

No. 92210-1

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SUPREME COURT  
OF THE STATE OF WASHINGTON

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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,

Petitioners,

vs.

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

Respondent.

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INTUITIVE SURGICAL'S  
REVISED SUPPLEMENTAL BRIEF

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Allen J. Ruby, pro hac vice  
Skadden, Arps, Slate, Meagher &  
Flom LLP & Affiliates  
525 University Avenue, Suite 1100  
Palo Alto, CA 94301  
(650) 470-4590

Philip A. Talmadge, WSBA #6973  
Sidney Tribe, WSBA #33160  
Talmadge/Fitzpatrick/Tribe  
2775 Harbor Avenue SW  
Third Floor, Suite C  
Seattle, WA 98126  
(206) 574-6661

Jeffrey R. Johnson, WSBA #11082  
Gregory P. Thatcher, WSBA #40902  
Scheer & Zehnder, LLP  
701 Pike Street, Suite 2200  
Seattle, WA 98101  
(206) 262-1200  
Attorneys for Intuitive Surgical, Inc.

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## A. INTRODUCTION

This is a product liability action arising out of the robotically-assisted surgery negligently performed by Dr. Scott Bildsten. Bildsten used a system (“da Vinci System”) manufactured by Intuitive Surgical, Inc. (“Intuitive”). Josette Taylor, Fred Taylor’s wife and personal representative (“Taylor”), seeks to re-write settled principles of Washington product liability law. The Court of Appeals majority opinion correctly articulated and resolved those issues in Intuitive’s favor.

Dr. Bildsten performed robotically-assisted surgery on Fred Taylor at Harrison Medical Center (“Harrison”) in Bremerton to remove Taylor’s prostate gland. Prior to the surgery, Dr. Bildsten specifically disclosed to Fred Taylor, and discussed with him, the possible risks of the surgical procedure, including risks specific to robotically-assisted surgeries using the da Vinci System. Dr. Bildsten exercised poor medical judgment in selecting Fred Taylor for such robotically-assisted surgery and performed the surgery negligently.

Having settled her corporate negligence claims with Harrison – a critical fact omitted from her petition for review – Taylor took her Washington Products Liability Act, RCW 7.72 (“WPLA”) failure to warn claims against Intuitive to trial. A jury found that Intuitive had properly

warned and trained<sup>1</sup> Dr. Bildsten in the use of the da Vinci System.

Taylor now asserts that although the jury found Intuitive to have properly warned Dr. Bildsten as a “learned intermediary,” she is entitled to a new trial against Intuitive because Intuitive allegedly breached a separate duty to warn Harrison that the “learning curve” for the device was highly variable. She asserts that Intuitive had a duty to train Harrison in how to run the hospital’s own credentialing program for physicians using the device. Taylor also contends that a strict liability standard governs the duty to warn learned intermediaries.

This Court should reject Taylor’s contentions that would distort Washington product liability law.

#### B. STATEMENT OF THE CASE

The Court of Appeals majority opinion adequately discusses the facts here, *op. at* 2-7, but several factual points bear emphasis. The da Vinci System may *only* be used by medical professionals upon a physician’s order or prescription for its use. CP 364. Intuitive provided extensive materials regarding the da Vinci System to purchasers and

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<sup>1</sup> The trial court erroneously instructed the jury that the WPLA duty to warn also includes a duty to train the individual in use of the device. Because the jury found that Intuitive did not violate this “duty to train,” Intuitive did not cross-appeal from the erroneous instruction.

surgeons.<sup>2</sup>

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.<sup>3</sup> Dr. Bildsten presented him with several cancer treatment options, one of which was a robotic prostatectomy using the da Vinci System. CP 180-81.

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 staff. RP 1067. Dr. Bildsten received Intuitive's general guide,

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<sup>2</sup> The User Manual for the da Vinci System, which was submitted to the United States Food and Drug Administration ("FDA"), contained a number of instructions, warnings, contraindications, and precautions, including a specific direction that robotically-assisted surgery should not occur on persons who are morbidly obese. CP 159, 366. Intuitive provided that manual to purchasers like Harrison. Ex. 503; RP 1819.

