fred Taylor's doctor, it should still be held liable for failing to warn the hospital where Dr. Bildsten performed the surgery. There is no basis in law for Taylor to claim that there was any duty to warn Harrison Hospital as a *second* learned intermediary.

Taylor also claims the trial court erred in instructing the jury that it should determine whether Intuitive was negligent in providing warnings to the learned intermediary, rather than strictly liable. To find the trial court's instruction erroneous, however, this Court would have to *overrule* controlling Supreme Court and Court of Appeals decisions holding that negligence, not strict liability, is the applicable standard where a learned

intermediary is warned about a prescription medical device under the WPLA.

Taylor then contends the trial court committed reversible error in refusing to admit a list of surgical complications, after an Intuitive representative stated his opinion that the da Vinci program at Harrison was successful overall. The trial court did not abuse its discretion in refusing to admit the list, nor was Taylor prejudiced in this six-week trial. Despite Taylor's failure to contemporaneously object to the statement, the trial court gave a curative instruction that the jury is presumed to follow.

Finally, Taylor raises two conditional arguments, one pertaining to superseding cause and the other to mitigation of damages. Regarding the superseding cause instruction, in a case where the manufacturer fulfilled its obligation to warn, but the warnings were ignored, a superseding cause instruction is appropriate. Dr. Bildsten was warned that he should not perform robotic surgery on persons such as Fred Taylor at all, given his obesity, diabetes, high blood pressure, and history of heart disease combined with Dr. Bildsten's level of experience using the da Vinci System. Regarding the damages instruction, there is no error. The question of whether a plaintiff took steps to mitigate damages is properly expressed in a verdict form as an allocation of percentage of fault.

If this Court reaches the issue of superseding cause, it should hold

that as a matter of law Taylor could not demonstrate any alleged fault on Intuitive's part was the legal cause of harm to him. Dr. Bildsten's negligence in choosing to employ the da Vinci System for Fred Taylor's surgery caused Taylor's injuries. The superseding cause instruction given by the court was correct.

E. ARGUMENT

(1) The Jury Found Intuitive Fulfilled Its Duty to Warn Taylor's Surgeon; the Trial Court Did Not Err in Declining to Impose on Intuitive the Additional Duty to Warn Harrison[8]

Taylor asserts that the trial court erred in instructing the jury on the WPLA duty to warn because the court declined to extend Intuitive's duty to warn to Harrison, and limited the duty only to Dr. Bildsten, the learned intermediary in this case. Br. of Appellants at 39-60. Taylor is wrong.

The trial court's instructions on the duty to warn under the WPLA are found in Instructions 10-14. CP 5397-5400. Instructions 10 and 11 described the duty to warn Dr. Bildsten as follows:

> A medical device manufacturer's duty to prove adequate warnings *or instructions/training* is to the patient's doctor.

[8] Jury instructions are reviewed de novo for errors of law. *Joyce v. Dep't of Corrs.*, 155 Wn.2d 306, 323, 119 P.3d 825 (2005). "Jury instructions are sufficient when they allow counsel to argue their theory of the case, are not misleading, and when read as a whole properly inform the trier of fact of the applicable law." *Bodin v. City of Stanwood,* 130 Wn.2d 726, 732, 927 P.2d 240 (1996). If any of these elements are absent, the instruction is erroneous. *See Joyce,* 155 Wn.2d at 323–25. An erroneous instruction is reversible error only if it prejudices a party. *Id.* at 323; *Anfinson v. FedEx Ground Package Sys., Inc.*, 174 Wn.2d 851, 860, 281 P.3d 289 (2012).

> A medical device manufacturer does not have a duty to adequately warn or instruct/train the patient. Therefore, any duty to adequately warn *or instruct/train* on the part of Intuitive ran only to Dr. Bildsten.... [Court's Instruction 10]
>
> [T]he manufacturer is under a duty to use reasonable care in regard to issuing warnings *or instructions/training* concerning any such danger. The duty is satisfied if the manufacturer exercises reasonable care to inform doctors who use the product. [Court's Instruction 11]

CP 5397, 5398 (emphasis added).[9] Taylor claims that the trial court should have employed Plaintiff's Proposed Instructions 12 and 28, extending the duty to warn and train to Harrison as well as Dr. Bildsten:

> Mrs. Taylor claims that ISI was negligent because it engaged in improper and misleading marketing of the robotic surgical system, provided inadequate and misleading warnings, and inadequately trained Dr. Bildsten *and the Harrison Medical Center staff.* [Plaintiff's Proposed Instruction 12]
>
> For purposes of this case, the "consumers" of the da Vinci robotic surgical system are Dr. Bildsten *and Harrison Medical Center.* [Plaintiff's Proposed Instruction 28]

CP 4145-46, 4164 (emphasis added).

Taylor claims the trial court erred because the flawed "duty to train" instructions were not applied to Harrison. In order to assess Taylor's claims of prejudicial reversible error, it is first important to

[9] It is noteworthy that in the court's Instruction 12, the trial court also allowed the jury to consider the adequacy of Intuitive's warnings in light of Intuitive's promotion, advertising, and sales of the da Vinci System. CP 5399.

understand that Taylor received the benefit of an improper instruction on the WPLA's duty to warn standard, the so-called "duty to train," and still did not prevail at trial.

(a) The WPLA Requires Product Manufacturers to Warn Users and Learned Intermediaries, Not to Train Them

Taylor's discussion of a duty to warn under the WPLA fundamentally misstates that statutory duty. Br. of Appellants at 40-42. The Legislature enacted the WPLA in 1981. It changed Washington's common law on product liability. The WPLA provides the sole remedy for product-related harm in Washington.[10] As part of the single product liability cause of action created by the WPLA, the WPLA affords a remedy to persons injured by an unavoidably unsafe product if the product manufacturer fails to properly warn users regarding that product's use:[11]

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[10] RCW 7.72.010(4) makes clear that the WPLA creates a single cause of action for product-related harm, pre-empting other traditional common law remedies. In *Wash. Water Power Co. v. Graybar Elec. Co.*, 112 Wn.2d 847, 774 P.2d 1199 (1989), our Supreme Court concluded that the WPLA preempted all common law remedies, including equitable remedies, relating to product liability in favor of a single statutory cause of action. *Id.* at 851-56. *See also, Wash. State Physicians Ins. Exch. & Ass'n v. Fisons Corp.*, 122 Wn.2d 299, 322-23, 858 P.2d 1054 (1993); *Hiner v. Bridgestone/Firestone, Inc.*, 138 Wn.2d 248, 262, 978 P.2d 505 (1999); *Bylsma v. Burger King Corp.*, 176 Wn.2d 555, 559, 293 P.3d 1168 (2013).

[11] This is a case largely guided by statutory interpretation principles. *See generally,* Philip A. Talmadge, *A New Approach to Statutory Interpretation in Washington*, 25 Sea. U. L. Rev. 179 (2001). The primary goal of statutory interpretation is to carry out legislative intent. *Cockle v. Dep't of Labor & Indus.*, 142 Wn.2d 801, 807, 16 P.3d 583 (2001). In Washington, this analysis begins by looking at the words of the statute. "If a statute is plain and unambiguous, its meaning must be primarily derived from the language itself." *Id.* Courts look to the statute as a whole, giving effect to all of

> 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 manufacture 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).

The WPLA's duty to warn does not extend to a duty to train product users like Dr. Bildsten in the product's use. *Nowhere* does the specific language of RCW 7.72.030(1)(b) reference a *duty to train* product users, notwithstanding Taylor's discussion of the statute in his brief at 40-42. To create a duty to train distorts the language and scope of RCW 7.72.030(1)(b). No reported case in Washington has held that RCW 7.72.030(1)(b) creates a duty to train. By its express terms, the liability

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its language. *Dot Foods, Inc. v. Wash. Dep't of Revenue*, 166 Wn.2d 912, 919, 215 P.3d 185 (2009). Courts must look to what the Legislature said in the statute and related statutes to determine if the Legislature's intent is plain. *Dep't of Ecology v. Campbell & Gwinn, L.L.C.*, 146 Wn.2d 1, 9-10, 43 P.3d 4 (2002). If the language of the statute is plain, that ends the courts' role. *Cerrillo v. Esparza*, 158 Wn.2d 194, 205-06, 142 P.3d 155 (2006).

If, however, the language of the statute is ambiguous, courts must then construe the statutory language. A statute is ambiguous if it is subject to two or more reasonable interpretations. *State v. McGee*, 122 Wn.2d 783, 864 P.2d 912 (1993). Merely because two interpretations of a statute are conceivable, that does not render a statute ambiguous. *Tesoro Refining & Marketing Co. v. State, Dep't of Revenue*, 164 Wn.2d 310, 318, 190 P.3d 28 (2008).

Courts do not read language into a statute even if they believe the Legislature *might* have intended it. *Kilian v. Atkinson*, 147 Wn.2d 16, 20, 50 P.3d 638 (2002).

under that statute extends to situations where the warnings or instructions were not provided or were inadequate, *and* the manufacturer could have provided warnings or instructions. Simply put, a duty to warn is not a duty to train, and nothing in the statutory language or in its history would permit distortion of a duty to warn into a duty to train.

The terms "warnings" or "instructions" are not expressly defined in .030 or in the WPLA generally. RCW 7.72.010. But the common understanding of such terms does not extend to training. Bryan A. Garner, *Black's Law Dictionary* (8th ed.) at 1615, for example, describes a warning as "[t]he pointing out of a danger, esp. to one who would not otherwise be aware of it." This is decidedly not a duty to train. By its plain terms, RCW 7.72.030(1)(b) does not extend to a duty to train product users.

Even if this Court were to conclude that RCW 7.72.030(1)(b) is ambiguous, a resort to legislative history of the WPLA would reveal that the Legislature never intended to create a duty to train in RCW 7.72.010(3)(b). The 1981 Senate Journal[12] indicates that the Legislature

[12] The Senate incorporated the section-by-section analysis of the WPLA by the Senate Select Committee on Tort Reform and Product Liability into its Journal; this analysis has been cited as authoritative by Washington courts. *See, e.g., Tegman v. Accident & Med. Investigations, Inc.*, 150 Wn.2d 102, 110, 75 P.3d 497 (2003); *Kottler v. State*, 136 Wn.2d 437, 452, 963 P.2d 834 (1998); *Scott v. Cascade Structures*, 100 Wn.2d 537, 547, 673 P.2d 179, 184 (1983).

did not intend to create a duty to train.

Additionally, the WPLA was strongly influenced by the United States Commerce Department's Model Uniform Product Liability Act. 44 Fed. Register 62714 (1979). In discussing warnings and instructions, the MUPLA contemplates *written* instructions because of its emphasis on "clarity and conspicuousness" of the warnings and instructions. *Id.* at 62724-25. Training cannot be "conspicuous;" to imply a duty to train within the duty to warn would be illogical. *Nowhere* in the Model Act, its provisions or analysis, is there any indication that a duty to train product users was even contemplated.