In addition to this Manual, Intuitive provided 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 provided "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. Hospitals received this document. RP 716. Intuitive also recommended that surgeons choose patients with no prior abdominal surgery. Ex. 509 at 4.

<sup>3</sup> Dr. Bildsten was a veteran urological surgeon with 15 years of experience, having performed more than one hundred open prostatectomy procedures; before Fred Taylor's surgery, he received training on how to use the da Vinci System from Intuitive, observed more than ten surgeries involving the da Vinci System, and 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.

the prostatectomy-specific guide, and 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 knew Fred Taylor was a poor choice for robotically-assisted surgery, and was negligent in selecting him for such surgery, contrary to Intuitive’s unambiguous warnings.<sup>4</sup>

Dr. Bildsten discussed da Vinci surgery with Fred Taylor, warning him of its risks and complications including possible rectal injury, incontinence, and even more significant complications. CP 243-48, 250. Fred Taylor signed the informed consent form that identified the risks that Dr. Bildsten discussed with him about da Vinci surgery, including damage to the rectal wall and other serious complications associated with the surgery. CP 243. *See* Appendix. *Id.* Dr. Bildsten testified that he told

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<sup>4</sup> At the time of his surgery, Fred Taylor weighed 280 pounds and had a BMI of approximately 39. CP 926. Dr. Bildsten admitted that “extreme obesity” was an “absolute contraindication” for the da Vinci surgery. RP 1138. 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’s physicians prescribed blood pressure, cholesterol, and diabetes medications, which he did not regularly take. *Id.*

Taylor of these risks, and that Fred Taylor *insisted* on surgery rather than treatment with radiation. RP 1067. Dr. Bildsten negligently selected Fred Taylor for robotically-assisted surgery, RP 1134, and was negligent in performing that surgery. CP 905-06, 977.

Prior to trial, Taylor settled with Dr. Bildsten, CP 764-77, and settled any claim, including corporate negligence claims, against Harrison. At trial, Taylor adduced no evidence from Harrison personnel regarding her claim of a distinct duty to warn owed by Intuitive to Harrison.<sup>5</sup>

C. ARGUMENT ON AFFIRMANCE

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

Taylor asks this Court to distort settled Washington law on the duty to warn in product liability cases in order to overturn an unfavorable jury verdict. Despite generous instructions imposing both a duty to warn and an erroneous "duty to train" Dr. Bildsten regarding the da Vinci System, in particular Instructions 10 and 11 (CP 5397, 5398), the jury ruled against Taylor. Taylor's appeal seeks to impose this same duty to warn and erroneous "duty to train" on Harrison, as stated in her proposed

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<sup>5</sup> In her proposed instructions 12 and 28 and in her Court of Appeals briefing, Taylor argued the duty to warn Harrison was essentially the same duty to warn owed to Dr. Bildsten. Br. of Appellant at 39-48; reply br. at 2-12. The jury, of course, exonerated Intuitive from liability for a breach of any duty to warn or train Dr. Bildsten. CP 5628-30.

instructions 12 and 28 (CP 4145-46, 4164), despite failing to present any evidence from anyone at Harrison regarding this novel theory.<sup>6</sup>

Taylor now argues that she had a claim against Intuitive for its alleged negligence in failing to provide what would presumably be identical warnings to Harrison that Intuitive provided to Dr. Bildsten.<sup>7</sup> She does not, and her argument would dramatically alter Washington law on product liability.

- (a) Harrison Is Not a Learned Intermediary to Which a Second Duty to Warn is Owed
  - (i) Taylor Did Not Preserve the Issue of a Duty to Warn Harrison Because Her Proposed Instructions Misstated the Law

Taylor did not preserve the issue of the duty to warn Harrison for appellate review because her proposed instructions on this alleged duty to warn Harrison were incorrect statements of Washington law. Taylor's proposed instructions 12 and 28 state that the WPLA imposes a duty on Intuitive in a product liability case to train Harrison's professional staff in the use of its product. These instructions incorrectly expanded the

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<sup>6</sup> 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*.

<sup>7</sup> If Taylor is contending *different* warnings should have been given to Harrison (and that is not clear from Taylor's argument), that demonstrates the impracticality of Taylor's duty to warn concept.

WPLA's duty to warn.<sup>8</sup>

The WPLA provides the sole remedy for product-related harm in Washington. RCW 7.72.010(4). It 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. RCW 7.72.030(1)(b).<sup>9</sup>

The WPLA does not impose on manufacturers a duty to train product users in the product's use. *Nowhere* does the specific language of RCW 7.72.030(1)(b) reference 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." No reported case in Washington has held that RCW 7.72.030(1)(b) creates a duty to train.

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;

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<sup>8</sup> The trial court was not obligated to give such erroneous statements of the law. *Havens v. C&D Plastics, Inc.*, 124 Wn.2d 158, 167, 876 P.2d 435 (1994).

<sup>9</sup> Washington's principles for statutory interpretation are clearly articulated in this Court's decisions. Br. of Resp't at 20 n.11. As the Court recently reaffirmed in *Saucedo v. John Hancock Life & Health Ins. Co.*, \_\_\_ Wn.2d \_\_\_, \_\_\_ P.3d \_\_\_, 2016 WL 852459 (2016) at \*3, courts are not free to add language to a statute not enacted by the Legislature.

Minnesota rejected such a concept in *Glorvigen v. Cirrus Design Corp.*, 816 N.W.2d 572, 583 (Minn. 2012) (rejecting duty to train as “unprecedented”) as have other courts across the country.<sup>10</sup>

If the Legislature did not impose a duty to train in enacting RCW 7.72.030(1)(b). Taylor's proposed instructions 12 and 28 misstate the law, and thus her proposed instructions failed to preserve this issue for appeal.

(ii) Taylor’s Proposed Instructions Were Also Erroneous in Suggesting Harrison Was a Second Learned Intermediary for Taylor

Even assuming Taylor’s erroneous proposed instructions correctly enunciated a duty to train, Dr. Bildsten, not Harrison, was the learned intermediary to whom a WPLA duty to warn was owed.<sup>11</sup> Dr. Bildsten, not Harrison, stood in Fred Taylor’s shoes to receive Intuitive’s warnings

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<sup>10</sup> See *Rounds v. Genzyme Corp.*, 440 F. Appx. 753, 754 (11th Cir. 2011), *cert. denied*, 132 S. Ct. 1913 (2012) (no duty to train doctors in use of a biologic as barred by learned intermediary doctrine); *Woodhouse v. Sanofi-Aventis U.S. LLC*, 2011 WL 3666595 at \*3 (W.D. Tex. 2011) (no claim for failure to “train, warn, or educate” prescribing doctors); *Adeyinka v. Yankee Fiber Control, Inc.*, 564 F. Supp. 2d 265, 286 (S.D.N.Y. 2008) (no duty to train under NY law); *York v. Union Carbide Corp.*, 586 N.E.2d 861, 871 (Ind. App. 1992) (court found “no authority for the proposition that a manufacturer has a legal duty to train the employees of its buyers.”); *Mason v. Texaco Inc.*, 862 F.2d 242, 248 (10th Cir. 1988) (prejudicial error to give instruction that benzene salesmen had duty to train users under Kansas law).

<sup>11</sup> Washington’s learned intermediary principle, first recognized by this Court in *Terhune v. A.H. Robins Co.*, 90 Wn.2d 9, 13-14, 577 P.2d 975 (1978) where it adopted comment k to the *Restatement (Second) of Torts* § 402A, provides that a warning about a medical device or pharmaceutical must be given to the physician, standing in the patient’s shoes, because the physician “decides what facts must be told to the patient” in that physician’s informed judgment as to the use of the device or substance in the patient’s best interest. *Id.* at 15.

about the use of the da Vinci robotically-assisted surgical system because it was Dr. Bildsten's *medical judgment* regarding its use in Taylor's specific case that is at issue.<sup>12</sup>

It is precisely because of the central importance of a physician's exercise of professional judgment that this Court 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). This Court noted 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, emphasizing the education, knowledge, and judgment of the physician upon which the patient relies for the patient's treatment. *Id.* at 711-12.<sup>13</sup>

This analysis applies with equal force to the application of the learned intermediary principle to a hospital where a physician, not the