Finally, the contemporaneous law review article on the WPLA written by the chair of the Senate Select Committee,[13] Philip A. Talmadge, *Washington's Product Liability Act*, 5 U. Puget Sd. L. Rev. 1 (1981), *nowhere* suggests that the Legislature intended to create a duty to train in RCW 7.72.030(1)(b). *Id.* at 9-10.[14]

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[13] This article has been cited as an authoritative source of WPLA legislative history by Washington courts. *See, e.g., Stanton v. Bayliner Marine Corp.*, 123 Wn. 2d 64, 84, 866 P.2d 15, 26 (1993); *Washington Water Power Co. v. Graybar Elec. Co.*, 112 Wn.2d 847, 858, 774 P.2d 1199 *amended sub nom. Washington Power Co. v. Graybar Elec. Co.*, 779 P.2d 697 (1989); *Staton Hills Winery Co., Ltd. v. Collons*, 96 Wn. App. 590, 595, 980 P.2d 784, 787 (1999).

[14] On the notion that a duty to train is required under RCW 7.72.030(1)(b), there is a direct analogy in the refusal of courts in Washington and elsewhere to adopt a cause of action for "educational malpractice" in the educational setting. *See Camer v. Seattle School Dist. No. 1*, 52 Wn. App. 531, 762 P.2d 356 (1988), *review denied*, 112 Wn.2d

An interpretation of RCW 7.72.030(1)(b) that excludes a duty to train is also consistent with product liability law in other jurisdictions. *See, e.g., Glorvigen v. Cirrus Design Corp.*, 816 N.W.2d 572 (Minn. 2012).[15] *See also, Rounds v. Genzyme Corp.*, 440 F. Appx. 753, 754 (11th Cir. 2011), *cert. denied*, 132 S. Ct. 1913 (2012) (court declined to adopt a duty to train that was independent from the duty to warn with respect to a biologic product); *Mason v. Texaco Inc.*, 862 F.2d 242, 248 (10th Cir. 1988) (same); *York v. Union Carbide Corp.*, 586 N.E.2d 861, 871 (Ind. App. 1992) (court rejected rejected the contention that a manufacturer owed a duty to train end users of its product finding "no authority for the proposition that a manufacturer has a legal duty to train the employees of

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1006, *cert. denied*, 493 U.S. 873 (1989) (no private right of action for alleged failure to instruct on state constitution or national and state government and history). *See also, Waugh v. Morgan Stanley & Co.*, 966 N.E.2d 540, 549 (Ill. App. 2012), *appeal denied*, 979 N.E.2d 890 (Ill. 2012) (claim of failure to train pilot akin to educational malpractice and rejected); *Glorvigen v. Cirrus Design Corp.*, 796 N.W.2d 541, 553 (Minn. App. 2011), *aff'd*, 816 N.W.2d 572 (Minn. 2012) (suit against airplane manufacturer for failure to train, appellate court treated action as akin to education malpractice action and rejected it).

[15] There, the Minnesota Supreme Court recognized that while a product manufacturer has a duty to provide proper warnings and instructions regarding a product's use that duty does not extend to training persons how to use its products, even if the manufacturer undertook to provide training as part of the purchase price of the product at issue. The Minnesota court held that while the manufacturer had a duty to warn, which included a "duty to give adequate instructions," that duty "has never before required a supplier or manufacturer to provide training, only accurate and thorough instructions on the safe use of the product." *Id.* at 582 (internal quotation marks and citation omitted). Thus, while there is a duty to warn or instruct, "there is no duty for suppliers or manufacturers to *train* users in the safe use of their product." *Id.* at 583 (emphasis in original).

its buyers."); *Woodhouse v. Sanofi-Aventis U.S. LLC,* 2011 WL 3666595 at *3 (W.D. Tex. 2011) (court rejected claims that the manufacturer failed to warn and had "failed to train, warn, or educate" prescribing doctors, and specifically, the plaintiff on the adverse side effects of Ambien).

Instructions 10 and 11 under RCW 7.72.030(1)(b) misstate the plain language of the duty to warn in the WPLA.[16] Just as our Supreme Court asserted in *Killian, supra* at 20, and *Washington State Coalition for the Homeless v. Dep't of Soc. & Health Servs.*, 133 Wn.2d 894, 904, 949 P.2d 1291 (1997), a court is not free to "add language to a clear statue even if [it believes] the Legislature intended something else but failed to express it adequately." If the Legislature had meant to require manufacturers to train product users as an element of a duty to warn under RCW 7.72.030(1)(b) it could have said so in the statute. It did not. Instruction 10 and 11 incorrectly imposed on Intuitive a "duty to train" that does not exist in the law.[17]

(b) Intuitive Had No Duty to Warn Harrison Under the WPLA

[16] Dr. Bildsten also went beyond Intuitive's training program to receive additional training. RP 1046.

[17] Because Intuitive believes the jury's verdict was correct, it has not cross-appealed to challenge the incorrect "duty to train" language in the jury instructions. However, this analysis is important as to Taylor's claim that the jury should have been instructed on a duty to warn Harrison.

Taylor argues that the trial court erred in refusing to include Harrison as a second "learned intermediary" to Dr. Bildsten in Instruction 6, 7, 10, 11, and 17. Br. of Appellants at 46-48. The trial court did not err.

As a threshold matter, Taylor waived, and was not prejudiced by, the claimed instructional error because the proposed instructions with their "duty to train" language are a patently erroneous statement of Washington law on the WPLA duty to warn. A party claiming instructional error with respect to an instruction not given must offer a proposed instruction that is a correct statement of the law; otherwise, the party asserting such instructional error cannot be prejudiced by the failure to give it. A trial court is under no obligation to give an incorrect statement of the law as this Court noted in *State v. Ehrhardt*, 167 Wn. App. 934, 939, 276 P.3d 332 (2012).

Here, for the reasons enumerated *supra*, Taylor failed to offer a correct statement of the law in its proposed Instructions 12 and 28 in which it contended that Intuitive had a duty under the WPLA to train anyone at Harrison utilizing a da Vinci System. The WPLA's duty to warn is *not* a duty to train.

In addition to Taylor's waiver problem, there is no additional duty to warn a *second* learned intermediary in the WPLA. Washington's

learned intermediary principle was first recognized by our Supreme Court in *Terhune v. A.H. Robins Co.*, 90 Wn.2d 9, 13, 577 P.2d 975 (1978) where our Supreme Court adopted comment k to the *Restatement (Second) of Torts* § 402A, noting:

> ... it has become a well-established rule that in such cases, 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.

Id. at 13-14 (citing cases).[18]

Harrison is not the learned intermediary here because Dr. Bildsten prescribed and utilized the da Vinci System in Fred Taylor's surgery. He had the unambiguous obligation under RCW 7.70 to exercise independent professional judgment in performing that surgery. Taylor's argument that Harrison is a second learned intermediary within the meaning of *Terhune* and subsequent case law is wrong. Comment k to the *Restatement* and

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[18] The Court further stated:

> The reasons for this rule should be obvious. 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. ...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. at 15.

case law in Washington since *Terhune* confine the scope of the learned intermediary doctrine to the persons *actually prescribing* the use of the product in question.

In this case, there is *no evidence* that Harrison prescribed the da Vinci System for Fred Taylor's surgery. Moreover, there is *no evidence* that Harrison personnel met with Fred Taylor regarding the da Vinci System, or attempted to obtain informed consent separate from that obtained by Dr. Bildsten. That burden appropriately fell on Dr. Bildsten as the *prescribing professional.* Taylor can cite to no authority to support the proposition that even when a treating physician obtains informed consent, a hospital has an obligation to secure a second, independent informed consent.

It is precisely due to a physician's professional responsibility that our Supreme Court has rejected the contention that the duty to warn extends to pharmacists. In *McKee v. American Home Products Corp.*, 113 Wn.2d 701, 782 P.3d 1045 (1989), the Court emphasized that the learned intermediary doctrine applies in connection with pharmaceuticals to professionals exercising medical judgment as to their use for a patient. *Id.* at 709-10. In rejecting the application of the learned intermediary doctrine to a pharmacist, the Court stated:

> Neither 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. Proper weighing of the risks and benefits of a proposed drug treatment and determining what facts to tell the patient about the drug requires an individualized medical judgment based on knowledge of the patient and his or her medical condition. ...We believe that duty, and any liability arising thereform, is best left with the physician.

Id. at 711-12. *See also, Silves v. King*, 93 Wn. App. 873, 970 P.2d 790 (1999) (pharmacist had no duty to warn of drug interactions or consult with doctor regarding them; hospital's discharge nurse had no duty to warn of such interactions as that was duty of prescribing physician). This analysis applies with equal vigor to the application of the learned intermediary principle to a hospital where a physician, not the hospital, prescribes the use of the da Vinci System in the case of a particular patient. *This is a matter of medical judgment not exercised by the hospital.*

Here, Dr. Bildsten, not Harrison, bore the responsibility under RCW 7.70 to exercise *professional judgment*, and to prescribe and then properly utilize the da Vinci System in Fred Taylor's case. To the extent that Taylor's proposed Instructions 12 and 28 seek to expand the learned intermediary principle beyond the professional actually prescribing the

product, they are an incorrect statement of law and were properly rejected by the trial court.

Taylor asks this Court to ignore the language of *Terhune* and comment k to the *Restatement (Second) of Torts* § 402A and to conclude that Harrison is an additional learned intermediary to Dr. Bildsten because Harrison purchased the da Vinci System and "credentialed" doctors. Br. of Appellants at 46. Lacking any Washington authority, Taylor cites to foreign authority. *Id.* at 46-47. However, the cases cited by Taylor for the proposition that a hospital can be a learned intermediary, *id.*, are readily distinguishable.

For example, *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1282 (11th Cir. 2002), simply suggests that a hospital *might* be a learned intermediary if its staff exercised discretion as to the application of a medical device. That case involved a patient activated morphine pump, a somewhat unique device that is inserted by the learned intermediary but operated by the patient. *Ellis,* 311 F.3d at 1276. However, the court clarified that when only a learned intermediary can prescribe and use the device, and that learned intermediary receives warnings, there is no *second* duty to warn other parties: "[W]hen a device can be prescribed and inserted *only* by a physician, that treating physician has *sole* responsibility for advising the patient of dangers associated with the use of the device." *Id.,* 311 F.3d at

1280 (emphasis added).

The other cases Taylor cites are also distinguishable because they turn on whether hospital staff actually prescribed the product in question to the patient. In *Wright v. Abbott Laboratories, Inc.*, 259 F.3d 1226 (10th Cir. 2001), the court applied the learned intermediary doctrine to a hospital where its staff administered concentrated sodium chloride to patients. The court found the manufacturer's warnings to be adequate. In *Brown v. Drake-Willock International, Ltd.*, 530 N.W.2d 510 (Mich. App. 1995), the court rejected application of the learned intermediary doctrine to a dialysis technician. The court emphasized that the devices' use was by prescription only and the doctors would instruct their employees on the use of formaldehyde to clean them. Again, the manufacturer was exonerated from liability for a failure to warn. Finally, in *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522 (Or. App. 1974), the manufacturer was again found not to be liable for a failure to warn regarding use of oral contraceptives. The Oregon court spoke of members of the medical profession but did not address hospitals at all. *McEwen,* 528 P.2d at 529.

None of these cases depart from the basic principle announced in *Terhune* and reinforced in *McKee* that the learned intermediary principle applies to prescribing physicians like Dr. Bildsten who exercise

professional medical judgment about a drug or medical device, and not to hospitals like Harrison that simply purchase the product for prescription and use by physicians.