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<sup>12</sup> As noted by the Fifth Circuit Court of Appeals in *Swayze v. McNeil Labs, Inc.*, 807 F.2d 464 (5th Cir. 1987), it is the learned intermediary who must address patient care. The court stated: "[i]t is both impractical and unrealistic to expect drug manufacturers to police individual operating rooms to determine which doctors adequately supervise their surgical teams." *Id.* at 471. Such an intrusion in the physician-patient relationship, which is at the core of the learned intermediary doctrine, would be unwise and potentially harmful to the patient. *Kennedy v. Medtronic, Inc.*, 851 N.E.2d 778, 786 (Ill. App. 2006), *appeal denied*, 221 Ill.2d 640 (2006). "It is well established that a medical device manufacturer is not responsible for the practice of medicine." *Sons v. Medtronic, Inc.*, 915 F. Supp. 2d 776, 783 (W.D. La. 2013).

<sup>13</sup> *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).

hospital, prescribes the use of the da Vinci System to treat 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 and utilizing the product, they are an incorrect statement of law and were properly rejected by the trial court. *Havens, supra*.

(b) Any Theoretical Duty to Warn Harrison Outside the Learned Intermediary Context Would Have Been Owed to Harrison, Not Taylor

Taylor contends that Intuitive owed Harrison an independent duty to warn under the WPLA, and that she was entitled to sue Intuitive for its putative breach of that duty. Pet. at 12-15. This argument was adopted in large measure by the Court of Appeals dissent. Op. at 19-23. Left unaddressed by Taylor or that dissent, however, is how Taylor could invoke a duty owed *to Harrison* and recover damages from Intuitive for its alleged breach, particularly when she has settled her corporate negligence claims against Harrison.

How this alleged duty to warn Harrison creates a cause of action for Taylor is unclear. She seemingly contends that Intuitive had a duty to

warn Harrison about the da Vinci System so that Harrison would have either concluded not to buy it or that Harrison would not have credentialed Dr. Bildsten in its use.<sup>14</sup>

No Washington case has held that a plaintiff like Taylor may invoke the breach of the duty to warn *another* as a second basis for recovery, even if a manufacturer fulfilled its duty to warn that plaintiff.<sup>15</sup> Insofar as Taylor claims that a duty to warn Harrison caused Harrison to take actions that injured her, those claims have been resolved because Taylor *settled* any corporate negligence claims against Harrison. Under cases like *Pedroza v. Bryant*, 101 Wn.2d 226, 677 P.2d 166 (1984) or *Douglas v. Freeman*, 117 Wn.2d 242, 814 P.2d 1160 (1991), a hospital owes a non-delegable duty to a patient to furnish appropriate staff or equipment to provide services to a patient.

Intuitive owes no duty to *Taylor* to assure that Harrison fulfills its non-delegable duty to properly credential its surgeons. Taylor has *no standing* to assert a product liability claim on behalf of Harrison as the product purchaser for Intuitive's warnings to the hospital regarding the da

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<sup>14</sup> That duty argument certainly raises a legal causation question, given the attenuated and speculative causal chain it asks this Court to accept. *Kim v. Budget Rent-a-Car Systems, Inc.*, 143 Wn.2d 190, 204, 15 P.3d 1283 (2001) (legal causation is not met if the connection between the ultimate result and the defendant's act is too remote or insubstantial to impose liability).

<sup>15</sup> Again, the jury found that Intuitive adequately warned Taylor by warning Dr. Bildsten as a learned intermediary.

Vinci System and the credentialing of physicians using it. *Haberman v. Wash. Pub. Power Supply Sys.*, 109 Wn.2d 107, 138, 744 P.2d 1032, 750 P.2d 254 (1987), *dismissed*, 488 U.S. 805 (1988) (“The doctrine of standing prohibits a litigant from raising another’s legal rights.”). Taylor has no claim against Intuitive for any breach of Intuitive’s alleged duty to warn/train Harrison.

(c) Any Alleged Error as to a Duty to Warn Harrison Is Harmless

Any alleged error in this case as to an independent duty to warn Harrison was ultimately harmless, where Dr. Bildsten warned Fred Taylor in detail regarding the risks of robotically-assisted surgery and secured his informed consent to the surgery. Intuitive specifically warned Dr. Bildsten, like all other surgeons who were trained in the use of the da Vinci System, about the risks of robotically-assisted surgery generally and on patients such as Fred Taylor; the jury exonerated Intuitive for any liability for failure to warn Dr. Bildsten. As noted *supra*, Taylor argued the same warnings were due Harrison as were due to Dr. Bildsten.

Even assuming *arguendo* that Intuitive had a duty to “train” Harrison as to how to run its physician credentialing program, failing to instruct the jury on that claim also fails because the jury found Dr. Bildsten was properly trained. If Dr. Bildsten was properly trained, then

any alleged deficiencies in Harrison's credentialing program would have no causal link to Fred Taylor's injuries.

There was no evidence at trial that any different or additional warnings to Harrison would have changed the outcome.<sup>16</sup> Such a theory is mere speculation, and the trial court properly rejected Taylor's proposed jury instructions regarding a failure to warn or train Harrison.

(d) No Evidence in the Record Supports Taylor's Argument that a Warning to Harrison Would Have Prevented Taylor's Injuries

There is no evidence supporting Taylor's proposed instructions on a duty to warn Harrison.<sup>17</sup> 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 purchase a da Vinci System or not to credential Dr. Bildsten personally, or that Intuitive should have

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<sup>16</sup> RCW 4.36.240 (error must affect substantial rights of parties); *State v. Britton*, 27 Wn.2d 336, 341, 178 P.2d 341 (1947) (harmless error is error that "is trivial, or formal, or merely academic; and was not prejudicial to substantial rights of the party assigning it, and in no way affected the final outcome of the case.").

<sup>17</sup> 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). Mere speculation is insufficient to support an instruction; it must be demonstrated by the evidence.

controlled Harrison's credentialing program.<sup>18</sup> Taylor adduced no evidence at trial from any Harrison witness to support this theory that warnings to Harrison would have had any effect on Harrison's purchasing or credentialing decisions.

In sum, this Court should reject Taylor's claims of instructional error in connection with Intuitive's alleged duty to warn/train Harrison.

(2) The Trial Court Properly Applied a Negligence Standard, Instead of Strict Liability, to the Duty to Warn a Learned Intermediary

Taylor claims that strict liability, rather than negligence,<sup>19</sup> governs Intuitive's duty to warn, contending that this Court has somehow "left open" the question of whether a negligence standard applies. Pet. at 15-

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<sup>18</sup> Taylor's implication in the petition at 7 that Intuitive controlled Harrison's committee on robotic surgery is simply false. Intuitive staff discussed credentialing with hospitals, providing information, RP 712-16, but the ultimate credentialing standards of a hospital were "really none of our business." RP 717. *See also*, RP 717-18. Dr. Bildsten was a voting member of Harrison's committee on robotic surgery technology; Intuitive's employees simply attended the meetings and provided information. RP 1035, 1695, 2484-85.

In her petition, Taylor also repeats the false assertion that Intuitive allegedly told Harrison that two proctored cases would suffice for credentialing. Pet. at 7-8. Intuitive stated that a surgeon's learning curve was variable, individual to that surgeon. RP 1983. Intuitive told Harrison how other hospitals set their credentialing requirements, which varied. RP 713-17, 721. Intuitive reminded hospitals that it is a hospital's responsibility for deciding privileges and credentials for its surgeons. Taylor presented *no evidence* at trial from a Harrison employee about what their credentialing standards were "based on," nor any discussion of Harrison's evaluation of the information provided by Intuitive. Intuitive recommended two proctored surgeries or hospital protocol. RP 1036, 1656, 1729.

<sup>19</sup> Taylor has never argued on appeal that substantial evidence did not support the jury's verdict on negligence with regard to the warnings and training given to Dr. Bildsten.

20. The Court of Appeals here *unanimously* disagreed. Washington law provides that negligence, not strict liability, governs the duty to warn a learned intermediary about a medical product.<sup>20</sup> Instruction 11 was based on WPI 110.02.01, and is a correct statement of the negligence standard in a medical device case, CP 5398, as this Court has decided. *Rogers v. Miles Labs., Inc.*, 116 Wn.2d 195, 802 P.2d 1346 (1991).<sup>21</sup>

In addition to discounting *Rogers*' holding as dictum, Taylor tries to avoid *Rogers* on multiple other grounds. Pet. at 17-19. Taylor references the fact that *Rogers* adopted the reasoning of a California case, and then *incorrectly* claims that the adopted reasoning was later "clarified" in California. Pet. at 18. However, the California case that *Rogers* relied upon is still good law in California.<sup>22</sup>

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<sup>20</sup> 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).