In sum, the trial court here did not err in rejecting Taylor's proposed Instructions 12 and 28 that attempted to provide that Intuitive had a duty under the WPLA to train Harrison as a learned intermediary when Washington does not recognize either a duty to train in the WPLA or that Harrison is a learned intermediary.

(c) Even Assuming the Trial Court Erred in Not Imposing on Intuitive a Duty to Warn and Train Harrison as a Second Learned Intermediary, the Error Was Harmless

To demonstrate reversible error, Taylor must not only prove that the trial court erred as a matter of law in refusing to extend Intuitive's duty to warn Harrison as well as Dr. Bildsten, but also demonstrate that the error was prejudicial to his case. *See Joyce,* 155 Wn.2d at 323.[19]

It is not error to deny a jury instruction where there is no substantial evidence upon which to base it. *Ramey v. Knorr*, 130 Wn. App. 672, 689, 124 P.3d 314, 323 (2005); *Lofgren v. W. Washington Corp. of Seventh Day Adventists*, 65 Wn.2d 144, 148, 396 P.2d 139, 141 (1964).

[19] The trial court's decision to offer or deny a particular jury instruction is reviewed for abuse of discretion. *Seattle W. Indus., Inc. v. David A. Mowat Co.,* 110 Wn.2d 1, 9, 750 P.2d 245 (1988).

Mere speculation is insufficient to support an instruction; it must be demonstrated by the evidence.

Taylor did not call any witnesses from Harrison to present testimony as to how Intuitive's alleged failure to warn or train Harrison staff about the da Vinci System caused Fred Taylor's injuries. Taylor's theory on appeal appears to be that Intuitive should somehow have warned Harrison not to credential Dr. Bildsten personally, or that Intuitive should have controlled Harrison's credentialing program. Taylor adduced no evidence at trial to support this theory from any Harrison witness. It is mere speculation, which is why the trial court properly rejected the theory.

Dr. Bildsten chose to perform robotic surgery on a morbidly obese patient with serious disqualifying factors in his medical history, despite his knowledge that "extreme obesity" was likely an "absolute contraindication" for the procedure. RP 1138. Intuitive specifically warned Dr. Bildsten, like all other surgeons who were trained in the use of the da Vinci System, about the risks of robotic surgery on patients such as Fred Taylor. There was no evidence at trial that any different or additional warnings to Harrison would have changed the outcome. Such a theory is mere speculation, and the trial court properly rejected Taylor's jury instruction regarding a failure to warn or train Harrison.

(d) The Trial Court Properly Applied a Negligence Standard, Rather than Strict Liability, to the Duty to Warn a Learned Intermediary

Taylor claims that the trial court erred in giving Instruction 11 on the applicable liability standard. Br. of Appellants at 48-57. Taylor claims that strict liability, rather than negligence, governs Intuitive's duty to warn, contending that the Supreme Court "left open" the question of whether a negligence standard applies. *Id.* at 49-54. But Taylor misrepresents our Supreme Court's decisional law. Washington law clearly holds that negligence, not strict liability, governs the duty to warn a learned intermediary about a medical product.

In general, as noted *supra,* the duty to warn regarding products utilized or prescribed by a learned intermediary runs not to the intermediary's client or patient, but rather to the professional prescribing the drug or medical device. *Terhune*, 90 Wn.2d at 17. Unlike the usual standard of strict liability in failure to warn cases under the WPLA,[20] the liability in a learned intermediary setting is based on negligence rather than strict liability. *Id.*

WPI 110.02.01, upon which jury Instruction 11 here was based, is a correct statement of the case law. CP 5398. In *Rogers v. Miles*

[20] RCW 7.72.030(1)(b); *Falk v. Keene Corp.*, 113 Wn.2d 645, 782 P.2d 974 (1989); *Ayers v. Johnson & Johnson Baby Products Co.*, 117 Wn.2d 747, 762, 818 P.2d 1337 (1991).

Laboratories, Inc., 116 Wn.2d 195, 207, 802 P.2d 1346 (1991), our Supreme Court applied a negligence standard to duty to warn cases involving learned intermediaries under the WPLA. *Rogers* addressed Washington's blood shield statute, RCW 70.54, because the WPLA exempts blood from the definition of a "product." RCW 7.72.010(3). With respect to product liability as to blood products, § 402A of the *Restatement* applied. The *Rogers* court applied comment k and the learned intermediary doctrine. The court concluded a negligence standard applied because the appropriate standard for blood products looked to the fault of the blood products' manufacturer. *Id.* at 207. The Supreme Court in *Young v. Key Pharmaceuticals, Inc.*, 130 Wn.2d 160, 168-69, 922 P.2d 59 (1996), a case that arose under pre-WPLA law, affirmed a Court of Appeals decision applying a negligence standard. The focus, the *Young* court said, is properly on the actions of the manufacturer and not on the product or consumer expectations, given the role of the learned intermediary. *Id.* at 178-79.

Division I of this Court agrees that a negligence standard applies to the WPLA duty to warn a learned intermediary. *Estate of La Montagne v. Bristol-Myers Squibb*, 127 Wn. App. 335, 111 P.3d 857 (2005). In *La Montagne*, Division I applied the comment k to § 402A negligence standard in a case arising under the WPLA. *Id.* at 343. *See also, Laisure-*

Radke v. Par Pharmaceutical, Inc., 426 F. Supp.2d 1163, 1171 (W.D. Wash. 2006).[21] Taylor *concedes* that *La Montagne* controls here. Br. of Appellants at 38.

Thus, Taylor's contention that a strict liability standard applies for warnings to learned intermediaries flies in the face of *Terhune, Rogers, Young, La Montagne,* and WPI 110.02.01. The Legislature is presumed to be aware of the state of the law generally and judicial construction of its enactments specifically. *Soproni v. Polygon Apartment Owners*, 137 Wn.2d 319, 327 n.3, 971 P.2d 500 (1999). As the Legislature has not acted to amend the WPLA in light of *La Montagne* and WPI 110.02.01, this Court can properly conclude the courts are applying the negligence standard in WPLA cases as it intended.

Courts applying Washington law have broadly concluded that some products are unavoidably unsafe, including pharmaceuticals[22] and medical products.[23] In *Ruiz-Guzman v. Amvac Chemical Corp.*, 141

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[21] Courts in other states hold that a negligence standard applies in warning learned intermediaries about unavoidably unsafe products. *See, e.g., Hahn v. Richter*, 673 A.2d 888 (Pa. 1996).

[22] *Luttrell v. Novartis Pharmaceuticals Corp.*, 894 F. Supp. 2d 1324 (E.D. Wash. 2012); *Wash. State Physicians Ins. Exch. Ass'n v. Fisons Corp.*, 122 Wn.2d 299, 313, 858 P.2d 1054 (1993) (recognizing that physician had CPA claim against drug manufacturer for loss of medical consultations and injury to professional reputation for misprescription of drug due to manufacturer's improper warnings about the drug to the physician as the learned intermediary).

[23] *See, e.g., May v. Dafoe*, 25 Wn. App. 575, 611 P.2d 1274, *review denied*, 93 Wn.2d 1030 (1980) (infant incubator); *Adams v. Synthen Spine Co. LP*, 298 F.3d 1114

Wn.2d 493, 7 P.3d 795 (2000), the Supreme Court put to rest any argument that comment k did not apply to WPLA claims, finding it implicit in the WPLA, particularly for design defect cases. *Ruiz-Guzman*, 141 Wn.2d at 506.

Nevertheless, Taylor asks this Court to treat comment k as an exception to the rule of strict liability on a case-by-case basis, citing *Ruiz-Guzman*. Br. of Appellants at 57-60. Taylor's reading of that case is imprecise. *Ruiz-Guzman* only addressed the predicate issue to the application of comment k – whether a product is unavoidably unsafe, not the consequence of such a determination.

Contrary to Taylor's contention that this Court should undertake a case-specific analysis as to whether the da Vinci System is unavoidably unsafe and qualifies for comment k, Br. of Appellants at 53-54, 57-60, the *Ruiz-Guzman* court *already resolved this issue.* "[W]e we hold that the question of whether a pesticide is government by comment k is to be determined on a product-by-product basis, *as opposed to a blanket exemption like that for medical products....*" *Ruiz-Guzman,* 141 Wn.2d at 511. The Court also noted:

(9th Cir. 2002) (surgically implanted spinal plate). Indeed, in *Terhune*, the learned intermediary principle applied to a prescription medical product, an intrauterine contraceptive device.

> *By its own terms, comment k is especially applicable to medical products.* The exceptions for medical products recognize the unique protection provided to the consumers of such products by the prescribing physician (and/or pharmacist) intermediary.

Ruiz-Guzman, 141 Wn.2d at 508-09 (emphasis added).

As a medical product, the da Vinci System is unavoidably unsafe and subject to comment k under *Ruiz-Guzman*. The question for the jury was whether Intuitive was negligent in its warnings to Dr. Bildsten. The jury properly concluded it was not; substantial evidence supports the jury's verdict.[24]

(2) The Trial Court Did Not Abuse Its Discretion in Addressing Testimony Regarding the General Success of Harrison's Robotics Program[25]

Taylor argues that the trial court abused its discretion by refusing to admit a proposed exhibit listing various surgical complications at Harrison. Br. of Appellants at 62-67. Taylor claims that Intuitive "opened

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[24] Taylor's brief nowhere argues that there was not substantial evidence to support the jury's verdict on negligence with regard to the warnings and training given to Dr. Bildsten.

[25] This Court reviews a trial court's decision to admit or deny evidence for abuse of discretion. *State v. Finch,* 137 Wn.2d 792, 810, 975 P.2d 967 (1999). A trial court abuses its discretion if its decision is manifestly unreasonable or is based on untenable grounds. *Stenson,* 132 Wn.2d at 701 (citing *State v. Powell,* 126 Wn.2d 244, 258, 893 P.2d 615 (1995)).

the door" to admission of the exhibit when a witness, Sean O'Connor, testified that the da Vinci program at Harrison had been successful. *Id.* Taylor concedes that the testimony did not violate an order in limine. *Id.* Taylor also acknowledges the proposed exhibit, 304, is not part of the record on appeal. *Id.* Although Taylor did not contemporaneously object to the testimony that allegedly "opened the door," RP 855, the trial court nevertheless offered a stipulated curative instruction. CP 4693-94. Taylor claims that the stipulated curative instruction the trial court issued was insufficient to cure the prejudice from O'Connor's statement. Br. of Appellants at 65-67.

Even if evidence might be considered marginally relevant, a trial court has discretion to exclude it if it may confuse the jury or has relatively low probative value. *State v. Everybodytalksabout*, 145 Wn.2d 456, 474, 39 P.3d 294, 304 (2002). Trial courts also have discretion to exclude evidence that necessitates a "mini-trial that would delay the trial proper." *State v. Kilgore*, 107 Wn. App. 160, 188, 26 P.3d 308, 323 (2001) *aff'd*, 147 Wn.2d 288, 53 P.3d 974 (2002).