<sup>21</sup> The *Rogers* court held that an inadequate failure to warn claim relating to an unavoidably unsafe product is a negligence claim, not strict liability. *Id.* at 207. The Court explicitly resolved the question of whether strict liability or negligence applied; it had to rule on the issue of the standard for inadequate warnings in doing so. *Id.* Moreover, *Rogers* does not state that the plaintiffs alleged only design defect claims and not inadequate warning claims. In fact, after the *Rogers* court explicitly resolved the inadequate warning issue, it determined that the federal court had to resolve the plaintiffs' negligence claims, acknowledging that there was a duty to warn issue remaining. *Id.* The inadequate warning holding in *Rogers* is not dictum. The *Rogers* holding has been good law for 23 years.

<sup>22</sup> In *Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal.3d 987, 1000, 810 P.2d 549, 281 Cal. Rptr. 528 (1991), the California Supreme Court *reaffirmed* the case that Taylor suggests is no longer the law in California, *Brown v. Superior Court*, 44 Cal.3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988).

Seeking another way to discount *Rogers*, Taylor references this Court's decision in *Young v. Key Pharmaceuticals, Inc.*, 130 Wn.2d 160, 168, 922 P.2d 59 (1996) which actually *affirmed Rogers*. Pet. at 17-18. Even the *Young* dissent did not deny that *Rogers* found precisely what the controlling plurality opinion described: "I agree with the majority that *Rogers* indeed considered the question and reached the attributed conclusion." *Id.* at 180-81 (Madsen, J., dissenting). In fact, because both the *Young* majority and the dissent *agreed* that *Rogers* concluded that under comment k inadequate warning claims are negligence claims, that particular conclusion was reached unanimously by the *Young* court.<sup>23</sup>

Washington and federal courts have had little difficulty in holding a negligence standard applies to comment k cases.<sup>24</sup> Moreover, although

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The current state of California law is pertinent not only because the *Rogers* Court adopted its reasoning, but because of the disposition of this case below. Taylor requested that the trial court apply California law to her claims, so that she could take advantage of California's punitive damages regime. After a choice of law analysis, the trial court ruled that California and Washington laws on duty to warn under comment k were not in conflict. If this Court were to change Washington law and retroactively apply a strict liability standard to the duty to warn under comment k, on remand, Taylor would have to choose between seeking punitive damages under California law, and thus apply California's negligence standard to the duty to warn (on which the jury already found Intuitive not liable), or to forego her claim for punitive damages and apply Washington's new strict liability standard.

<sup>23</sup> In a plurality opinion, the holding of the court is the position of the justices concurring on the narrowest grounds, *Davidson v. Hensen*, 135 Wn.2d 112, 128, 954 P.2d 1327 (1998), a point not addressed by Taylor.

<sup>24</sup> Division I in *Estate of La Montagne v. Bristol-Meyers Squibb*, 127 Wn. App. 335, 343-44, 111 P.3d 857 (2005) applied the rule in *Rogers* and *Young*. Division I reaffirmed in *Payne v. Paugh*, 190 Wn. App. 383, 408-13, 360 P.3d 39 (2015) that the

*Rogers, Young*, and other cases have long interpreted the WPLA to apply a negligence standard in duty to warn cases under comment k, the Legislature has taken no steps to override such an interpretation, acquiescing in that interpretation of its statute.<sup>25</sup>

This Court should adhere to that principle.<sup>26</sup>

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negligence standard of comment k applies and an instruction based on WPI 110.02.01 was proper in a design defect case brought against the manufacturer of a medical device. The negligence standard has also been recognized by federal courts in Washington. *E.g.*, *Laisure-Radke v. Par Pharmaceutical, Inc.*, 426 F. Supp. 2d 1163, 1171 (W.D. Wash. 2006); *Luttrell v. Novartis Pharmaceuticals Corp.*, 894 F. Supp. 2d 1324, 1342 (E.D. Wash. 2012), *aff'd*, 555 F. App'x 710 (9th Cir. 2014).