A trial court also has considerable discretion regarding whether the door has been opened to a line of inquiry. *Burchfiel v. Boeing Corp.*, 149 Wn. App. 468, 490, 205 P.3d 145, *review denied*, 166 Wn.2d 1028 (2009); *Ang v. Martin,* 118 Wn. App. 553, 562, 76 P.3d 787 (2003), *aff'd,* 154

Wn.2d 477, 114 P.3d 637 (2005). When a party raises a topic upon examination, and the opposing party's counsel raises the same subject and does not exceed the scope of the prior testimony, the door has not been opened to "any and all" evidence related to that topic. *Burchfiel,* 149 Wn. App. at 490. In *Burchfiel,* the defendant employer wanted to introduce hearsay evidence that the plaintiff employee had sexually assaulted and threatened co-workers, particularly evidence relating to one incident. *Id.* at 486. While examining a witness, the defendant asked about the incident. The witness offered some general descriptions of the incident before objections were lodged. The plaintiff later testified generally responded to the testimony the defendant had raised, again not going into detail or making any specific denials regarding his behavior. *Id.* at 490. This Court concluded that responding to an issue first raised by the other party does not open the door as long as the responsive testimony is within the scope of the testimony initially raised. *Id.*

A trial court likewise has discretion to decide whether particular evidence constitutes proper impeachment evidence. Impeachment evidence, which contradicts the statement of a witness, must meet the standard for admissibility, including relevance. *See Jacqueline's Washington, Inc. v. Mercantile Stores Co.*, 80 Wn.2d 784, 789, 498 P.2d 870 (1972) (distinguishing impeachment by prior inconsistent statement

from impeachment by contradiction); *State v. Allen S.*, 98 Wn. App. 452, 466, 989 P.2d 1222 (1999), *review denied*, 140 Wn.2d 1022 (2000) (noting impeachment evidence must be relevant).

Finally, even if Taylor can demonstrate that the trial court abused its discretion, that abuse only constitutes reversible error if it prejudiced Taylor. *State v. Bourgeois,* 133 Wn.2d 389, 403, 945 P.2d 1120 (1997) (evidentiary error is grounds for reversal only if the error is prejudicial). An error is prejudicial if, within reasonable probabilities, had the error not occurred, the outcome of the trial would have been materially affected. *State v. Asaeli*, 150 Wn. App. 543, 579, 208 P.3d 1136, 1157 (2009).

Thus, for this Court to reverse on this issue, the list of surgical complications must be (1) probative enough to justify multiple "mini-trials" about the details of all of the complications, (2) responsive to testimony by Intuitive that "opened the door," to the list, (3) actually contradict O'Connor's statement that the program was successful overall, (4) incapable of being remedied by the stipulated curative instruction, and (5) of such import that failure to admit it materially affected the outcome of the trial. *Id.*

Taylor, not Intuitive, initially requested to exclude as irrelevant all evidence of the results of other robotic surgical procedures at Harrison from the trial. CP 2723. Taylor argued that a list of the outcomes of other

surgeries at Harrison, "without reliable supporting material, would be unfairly prejudicial, a waste of time, and would require the parties to engage in many mini-trials – one for each surgery presented." *Id.*

Despite initially wanting the evidence at trial to address only Taylor's surgery, Taylor admittedly raised the subject of the general quality of the robotic surgery program while examining O'Connor. Br. of Appellants at 62. Taylor wanted to make use of a 2008 email admission that suggested O'Connor had doubts about the "potential quality" of Harrison's new robotic surgery program. RP 730-31; Ex. 116. When asked whether in 2008 he had communicated doubts to Harrison about the program's potential quality, O'Connor said "No." RP 733.

On cross-examination, Intuitive addressed the issue raised by Taylor, asking O'Connor if he had ever expressed concerns to Harrison about the robotic surgery program's quality. He again answered no, and stated that the program had been successful overall. RP 855. Taylor did not object to the statement when O'Connor made it. *Id.*

Taylor claims that O'Connor's brief and unobjected-to statement necessitated admission of a list of other surgical complications. Taylor claims that O'Connor's statement suggested that all other robotic surgeries at Harrison had been complication-free. Br. of Appellants at 63. Taylor argues that questions about the 2008 email did not "open the door" to

O'Connor's statement because Taylor was only interested in O'Connor's 2008 opinion, not his present assessment. RP 730-31; Ex. 116. Thus, Taylor argues, only O'Connor's doubts about the program's quality in 2008 were within the narrow scope of inquiry on cross-examination. Br. of Appellants at 63.

The trial court carefully weighed the probative value of the list of complications against its prejudicial effect, and concluded that the evidence should be excluded under ER 403. RP 1429. In particular, the court noted that the list does not explain what the various "complications" were, their severity, their cause, etc., and that admitting the list would require multiple mini-trials, complete with extensive witness inquiry into all of the surgeries listed, in order to be probative:

> The issue is that there's no one here to explain the significance or lack of significance of any of those notations. As I've indicated before, each side has taken opposite positions with regard to this at various times during the course of the trial. 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.[26]

RP 1429.

Also, Exhibit 304 did not constitute a "contradiction" of O'Connor's testimony for impeachment purposes. This case is not like

[26] Notably, this is precisely what Taylor argued in pretrial motions as the grounds for excluding such evidence in the first place. CP 2723.

State v. Gallagher, 112 Wn. App. 601, 51 P.3d 100 (2002), *review denied*, 148 Wn.2d 1023 (2003), as Taylor argues. Br. of Appellants at 64. In *Gallagher*, a drug-related criminal case, the trial court had excluded *in limine* the admission of used and unused syringes found throughout the defendant's home. *Id.* at 609. Defense counsel then cross-examined a police detective and asked him about the absence of a number of specific drug-related items at the home. *Id.* On redirect, counsel for the State was permitted to elicit testimony about the syringes, because that evidence specifically contradicted the "evidence" that the defense sought to introduce, i.e., that *no* drug-related items were found at the home. *Id.* at 610.

Here, unlike *Gallagher*, the fact that other robotic surgeries allegedly had "complications" does not contradict O'Connor's opinion that the program was successful "overall." O'Connor *never said,* as Taylor repeatedly suggests, that there were no other incidents or complications with robotic surgeries. He simply said he had confidence in the overall quality of the program, and that it has been successful despite the incident with Dr. Bildsten.

Finally, the exclusion of the list was not prejudicial to Taylor's case. This case involved the question of whether Intuitive issued adequate warnings to Dr. Bildsten about the safe use of its product. The fact that

other surgeries performed by other surgeons had complications is not probative of whether Intuitive issued proper warnings. O'Connor's statement that the robotic surgery program had been "successful overall" was not equivalent to a claim that there were no other surgical complications at Harrison. The jury was not misled about any relevant fact.

Instead of admitting the problematic list, the trial court issued a curative instruction telling the jury to disregard any suggestion by O'Connor that there were other no incidents or complications at Harrison. CP 4693. The jury is presumed to have followed that instruction. *State v. Weber*, 99 Wn.2d 158, 166, 659 P.2d 1102 (1983); *In re Det. of Smith*, 130 Wn. App. 104, 113, 122 P.3d 736 (2005), *review denied,* 157 Wn.2d 1022 (2006).[27]

The curative instruction specifically and directly addressed the issue that Taylor now argues is prejudicial error that could only have been

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[27] Taylor cites older authority for the proposition that a curative instruction may not remedy the introduction of prejudicial evidence. Br. of Appellants at 67. Generally, curative instructions are more than ample to remedy an isolated evidentiary error. *See, e.g., State v. Hager*, 171 Wn.2d 151, 248 P.3d 512 (2011) (detective characterized defendant as evasive in violation of court order; court sustained objection and gave curative instruction); *Kimball v. Otis Elevator Co.*, 89 Wn. App. 169, 178, 947 P.2d 1275 (1997) (defense counsel in closing referenced absence of witnesses; court gave curative instruction). A case like *State v. Suleski*, 67 Wn.2d 45, 406 P.2d 613 (1965) where the introduction of tainted evidence *permeated* the trial stands in stark contrast to *Hager* or *Kimball* and the facts here.

remedied by the admission of Exhibit 304.[28] Given the context of the matter as it was presented, a brief question during a lengthy trial, the trial court properly and thoroughly resolved this issue with a curative instruction. The trial court did not abuse its discretion in refusing to admit Exhibit 304, and Taylor was not prejudiced.

(3) The Instructional Issues of Superseding Cause and Damages Mitigation Were Properly Addressed Below

Taylor argues that, in the event of reversal and remand for a new trial, this Court should address two additional alleged "errors" in the jury instructions. Br. of Appellants at 68-71. Taylor claims that (1) the jury should not have been instructed on superseding cause, and (2) the jury was improperly instructed on mitigation of damages.[29]

(a) A Superseding Cause Instruction Is Appropriate in a Failure-to-Warn Case Where There Is Evidence that Warnings Were Issued

The instruction at issue specified that superseding cause is "a new, independent cause that breaks the chain" of causation between the defendant's failure to warn and an injury. CP 5406. The instruction

[28] Taylor's claim that O'Connor's testimony was so prejudicial that a curative instruction was insufficient, Br. of Appellants at 67, stands in stark contrast to Taylor's initial claims that evidence of other surgical complication "has no bearing on any issue in this trial." CP 2628.

[29] Taylor raises these issues conditionally, as the jury did not reach them. Br. of Appellants at 68. This Court need not reach them if it agrees the judgment on the verdict should be affirmed here.

explained in detail to the jury that a superseding cause exists if Dr. Bildsten's negligent actions were independent and not reasonably foreseeable. *Id.*

Superseding cause instructions are permissible in products liability actions, including those involving the duty to warn. *Minert v. Harsco Corp.*, 26 Wn. App. 867, 874-76, 614 P.2d 686 (1980); *Anderson v. Dreis & Krump Mfg. Corp.*, 48 Wn. App. 432, 446, 739 P.2d 1177, *review denied*, 109 Wn.2d 1006 (1987).

Specifically, a superseding cause instruction is proper when a product purchaser was adequately warned by the manufacturer, but unforeseeably failed to heed that warning. *Minert,* 26 Wn. App. at 875. In *Minert,* an employee was injured when a scaffolding he was disassembling tipped and fell. *Id.* at 869. The employee sued the manufacturer of the scaffolding, arguing that it had failed to properly warn of the proper safety protocols for disassembling its product. *Id.* The evidence at trial indicated that the scaffolding manufacturer had issued careful instructions and warnings to the purchaser of the product, the employer. However, the employer failed to follow the instructions, and failed to ensure that the warnings and safety protocols were passed on to its employees. *Id.* The employee argued that the superseding cause doctrine was inappropriate to the case, because it would allow the

manufacturer to shift its duty to warn. *Id.* at 874. The court held that, when the manufacturer has issued warnings, the duty has been fulfilled, and the remaining question for the jury is causation. *Id.* at 875. The court concluded that because superseding cause is a viable doctrine in product liability cases, an instruction almost identical to the one offered here was appropriate. *Id.* at 875.

This case is in line with *Minert.* There was evidence that Dr. Bildsten was given ample, adequate warnings about the safe use of Intuitive's product, including what kinds of cases were appropriate for use of robotic surgery, and what kinds of cases were not. The jury was entitled to find that, given the warnings that Dr. Bildsten ignored, Dr. Bildsten's own actions were a superseding cause of Fred Taylor's injuries that was not foreseeable by Intuitive.