<sup>25</sup> The Legislature is presumed to be aware of judicial interpretations not only of its own enactments, but also the common law. *City of Federal Way v. Koenig*, 167 Wn.2d 341, 350-51, 217 P.3d 1172 (2009). The Legislature's failure to change the common law or to amend the WPLA following a judicial decision interpreting it indicates legislative acquiescence in that decision. *Soproni v. Polygon Apartment Partners*, 137 Wn.2d 319, 327 n.3, 971 P.2d 500, 512 (1999) (ruling that Legislature acquiesced in Court's interpretation of design defect cases under the WPLA).

Taylor makes the strange argument that *Rogers* is not controlling because a case-by-case analysis of whether a product is unavoidably unsafe should be applied to the da Vinci System. Pet. at 19-20. But Taylor's argument is perplexing precisely because this Court has already ruled that comment k is applicable to medical products, including medical devices like the da Vinci System. *Terhune*, 90 Wn.2d at 17 (intrauterine contraceptive device). *See also*, *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 (9<sup>th</sup> Cir. 2002) (surgically implanted spinal plate).

Taylor neglects to reference *Terhune* on this point, and the case Taylor cited in support of her contention, *Guzman v. Amvac Chemical Corp.*, 141 Wn.2d 493, 7 P.3d 795 (2005), does not support her position. There, this Court specifically noted that comment k is "especially applicable to medical devices." *Id.* at 508. It recognized a "blanket exemption" for medical products. *Id.* at 511. Contrary to Taylor's argument, there is no need for a case-by-case analysis of whether comment k applies to a medical device like a robotic surgical system. The da Vinci System is an unavoidably unsafe product under comment k.

<sup>26</sup> Were this Court to alter the common law burden of proof in comment k cases, as Taylor invites the Court to do, it should do so prospectively only in any event. While this Court generally applies the overruling of a common law principle retrospectively as well as prospectively, *Lunsford v. Saberhagen Holdings, Inc.*, 166 Wn.2d 264, 270-71,

(3) Dr. Bildsten's Actions Were the Superseding Cause of Taylor's Injury as a Matter of Law

This Court can affirm on alternate grounds not addressed in the Court of Appeals' opinion: the trial court should have ruled that any alleged fault on Intuitive's part was not the legal cause of Fred Taylor's injuries.<sup>27</sup> Where a physician ignores a manufacturer's warnings regarding the use of a medical instrument and 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. *Campbell v. ITE Imperial Corp.*, 107 Wn.2d 807, 812-14, 733 P.2d 969 (1987); *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).

In the specific context of warnings to learned intermediaries, the physician's conduct may break the causal chain a matter of law. *Washington State Physicians Ins. Exch. & Ass'n v. Fisons Corp.*, 122

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208 P.3d 1092 (2009), this Court reserves to itself the choice of whether to apply a new common law rule prospectively only in the appropriate circumstances. *Id.* at 278-79.

In *McDevitt v. Harborview Medical Center*, 179 Wn.2d 59, 316 P.3d 469 (2013), this Court decided to apply the principle of presuit notification of medical negligence claims against government defendants prospectively only because to apply the rule retroactively would engender substantially inequitable results. *Id.* at 76. A similarly inequitable result should be avoided here.

<sup>27</sup> 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). Intuitive argued legal causation in its motion for summary judgment and its trial brief. CP 114-16, 4311-18. This was raised in the answer to the petition for review at 7 n.8.

Wn.2d 299, 315, 858 P.2d 1054 (1993). The causal chain is broken when a product user, like Dr. Bildsten here, “is aware of a risk and chooses to disregard it.” *Baughn v. Honda Motor Co.*, 107 Wn.2d 127, 144, 727 P.2d 655 (1986). *See also, LaMontagne*, 127 Wn. App. at 351.<sup>28</sup>

Dr. Bildsten was negligent in selecting Fred Taylor for robotically-assisted surgery and was negligent in performing that surgery, as Taylor’s own urological expert, Dr. S. Adam Ramin, testified. CP 905-06, 977. Despite Intuitive’s ample warnings about patient selection, Dr. Bildsten exercised his medical judgment and conducted the surgery on an obese patient with a complex medical history. RP 1134. The difficulties Dr. Bildsten experienced during the surgery were directly attributable to his decision to choose Fred Taylor as a candidate despite Intuitive’s adequate warnings. RP 982, 1072, 1080, 1143.

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, 955. If surgeons pressed Intuitive for a precise number of cases in the learning

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<sup>28</sup> Failure of a physician to heed manufacturer warnings about a product’s use has been held to break the causal chain in other jurisdictions. *See, e.g., 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); *Wheat v. Sofamor, S.N.C.*, 46 F. Supp. 2d 1351, 1363 (N.D. Ga 1999).

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.

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. RP 905-06.

This Court should affirm the trial court’s judgment on the grounds that the trial court should have granted Intuitive’s CR 50 motion.

(4) Other Issues Raised by Taylor

There are three remaining issues on which this Court granted review: (1) whether the trial court properly exercised its discretion to

reject exhibit 304; (2) whether a superseding cause instruction was appropriate on the facts of this case; and (3) whether the jury was properly instructed on damages mitigation. Due to space constraints, Intuitive must rest on its Court of Appeals briefing, located in Brief of Respondents at 38-50. Should this Court reach these issues, Intuitive respectfully urges this Court to carefully consider those arguments.

D. CONCLUSION

The Court of Appeals correctly addressed the issues here. 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 Court of Appeals and the judgment on the jury's verdict. Costs on appeal should be awarded to Intuitive.

DATED this ~~21~~<sup>22</sup> day of April, 2016.

Respectfully submitted,



Philip A. Talmadge, WSBA #6973  
Sidney Tribe, WSBA #33160  
Talmadge/Fitzpatrick/Tribe  
2775 Harbor Avenue SW  
Third Floor, Suite C  
Seattle, WA 98126  
(206) 574-6661

Jeffrey R. Johnson, WSBA #11082  
Gregory P. Thatcher, WSBA #40902  
Scheer & Zehnder, LLP  
701 Pike Street, Suite 2200  
Seattle, WA 98101  
(206) 262-1200

Allen J. Ruby, pro hac vice  
Skadden, Arps, Slate, Mcagher &  
Flom LLP & Affiliates  
525 University Avenue, Suite 1100  
Palo Alto, CA 94301  
(650) 470-4590  
Attorneys for Respondent Intuitive  
Surgical, Inc.

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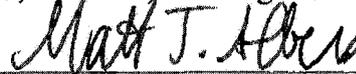
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Kenneth W. Masters Shelby Lemmel Masters Law Group P.L.L.C. 241 Madison Avenue N. Bainbridge Island, WA 98110-1811	Allen J. Ruby Skadden, Arps, Slate, Meagher & Flom 525 University Avenue Palo Alto, CA 94301
Karen M. Firstenberg Morris Polich & Purdy LLP 1055 W. 7 <sup>th</sup> Street, Suite 2400 Los Angeles, CA 90017	Catherine B. Stevens Quinn Emanuel 51 Madison Avenue New York, NY 10010
Jeffrey R. Johnson Tami Baldwin Scheer & Zehnder 701 Pike Street, Suite 2200 Seattle, WA 98101-2358	Barbara Allan Shickich Brett S. Durbin Riddell Williams PS 1001 4 <sup>th</sup> Ave Ste 4500 Seattle, WA 98154-1065
Hugh F. Young, Jr. Product Liability Advisory Council, Inc. 1850 Centennial Park Drive Suite 510 Reston, VA 20191	Christopher W. Tompkins Betts, Patterson & Mines, P.S. One Convention Place 701 Pike Street, Suite 1400 Seattle, WA 98101-3927
James M. Beck Reed Smith LLP Three Logan Square Suite 3100 1717 Arch Street Philadelphia, PA 19103-7301	

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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: April 21, 2016, at Seattle, Washington.



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Matt J. Albers, Paralegal  
Talmadge/Fitzpatrick/Tribe

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- bshickich@riddellwilliams.com

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Sender Name: Matt Albers - Email: matt@tal-fitzlaw.com

**Filing on Behalf of:** Sidney Charlotte Tribe - Email: sidney@tal-fitzlaw.com (Alternate Email: matt@tal-fitzlaw.com)

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Third Floor Ste C

Seattle, WA, 98126

Phone: (206) 574-6661

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