Taylor relies on *Campbell v. ITE Imperial Corp.*, 107 Wn.2d 807, 733 P.2d 969 (1987), but that case is inapposite. In *Campbell,* no warnings of any kind were issued, either to the end user or to the purchaser of the dangerously designed product. *Id.* at 810-11, 817. The manufacturer argued that the purchaser (the plaintiff's employer) should have *discovered and warned its employees of* the dangerous design, despite the fact that the manufacturer had not warned the purchaser. *Id.* at 817. Our Supreme Court concluded that when a manufacturer delivers a

dangerous product without a warning to the purchaser, the purchaser's failure to warn end users cannot constitute a superseding cause.

The jury instructions here did not shift the duty to warn under the guise of a superseding cause instruction. That is the only way *Campbell* could be properly applied. Instead, the instructions properly stated that if the "user," Dr. Bildsten, was adequately warned and still committed some independent act of negligence, his actions would break the chain of causation. CP 5406.

When a manufacturer supplies adequate product warnings to the end user, and that user ignores and contravenes those warnings without any explanation, a jury may evaluate whether that end user's actions were a superseding cause of the plaintiff's injuries. The superseding cause instruction is appropriate for the facts and circumstances of this case, and should not be stricken in the event the Court remands for a new trial.

(b) The Verdict Form Allowed the Jury to Allocate a Percentage of, It Did Not Shift the Burden of Proof

Taylor argues that the Instruction 20 and the verdict form invited the jury to twice deduct from any award those damages attributable to Taylor's failure to mitigate. Br. of Appellants at 70-71. Taylor claims that including the failure to mitigate as a percentage of fault impermissibly shifted the burden of proving mitigation to Taylor. *Id.* Taylor contends

that, upon remand, the verdict form must be changed because the jury might eliminate specific items of damage "off the top," and also reduce the overall award by a percentage. *Id.*[30]

Under Washington's comparative fault statute, any contributory fault – including the plaintiff's failure to mitigate – diminishes proportionately the amount of damages. RCW 4.22.005.[31] "A comparison of fault for any purpose under RCW 4.22.005 through 4.22.060 shall involve consideration of both the nature of the conduct of the parties to the action and the extent of the causal relation between such conduct and the damages." *Id.*

Allocating each party's respective fault according to percentages is an appropriate method to account for the necessary reduction in damages. *ESCA Corp. v. KPMG Peat Marwick*, 135 Wn.2d 820, 830, 959 P.2d 651, 656 (1998). The defendant is not required to catalogue each specific item of damage attributable to the plaintiff's fault. *Id.*

No reasonable reading of the verdict form supports Taylor's contention that Intuitive's burden of proof was shifted to Taylor, or that

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[30] Most of Taylor's citations in this section of the brief refer to arguments advanced in briefing below. *Id.* Taylor does cite one case, *Young v. Whidbey Island Bd. of Realtors*, 96 Wn.2d 729, 730, 638 P.2d 1235, 1236 (1982). That case contains only a general discussion of the principle that the defendant bears the burden of proving failure to mitigate.

[31] "Fault" includes an "unreasonable failure to avoid an injury or to mitigate damages." RCW 4.22.015.

the jury would have twice reduced Taylor's recovery. The verdict form stated nothing about shifting the burden of proof. CP 5637-39. The jury was properly instructed that the burden of proof of mitigation lay with Intuitive, and nothing in the verdict form suggested otherwise. CP 5407. Regarding "deductions" for failure to mitigate, the verdict form addressed it only in Question 7 where the jury was asked to allocate fault. CP 5639. Nowhere in Questions 8 and 9, where the jury was asked to indicate damages, was there any suggestion to deduct damages for a failure to mitigate. CP 5939-40.

The jury was properly instructed on superseding cause and how to account for Taylor's failure to mitigate.

(4) This Court Can Affirm the Verdict on the Ground that Dr. Bildsten's Actions Were the Superseding Cause of Taylor's Injury as a Matter of Law

Not only was the jury properly instructed on Dr. Bildsten's conduct constituting the superseding cause of Fred Taylor's injuries, the trial court should have ruled that any alleged fault on Intuitive's part was not the legal cause of Fred Taylor's injuries.[32] Where a physician ignores a manufacturer's warnings regarding the use of a medical instrument and

[32] A respondent may argue alternate grounds for affirming the trial court's decision so long as the issue was presented to the trial court for its consideration. *Otis Housing Ass'n, Inc. v. Ha*, 165 Wn.2d 582, 587, 201 P.3d 309 (2009) ("We may affirm the trial court on any grounds established by the pleadings and supported by the record."). Intuitive argued legal causation in its motion for summary judgment and its trial brief. CP 114-16, 4311-18.

negligently selects a poor candidate for a surgical procedure, any alleged fault on the manufacturer's part cannot be the cause of the patient's injury.

"[P]roximate cause consists of two elements: cause in fact and legal causation." *City of Seattle v. Blume*, 134 Wn.2d 243, 251, 947 P.2d 223 (1997). Legal causation "involves the question of whether liability should attach as a matter of law, even if the proof establishes cause in fact." *Blume*, 134 Wn.2d at 252. "Legal causation involves a determination whether liability should attach given cause in fact and is a question of law for the court based on policy considerations as to how far the consequences of the defendant's act should go." *Colbert v. Moomba Sports, Inc.*, 163 Wn.2d 43, 51, 176 P.3d 497 (2008). The concept of legal causation involves considerations of "logic, common sense, justice, policy and precedent." *Hartley v. State*, 103 Wn.2d 768, 779, 698 P.2d 77 (1985). "The focus in the legal causation analysis is whether, as a matter of policy, the connection between the ultimate result and the act of the defendant is too remote or insubstantial to impose liability." *Schooley v. Pinch's Deli Market, Inc.*, 134 Wn.2d 468, 478-79, 951 P.2d 749 (1998).

The cases on legal causation illustrate the application of the principle. In *Hartley*, our Supreme Court found that legal causation principles applied where the plaintiffs argued that the State was liable for wrongful death and injuries caused by an intoxicated person because it had

not revoked that person's driver's license. The Court stated that the failure to revoke was "too remote and insubstantial," a basis for liability. *Hartley*, 103 Wn.2d at 784. In *Kim v. Budget Rent A Car Sys., Inc.*, 143 Wn.2d 190, 15 P.3d 1283 (2001), the Court held that legal causation could not be established where the defendant negligently left keys in its van and a third party stole it, but that third party went home, slept overnight, drank to intoxication, and the next day criminally caused the accident that injured the plaintiff. The remoteness in time between the negligence and the injury was "dispositive." *Id.* at 205. In *Colbert,* the Court found that legal causation principles limited the duty owed to family members to avoid negligent infliction of emotional distress to persons physically present at an accident scene or who arrive shortly thereafter. 163 Wn.2d at 51-53, 63.

Under Washington law, principles of intervening or superseding cause apply in product liability cases. *Campbell,* 107 Wn.2d at 812-14. In the specific context of warnings to learned intermediaries, the physician's conduct may break the causal chain a matter of law. For example, a "manufacturer's failure to warn a prescribing physician cannot be the proximate cause of the patient's injury if the physician was already aware of the risk involved in the use of the" product. *Wash. State Physicians Ins. Exch.*, 122 Wn.2d at 315.

The causal chain is also broken when the prescribing physician "is aware of a risk and chooses to disregard it," as this Court noted in *Anderson v. Weslo, Inc.*, 79 Wn. App. 829, 839, 906 P.2d 336 (1995). A manufacturer's warning cannot cause (or prevent) a harm when the physician ignores it. *Id.* In *LaMontagne,* Division I of this Court concluded that whether a physician chooses to follow a manufacturer's specific warnings is a "matter of medical judgment." *LaMontagne,* 127 Wn. App. at 351. As such, the resulting harms are not caused by a lack of warning, but by the failure of that physician's medical judgment. *Id.*

The facts here are too attenuated to allow for liability. Legal causation cannot be present where Dr. Bildsten ignored Intuitive's warnings regarding use of the da Vinci System. The evidence below demonstrated that Dr. Bildsten was amply warned of risks pertaining to Fred Taylor's robotic surgery, but he, in his professional judgment, chose to disregard them.

Intuitive properly warned surgeons, including Dr. Bildsten, of the risks of performing any endoscopic surgery on a morbidly obese patient. Ex. 503 at 17. Intuitive warned that in their early cases, surgeons should chose simple cases, patients with a low BMI, and patients with no prior abdominal surgery. Ex. 509 at 4; Ex. 511 at 3. Also, as part of its training program, Intuitive warned that it would "unsafe" not to put a patient in a

steep Trendelenburg position during a robotic prostatectomy. RP 1048.

In the face of all of these specific warnings to Bildsten, Taylor represented below that the heart of the failure to warn case was that Intuitive did not sufficiently warn Dr. Bildsten about the learning curve:

> I mean, what are we really saying they failed to warn about, Your Honor? We're saying they failed to warn about the learning curve. That they failed to tell these doctors that for the first X number of surgeries, you're going to be in training; you're not going to be competent to do this alone.

RP 1416. But Intuitive told surgeons that the learning curve for use of its robotic surgical system depended on the surgeon and "differs from surgeon to surgeon" and is "highly variable." RP 1983, *see also*, RP 708 ("Some folks take longer than 15. Some do it in three."); RP 779; RP 955. If surgeons pressed Intuitive for a precise number of cases in the learning curve, Intuitive would tell them that it was "probably between 20 to 30," as supported by an article authored by Dr. Patel, while maintaining that this figure was "very unspecific." RP 779.

Dr. Bildsten was aware of the warnings regarding, and risks associated with, the da Vinci System and that he should avoid operating on patients like Fred Taylor, especially given his experience. Ex. 109 at 1; Ex. 509 at 4; RP 1143, 1808. Intuitive provided Dr. Bildsten with "lots of information" that the learning curve was 20 cases, and Dr. Bildsten knew that he was "early in the learning curve." RP 1133-38. Indeed, Dr.

Bildsten *admitted* that Taylor "was not an optimal candidate" for robotic prostatectomy. RP 1063.

Dr. Bildsten ignored Intuitive's warnings about the type of patient that was an appropriate candidate for robotic surgery. Fred Taylor, with his obesity and history of prior surgeries, was not a proper candidate for robotic surgery at all, as Dr. Bildsten well knew. Dr. Bildsten's disregard of Intuitive's warnings broke the causal chain.[33]

Finally, Dr. Bildsten's negligence was the superseding cause of any harm to Taylor as a matter of law. In Washington, superseding cause is ordinarily a question of fact for the jury, but it may be decided as a matter of law where the factual predicate to the application of the doctrine

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[33] "[C]ausation is broken between the manufacturer and patient" where, as here, "the doctor disregards warnings." *Dyer v. Best Pharmacal*, 577 P.2d 1084, 1087 (Ariz. Ct. App. 1978); *Bodie v. Purdue Pharma Co.*, 236 F. App'x 511, 521 (11th Cir. 2007) (recognizing that "'[i]f [the doctor] was aware of the possible risks involved in the use of the drug, yet chose to use it regardless of the adequacy of the warning, then, as a matter of law, the adequacy of the warning was not a producing cause of the plaintiff's injury'" (citation omitted)); *Wheat v. Sofamor, S.N.C.*, 46 F. Supp.2d 1351, 1363 (N.D. Ga. 1999) ("Where a learned intermediary has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided, courts typically conclude that the learned intermediary doctrine applies or that the causal link is broken and the plaintiff cannot recover."); *Dunkin v. Syntex Labs., Inc.*, 443 F. Supp. 121 (W.D. Tenn. 1977) (the prescribing physician's "familiarity with the risks associated with [the medication at issue] . . . negates the proposition that any presumed breach of the duty to warn on the part of the defendants herein could have been the proximate cause of [the plaintiff's] injury"); *Felix v. Hoffman-LaRoche, Inc.*, 540 So.2d 102, 105 (Fla. 1989) (holding that "any inadequacy in [the product's] warning could not have been the proximate cause of the birth defects in this case" because the prescribing physician understood the risks); *Magee v. Wyeth Labs., Inc.*, 214 Cal. App.2d 340, 351-52 (1963) ("Failure to follow an unchallenged method of use prescribed by the manufacturer constitutes a break in causation which exonerates the manufacturer from any liability.").

is essentially undisputed. *Kim,* 143 Wn.2d at 203. If the conduct was unexpected and outside the realm of foreseeability, it breaks the causal chain as a matter of law.

Here, there is little question but that Dr. Bildsten was negligent in his decision to use the da Vinci System in Fred Taylor's surgery, that he ignored proper warnings from Intuitive about patient selection. Intuitive could not have foreseen that a trained, board-certified surgeon would ignore warnings about patient selection early in the learning curve. In particular, the jury heard from Dr. Ramin, a board-certified urologist and one of *Taylor's* witnesses, that Dr. Bildsten's negligence caused Fred Taylor's injuries:

> Q: I want to ask you, Dr. Ramin, do you believe that Fred Taylor got an operation that met the standard of care?
>
> A: No, I don't.
>
> Q. You have a list of things that you believe Dr. Bildsten did wrong in this surgery; is that right?
>
> A. Yes.
>
> Q. Generally speaking, your opinion is that those things led to various injuries that he suffered?
>
> A. Yes.

RP 905-06.

Dr. Bildsten's negligent patient selection broke the causal chain.

The difficulties Dr. Bildsten experienced during the robotic surgery were directly attributable to his poor selection of an obese patient as a candidate. RP 892, 1072, 1080, 1143. Dr. Bildsten stated that he started with Taylor in the steep Trendelenburg position but had to alter it because of the "abdominal girth." RP 1072.[34] The steep Trendelenburg position helps to increase visual access. RP 892. Dr. Bildsten was having trouble seeing during the procedure. RP 1080. Dr. Bildsten also acknowledged that a patient such as Taylor with prior abdominal surgeries was not ideal because of the risk of adhesions and altered anatomy. RP 1143. Dr. Bildsten testified that he tore Taylor's rectum during an attempt to release an adhesion between Taylor's rectal wall and prostate. RP 1080.

This Court should affirm the trial court's judgment, albeit on the grounds that the trial court should have granted Intuitive's CR 50 motion that articulated legal causation and/or superseding cause grounds.

F. CONCLUSION

Taylor has failed to demonstrate that the trial court committed prejudicial error in its instructions to the jury on Intuitive's duty to warn under the WPLA. The trial court properly rejected an instruction designed to make Harrison the recipient of any duty to warn under the WPLA as a

[34] Even if Dr. Bildsten was able to get Taylor into a steep Trendelenburg position, he was aware that there were risks of putting an obese patient like Taylor in a Trendelenburg position. RP 1134.

learned intermediary where Dr. Bildsten, not Harrison, actually prescribed and used the da Vinci system. The trial court also properly instructed to jury to apply a negligence standard, rather than strict liability.

Taylor received a fair trial based on exceedingly favorable jury instructions and still did not prevail. Taylor simply failed to persuade the jury that Intuitive was culpable for Fred Taylor's injuries given Dr. Bildsten's negligent patient selection *despite* adequate warnings, and the injury he caused to Taylor during his surgery was unrelated to any action by Intuitive.

This Court should affirm the judgment on the jury's verdict. Costs on appeal should be awarded to Intuitive.

DATED this 9th day of May, 2014.

Respectfully submitted,

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Attorneys for Respondent Intuitive
Surgical, Inc.

APPENDIX

SUPERIOR COURT OF THE STATE OF WASHINGTON
IN AND FOR THE COUNTY OF KITSAP

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, Plaintiff, v. INTUITIVE SURGICAL, INC., Defendant.	No. 09-2-03136-5 ORDER ON DEFENDANT ISI'S (1) MOTION FOR SUMMARY JUDGMENT ON ALL CLAIMS AND (2) MOTION FOR SUMMARY JUDGMENT ON THE ISSUE OF PUNITIVE DAMAGES

THIS MATTER comes before the Court upon Defendant Intuitive Surgical's ("Defendant"), Motions for Summary Judgment (1) on all claims and (2) on the issue of punitive damages; Defendant filed both Motions on July 5, 2012. In conjunction with these Motions, on February 19, 2013, Defendant also filed its Motion to Strike Unauthenticated and Inadmissible Evidence Submitted by Plaintiffs in Their Opposition to Summary Judgment. On February 26, 2013, the Court heard oral argument on the Motions for Summary Judgment.

In considering the Motions, the Court reviewed the following evidence:

1. Defendant's Motion for Summary Judgment on all claims;
2. Plaintiffs' Response to Defendant's Motion for Summary Judgment on all claims;
3. Defendant's Reply to Defendant's Motion for Summary Judgment on all claims;

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4. Defendant's Motion for Summary Judgment on the Issue of Punitive Damages;
5. Plaintiffs' Response to Defendant's Motion for Summary Judgment on the Issue of Punitive Damages;
6. Defendant's Reply to Defendant's Motion for Summary Judgment on the Issue of Punitive Damages;
7. Defendant's Motion to Strike Unauthenticated and Inadmissible Evidence Submitted by Plaintiffs in Their Opposition to Summary Judgment; and
8. Any and all declarations, exhibits, and evidence included with and attached to the aforementioned pleadings, except for the following:

- PT-68 – *A Consensus Document on Robotic Surgery*
- PT-70 – 2010 email from Chris Duffie
- PT-82 – June 11, 2008 Harrison Medical Center da Vinci Taskforce notes
- PT-83 – June 18, 2008 Harrison Medical Center da Vinci Steering Committee notes
- PT-84 – July 1, 2008 Harrison Medical Center da Vinci Robot Steering Committee notes
- PT-99 – May 2011 email from Chris Duffie
- PT-122 – *Essential elements to the establishment and design of a successful robotic surgery programme*
- PT-188 – 2008 email from Dave Carson
- PT-215 – June 8 and June 9, 2011 emails
- PT-232 – *Difficulties in Robotic Radical Prostatectomy*
- PT-240 – *Has the Real MIS Revolution Finally Arrived?*
- PT-243 – *Training and outcome monitoring in robotic urologic surgery*
- PT-250 – Medical Record
- PT-260 – Earnings call transcript
- PT-264 – Risk management document

The Court being otherwise fully informed in these premises,

It is hereby **ORDERED**[1] that

(1) Defendant's Motion for Summary Judgment on all Claims is **GRANTED IN PART** and **DENIED IN PART** as follows:

[1] The Court's detailed rulings are memorialized in its Memorandum Opinion, filed in conjunction with this Order.

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Plaintiffs' claims for Design Defect, Manufacturing Defect, Breach of Express Warranty, Breach of Implied Warranty, Breach of Contract, Violation of Washington's Consumer Protection Act, and Negligence are hereby **DISMISSED**; Plaintiffs' claims under the WPLA remain;

(2) Defendant's Motion for Summary Judgment on the Issue of Punitive Damages is **DENIED**; and

(3) The punitive damages phase of the trial shall be bifurcated from the rest of the trial,

Dated: This 15th day of March, 2013.

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CERTIFICATE OF SERVICE

I, Gemma N. Zanowski, certify under penalty of perjury under the laws of the State of Washington that I am now and at all times herein mentioned, a resident of the State of Washington, over the age of eighteen years, not a party to or interested in the above entitled action, and competent to be a witness herein.

On March 25, 2013, I caused a copy of the foregoing document to be served in the manner noted on the following:

Jeffery R. Johnson Greg Thatcher Scheer & Zehnder, LLP 701 Pike Street, Suite 2200 Seattle, WA 98101 jjohnson@scheerlaw.com	☑	Via U.S. Mail ☐ Via Fax: ☐ Via Hand Delivery ☑ Via E-mail
Carol Johnston Otorowski Johnston Morrow & Golden, PLLC 298 Winslow Way West Bainbridge Island, WA 98110 cnj@medilaw.com	☑	Via U.S. Mail ☐ Via Fax: ☐ Via Hand Delivery ☑ Via E-mail
Richard Friedman Friedman Rubin 1126 Highland Ave Bremerton, WA 98337-1828 rfriedman@friedmanrubin.com	☑	Via U.S. Mail ☐ Via Fax: ☐ Via Hand Delivery ☑ Via E-mail

DATED March 25, 2013, at Port Orchard, Washington.

Gemma N. Zanowski
Judicial Law Clerk
Kitsap County Superior Court

SUPERIOR COURT OF THE STATE OF WASHINGTON
IN AND FOR THE COUNTY OF KITSAP

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,

Plaintiff,

v.

INTUITIVE SURGICAL, INC.,

Defendant.

No. 09-2-03136-5

MEMORANDUM OPINION ON DEFENDANT ISI'S (1) MOTION FOR SUMMARY JUDGMENT ON ALL CLAIMS AND (2) MOTION FOR SUMMARY JUDGMENT ON THE ISSUE OF PUNITIVE DAMAGES

THIS MATTER comes before the Court upon Defendant Intuitive Surgical's ("Defendant"), Motions for Summary Judgment (1) on all claims and (2) on the issue of punitive damages; Defendant filed both Motions on July 5, 2012. In conjunction with these Motions, on February 19, 2013, Defendant filed its Motion to Strike Unauthenticated and Inadmissible Evidence Submitted by Plaintiffs in Their Opposition to Summary Judgment. On February 26, 2013, the Court heard oral argument on the Motions for Summary Judgment.

BACKGROUND

On September 9, 2008, Fred Taylor underwent a robotic prostatectomy procedure during which surgeon Dr. Scott Bildsten used Defendant's da Vinci surgical system. During and after the surgery, Fred Taylor suffered complications and sustained injuries.

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The timing and the nature of the injuries is disputed. On August 25, 2012, approximately four years subsequent to the surgery, Fred Taylor passed away.

On December 17, 2009, Plaintiffs filed suit. Thereafter, Plaintiffs amended their complaint three times, most recently on December 12, 2012, after Fred Taylor's death. Plaintiffs' remaining claims include a common law negligence claim, claims under the Washington Products Liability Act, and claims for wrongful death and survival. Plaintiff also seeks punitive damages under an application of California law.

ANALYSIS

The Court should grant a motion for summary judgment when there is "no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law."[1] That is, if, based upon the evidence construed in the light most favorable to the non-moving party, "reasonable minds could only reach one conclusion as to the evidence presented."[2]

I. Defendant's Motion for Summary Judgment on all Claims

Washington courts have recognized no common law manufacturer duty to train. Generally, a duty may arise either as a consequence of the general duty to engage in reasonable conduct or where a special relationship exists that independently generates the duty. In the case of products liability claims, the Washington Products Liability Act, RCW 7.72 *et. seq.* ("WPLA"), creates such a special relationship and establishes that product manufacturers have duties to warn and instruct on the use of their products,[3] but in doing so extinguishes the possibility that a general duty based in negligence may lie. The WPLA contains language that broadly preempts all product liability claims or actions[4] based on

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[1] *Ballard Square Condominium Owners Ass'n v. Dynasty Const. Co.*, 158 Wn.2d 603, 146 P.3d 914 (2006).
[2] *Id.*
[3] RCW 7.72.030.
[4] RCW 7.72.010(4) defines a products liability claim as "any claim or action brought for harm caused by the manufacture, production, making, construction, fabrication, design, formula, preparation, assembly,

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any substantive legal theory not expressly excluded therein.[5] Claims based on strict liability in tort and negligence expressly are preempted.[6] Thus, if there is a negligence cause of action against Defendant in this case, it must come under the WPLA. This Court finds that the WPLA does contemplate such a duty.

Finding that a duty exists, and, consequently, that Plaintiffs properly may entertain a cause of action under the WPLA for harm allegedly caused by improper marketing of the da Vinci surgical system, Defendant's alleged failure to provide adequate warnings regarding use of the da Vinci surgical system, and Defendant's alleged failure to properly train and instruct Dr. Bildsten and Harrison Medical Center staff on the safe use of the da Vinci surgical system, the Court also finds that material issues of fact exist regarding breach, causation, and damages; these material issues of fact preclude summary judgment on Plaintiffs' WPLA claims.

The Court grants Defendant's Motion for Summary Judgment in part, finding that the WPLA preempts any common law negligence claim in this case; the Court dismisses Plaintiff's claim against Defendant for negligence. The Court denies Defendant's Motion for Summary Judgment in part, finding that Plaintiffs may proceed with their WPLA claims.

II. Defendant's Motion for Summary Judgment on the Issue of Punitive Damages

When resolving conflict of law questions in tort law cases, "Washington courts apply the 'most significant relationship' test set forth in the Restatement (Second) Conflict of Laws § 145 (1971)."[7] The contacts to be analyzed include (1) the place where the injury occurred; (2) the place where the conduct causing the injury occurred; (3) the domicil,

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installation, testing, warnings, instructions, marketing, packaging, storage or labeling of the relevant product." Plaintiffs' complaint indicates that "ISI had a duty to Fred Taylor ... to use reasonable care in designing, promoting, and marketing the da Vinci robotic surgery system, and in warning and training about it." Since all Plaintiffs' opined harms are explicitly listed in the WPLA's definition of a "product liability claim," the Court finds that Plaintiffs' negligence claims properly are classified as "products liability claims" for the purpose of determining preemption.

[5] RCW 7.72.010(4).

[6] *Id.*

[7] *Martin v. Goodyear Tire & Rubber Co.*, 114 Wn.App. 823, 829, 61 P.3d 1196 (Wash. Ct. App. 2003).

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residence, nationality, place of incorporation and place of business of the parties; and (4) the place where the relationship, if any, between the parties is centered.[8] The Court weighs the contacts according to their relative importance to the particular issue at hand.[9] If balanced, the Court must "evaluate the public policies and governmental interests of the concerned states."[10] In performing their choice of law analyses, Washington Courts have considered the parties' justified expectations.[11]

Although in this case there exist numerous contacts with both Washington and California, at this juncture, considering the issues and parties remaining in the case, the focus of a choice of law analysis is on the contacts pertinent to the products liability claims against Defendant ISI. As in *Singh*, the conduct that Plaintiff here claims resulted in the injury – that is, the alleged failure to warn and the alleged failure to orchestrate and implement a reasonable training regimen – occurred in California. Defendant's corporate headquarters are in California. The da Vinci User Manual, and the warnings incorporated therein, originated from California. Defendant's training program was designed in California. Although some portions of the training occurred in Washington, Plaintiffs' complaint is not that Defendant created an appropriate training program in California and that Defendant's employees or agents then failed to follow that program in Washington; Plaintiffs' complaint is that Defendant created an inappropriate and substandard training program in California that Defendant's employees then followed in Washington (and other states). Put another way, the conduct at the root of Plaintiffs' claims originated in California, even if it manifested itself, in part, in Washington.

When contemplating the policy issues at hand here, it is apparent that California has an interest in deterring activities that illustrate a "conscious disregard of safety" of others,[12] originating from corporations that have "a substantial business presence within its

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[8] Restatement (Second) Conflict of Laws § 145.
[9] *Martin*, 114 Wn.App. at 829.
[10] *Singh v. Edwards Lifesciences Corp.*, 151 Wn. App. 137, 144, 210 P.3d 337 (Wash. Ct. App. 2009).
[11] *Johnson v. Spider Staging Corp.*, 87 Wn.2d 577, 555 P.2d 997 (1976).
[12] *G.D. Searle & Co. v. The Superior Court of Sacramento County*, 49 Cal.App. 3d 22, 32, 122 Ca. Rptr. 218 (Cal. Ct. App. 1975).

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borders."[13] Washington has no interest in shielding from liability individuals who partake in such activities. And, as in *Johnson*, Defendant sells its products nationwide and cannot justifiably rely on a single state's rejection of punitive damage recovery. In addition to the presence of more substantial contacts with California on the particular issues at bar in this case, California has compelling interests at stake that justify application of California law.

A punitive damages claim in this case may proceed under California law. Material issues of fact exist as to whether Plaintiffs are entitled to punitive damages, but these are issues for the jury to resolve.

III. Bifurcation

Finally, the Court notes that Defendant in its Motion in Limine No. 2 moved the Court for an order bifurcating the punitive damages phase of the trial, and Plaintiffs had no objection. The decision to bifurcate is within the discretion of the trial court; the Court may order bifurcation in furtherance of convenience, when separate trials will be conducive to expedition and economy, or to avoid prejudice.[14] The Court elects to exercise its discretion to order the trial bifurcated as to the punitive damages phase.

Dated: This 25th day of March, 2013.

JUDGE JAY B. ROOF

[13] *Singh*, 151 Wn.App. 137 at 144.
[14] CR 42(b); *Myers v. Boeing Co.*, 115 Wn.2d 123, 794 P.2d 1272 (1990).

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CERTIFICATE OF SERVICE

I, Gemma N. Zanowski, certify under penalty of perjury under the laws of the State of Washington that I am now and at all times herein mentioned, a resident of the State of Washington, over the age of eighteen years, not a party to or interested in the above entitled action, and competent to be a witness herein.

On March 25, 2013, I caused a copy of the foregoing document to be served in the manner noted on the following:

Jeffery R. Johnson Greg Thatcher Scheer & Zehnder, LLP 701 Pike Street, Suite 2200 Seattle, WA 98101 jjohnson@scheerlaw.com	☑ ☐ ☐ ☑	Via U.S. Mail Via Fax: Via Hand Delivery Via E-mail
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DATED March 25, 2013, at Port Orchard, Washington.

Gemma N. Zanowski
Judicial Law Clerk
Kitsap County Superior Court

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Physician's Surgical Procedure Disclosure and Patients Consent

TO THE PATIENT: You have the right to be informed about your condition and the recommended surgical, medical or diagnostic procedure so that you may make the decision whether or not to undergo the procedures after knowing the risks involved and any treatment alternatives available to you. This information is not meant to alarm you; it is an effort to make you better informed so that you may give or withhold your consent to the procedure. If you do not understand any of the information provided, ask your physician to explain it.

1. PATIENT NAME
TAYLOR, FRED

2. PRACTITIONER PERFORMING THE TREATMENT/PROCEDURE
SCOTT A. BILDSTEN, D.O.

3. SUPERVISING PRACTITIONER (IF APPLICABLE)

4. OTHER PRACTITIONERS PERFORMING THE TREATMENT/PROCEDURE (IF APPLICABLE)
JOHN C. HEDGES, M.D.

5. COUNSELING PROVIDER (IF APPLICABLE)

6. WHAT IS THE CONDITION OR DIAGNOSIS FOR WHICH THIS TREATMENT/PROCEDURE IS RECOMMENDED?
Prostate Cancer

7. WHAT DOES THIS TREATMENT/PROCEDURE INVOLVE?
Removal of entire prostate & seminal vesicles and regional pelvic lymph nodes. (radical retropubic prostatectomy)using the Da Vinci Robotic System

8. ON WHAT PART OF THE BODY WILL THIS TREATMENT/PROCEDURE BE

PERFORMED?
Prostate

9. WHAT ARE THE EXPECTED BENEFITS OF THIS TREATMENT/PROCEDURE?
Possible cure of tumor or cancer.

10. WHAT ARE THE KNOWN RISKS OF THIS TREATMENT/PROCEDURE?
- Impotence (inability to achieve adequate erections)
- Incontinence (inability to maintain urinary control)
- Strictures of bladder and/or urethra requiring stretching or further procedures.
- Damage to rectal wall (possibly requiring temporary colostomy).
- No guarantee of cancer cure and need for further cancer treatment such as radiation or hormone therapy.
- Infection of incision requiring further treatment.
- Emboli (blood clots) from veins into the lung
- Anesthetic or cardiovascular problems during or after surgery
- Pain or hernia formation in area of incision
- Significant blood loss, possibly requiring transfusions
- Urinary infection
- Death
- Renal (kidney) failure
- Decreased penile length
- Urinary fistula
- Urinary retention

11. WHAT ARE THE ALTERNATIVES TO THIS TREATMENT/PROCEDURE?
Radiation therapy, radioactive implant, removal of all male hormones, observation (no immediate treatment), cryotherapy, different surgical approaches.

12. WHAT WILL HAPPEN IF THE TREATMENT/PROCEDURE IS NOT DONE?
Continued growth and possible spread of malignant (cancerous) tumor, making tumor incurable or later removal impossible; urinary retention, pain, bleeding, renal (kidney) failure, death

13. IS IT EXPECTED THAT AN ANESTHESIA PRACTITIONER WILL BE INVOLVED IN THIS TREATMENT/PROCEDURE?
IT IS EXPECTED that an anesthesia practitioner will be involved in this treatment/procedure.

An anesthesia practitioner will visit me before my treatment/procedure to discuss the type(s) of anesthesia I may need. All forms of anesthesia involve some risk. Although rare, unexpected severe complications with anesthesia can occur and include the

remote possibility of infection, bleeding, drug reactions, blood clots, loss of sensation, loss of limb function, paralysis, stroke, brain damage, heart attack or death.

Types of anesthesia include:

General anesthesia: Drug injected into the bloodstream, breathed into the lungs, or by other routes with possible placement of a tube into the windpipe.
Anticipated benefit: Total unconscious state, assistance with breathing.
Possible risks: Pain where injection is given, mouth or throat pain, hoarseness, injury to mouth or teeth, awareness under anesthesia, nausea, injury to blood vessels, pneumonia.

Spinal or epidural analgesia/anesthesia: Drug injected through a needle/catheter placed either directly into the spinal canal or immediately outside.
Anticipated benefit: Temporary decreased feeling and/or movement to lower part of the body.
Possible risks: Pain where injection is given, headache, backache, buzzing in the ears, convulsions, infection, persistent weakness, numbness, residual pain, injury to blood vessels, 'total spinal.'

Major/minor nerve block: Drug injected near nerves providing loss of sensation to the area.
Anticipated benefit: Temporary loss of feeling and/or movement of a specific limb or area.
Possible risks: Pain where injection is given, infection, convulsions, weakness, persistentnumbness, residual pain, injury to blood vessels.

14. IS IT EXPECTED THAT BLOOD PRODUCTS MAY BE NEEDED IN THIS TREATMENT/PROCEDURE?
IT IS EXPECTED that blood products may be used in this treatment/procedure.

Anticipated Benefits: The benefit of the blood products is that is may improve my overall condition or save my life.

Potential Risks: The more common risks include (but are not limited to) infection/irritation where the needle is placed, fever, chills, and skin rashes. Other rare but more serious complications may occur such as allergic reactions, shock, or death. I also know there is a very small risk of infection, including the risk of hepatitis (<1 in 200,000) and/or HIV/AIDS (<1 in 2 million).

Alternatives: Alternatives to blood or blood products such as auto-donation (using my own previously donated blood), directed donation (blood donated by people whom I have asked to donate for me) and intra-operative salvage (my own blood collected during surgery) may be available if my health, time, and procedure permit. In addition, medications may be used to reduce the need for blood products.

15. CONSENT TO BLOOD PRODUCTS (IF APPLICABLE)
The patient (or surrogate) consents to the use of blood products.

16. TREATMENT LIMITATIONS: I impose no specific limitations or prohibitions regarding treatment other than those that follow:

_____

_____

17. DISPOSAL OF TISSUE: I authorize the disposal of any surgically removed tissue or parts resulting from the procedure according to accustomed practice.

18. CONSENT TO TREATMENT OF UNFORESEEN CONDITIONS: I understand that my physician may encounter or discover other or different conditions which require additional or different procedures than those planned. I authorize my physician, and associated technical assistants, and other health care providers to perform such other procedures which are advisable in their professional judgment.

19. OUTCOME: I understand that the practice of medicine is not an exact science, and that no warranty or guarantee has been made to me as to result or cure.

20. CONSENT TO TRAINING PARTICIPATION: This facility may have an educational role in the training of paramedical personnel.

Admittance of students and/or technical representatives

[ ] I consent to the admittance of students and/or technical representatives for the purpose of advancing medical education and/or product usage.

[ ] I do not consent to the admittance of students and/or technical representatives for the purpose of advancing medical education and/or product usage.

Participation of students and/or technical representatives

[ ] I consent to the participation of students and/or technical representatives for the purpose of advancing medical education and/or product usage.

[ ] I do not consent to the participation of students and/or technical representatives for the purpose of advancing medical education and/or product usage.

17. ADDITIONAL INFORMATION
I understand that during the treatments/procedures, the doctor or dentist may need to place a medical device in my body. If a medical device is implanted in my body, personal information (such as my name, social security number, and medical information) will be given to the maker of the device for quality control purposes.

After my surgery, I ask that the medical staff dispose of any of my tissues or body parts that were removed during the treatments/procedures, as long as my doctor or dentist does not think that further pathological examination is needed.

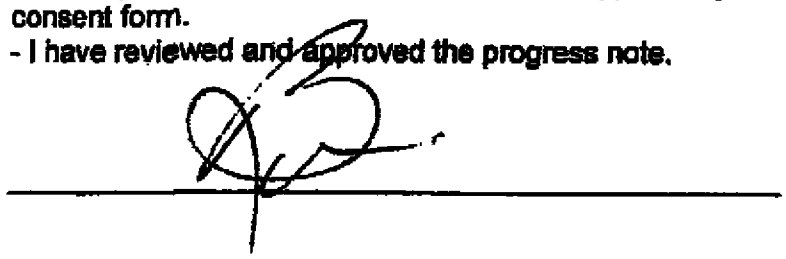
KITSAP111

If you have questions concerning the scheduling of your procedure, call 1-800-555-1111.

16. COMMENTS

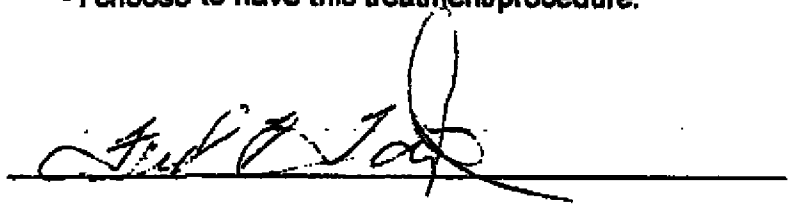
SIGNING PRACTITIONER:

By signing below, I attest to the following:
- All relevant aspects of the treatment/procedure, including indications, benefits, risks, and alternatives including no treatment have been discussed with the patient (or surrogate) in language that s/he could understand, and the patient (or surrogate) indicated comprehension of the discussion.
- I have given the patient (or surrogate) an opportunity to ask questions.
- I did not use threats, inducements, misleading information, or make any attempt to coerce the patient/surrogate to consent to this treatment/procedure.
- I have given the patient (or surrogate) the opportunity to review a printed copy of the consent form.
- I have reviewed and approved the progress note.



PATIENT OR SURROGATE:

By signing below, I attest to the following:
- Someone has explained this treatment/procedure and what it is for.
- Someone has explained how this treatment/procedure could help me, and things that could go wrong.
- Someone has told me about other treatments or procedures that might be done instead, and what would happen if I have no treatment or procedure.
- Someone has answered all my questions.
- I know that I may refuse or change my mind about having this treatment or procedure. If I do refuse or change my mind, I will not lose my health care.
- I have read a printed copy of the consent form and I understand it.
- I choose to have this treatment/procedure.



KITSAP112

WITNESS(ES):

By signing below, I attest to the fact that I have witnessed the patient (or surrogate) and the practitioner sign this consent form.

Kim Huff 9.5-08

Second Witness (required if patient/surrogate signed with an "X"):
Signature: Witness2

000250

Patient: Fred Taylor

I hereby authorize Dr. Bildsten

and/or such associates or assistants as may be selected by said physician to perform the following procedure(s) which has (have) been explained to me:

Radical Robotic Prostatectomy

② The treatment(s) planned for my condition(s) has (have) been explained to me by my physician. I understand them to be: alternatives

③ I recognize that, during the course of the operation, post operative care, medical treatment, anesthesia or other procedure, unforeseen conditions may necessitate additional or different procedures than those above set forth. I therefore authorize my above named physician, and his or her assistants or designees, to perform such surgical or other procedures as are in the exercise of his, her or their professional judgement necessary and desirable.

④ I have been informed that there are significant risks such as severe loss of blood, infection and cardiac arrest that can lead to death or permanent or partial disability, which may occur from the performance of any procedure. I acknowledge that no warranty or guarantee has been made to me as to result or cure.

⑤ I consent to the administration of anesthesia by my attending physician, by an anesthesiologist, or other qualified party under the direction of a physician as may be deemed necessary. I understand that all anesthetics involve risks of complications and serious possible damage to vital organs such as the brain, heart, lung, liver and kidney and that in some cases may result in paralysis, cardiac arrest and/or brain death from both known and unknown causes.

⑥ Any tissues or parts surgically removed may be disposed of by the hospital or physician in accordance with accustomed practice.

Full/Limited Disclosure

⑦ I recognize that I have the right to have clearly described to me by my physician the following points:
a) the nature and character of the proposed treatment;
b) the anticipated results of the proposed treatment;
c) the alternative forms of treatment; and
d) the recognized serious possible risks, complications, and anticipated benefits involved in the proposed treatment, and in the alternative forms of treatment, including non-treatment.

(check one)

☒ My physician has informed me of the above points to my satisfaction prior to my authorization of the proposed treatment.

☐ I have decided that I do not want to be told of the above points.

⑧ I consent to the use of transfusion of blood and blood products as deemed necessary. ☒ YES ☐ NO

⑨ I give permission for pertinent data including my name and social security number to be released to manufacturers or the Food and Drug Administration upon their request to track certain medical devices. (This tracking is done in compliance with the Safe Medical Device Act.)

☐ Yes ☒ No

I certify this form has been fully explained to me, that I have read it or have had it read to me, that the blank spaces have been filled in, and that I understand its contents.

Patient Signature	Date	Time	Witness
	9/5/08	3:45	
Other Responsible Person	Date	Time	Witness
Relationship of Other Responsible Person			

HARRISON MEDICAL CENTER
BREMERTON, WASHINGTON
PHONE 360.377.3911

SPECIAL CONSENT TO OPERATION, POST OPERATIVE CARE, MEDICAL TREATMENT, ANESTHESIA, OR OTHER PROCEDURE

08249-00344
MR#: 210219 AGE:67Y
SEX:M DOB:12/14/1940
TAYLOR,FRED E

WHITE – MEDICAL RECORD COLDENROD – PATIENT

HARRISONMC_00238

DECLARATION OF SERVICE

On said day below I emailed a courtesy copy and deposited in the U.S. Mail for service a true and accurate copy of the Motion for Leave to Submit Over-Length Brief of Respondent and the Brief of Respondent Intuitive Surgical in the Court of Appeals Cause No. 45052-6-II to the following parties:

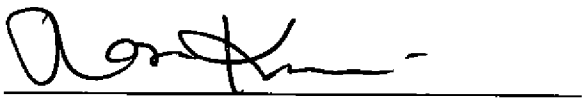
William S. Cummings Richard Friedman Peter J. Mullenix Friedman | Rubin 1126 Higland Avenue Bremerton, WA 98337	Carol N. Johnston Jane Morrow Otorowski, Johnston, Morrow & Golden PLLC 298 Winslow Way West Bainbridge Island, WA 98110
Kenneth W. Masters Masters Law Group P.L.L.C. 241 Madison Avenue N. Bainbridge Island, WA 98110-1811	Allen J. Ruby Skadden, Arps, Slate, Meagher & Flom 525 University Avenue Palo Alto, CA 94301
Karen M. Firstenberg Morris Polich & Purdy LLP 1055 W. 7th Street, Suite 2400 Los Angeles, CA 90017	Catherine B. Stevens Quinn Emanuel 51 Madison Avenue New York, NY 10010

Original efiled with:

Court of Appeals, Division II
Clerk's Office
950 Broadway, Suite 300
Tacoma, WA 98402

I declare under penalty of perjury under the laws of the State of Washington and the United States that the foregoing is true and correct.

DATED: May 9th, 2014, at Seattle, Washington.



Roya Kolahi, Legal Assistant
Talmadge/Fitzpatrick

TALMADGE FITZPATRICK LAW

May 09, 2014 - 11:42 AM

Transmittal Letter

Document Uploaded: 450526-Respondent's Brief.pdf

Case Name:

Court of Appeals Case Number: 45052-6

Is this a Personal Restraint Petition? Yes ■ No

The document being Filed is:

Designation of Clerk's Papers Supplemental Designation of Clerk's Papers

Statement of Arrangements

Motion: ____

Answer/Reply to Motion: ____

■ Brief: __Respondent's__

Statement of Additional Authorities

Cost Bill

Objection to Cost Bill

Affidavit

Letter

Copy of Verbatim Report of Proceedings - No. of Volumes: ____
Hearing Date(s): _____

Personal Restraint Petition (PRP)

Response to Personal Restraint Petition

Reply to Response to Personal Restraint Petition

Petition for Review (PRV)

Other: _____

Comments:

No Comments were entered.

Sender Name: Irelis E Colon - Email: assistant@tal-fitzlaw.com

A copy of this document has been emailed to the following addresses:

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jjohnson@scheerlaw.com
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