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No. 92210-1

IN THE SUPREME COURT FOR  
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,

Petitioner,

v.

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

Respondent

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PETITIONER'S SUPPLEMENTAL BRIEF

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



ORIGINAL

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## INTRODUCTION

Throughout this case, ISI has touted the virtues of the da Vinci robot, an unavoidably unsafe medical device used in the prostatectomy operation that seriously injured Fred Taylor. But with great innovation comes greater responsibility. There, ISI fell short.

As discussed fully below, ISI told Harrison that two proctored procedures was sufficient to obtain surgical proficiency without any medical support, while also failing to disclose studies showing the learning curve for robotic prostatectomy is between 150 to 250 surgeries. Harrison plainly needed adequate warnings and instructions to keep Fred safe, but the trial court refused to instruct the jury that ISI had a duty to warn Harrison. Harrison purchased the robot, credentialed the surgeon to use it, and obtained Fred's informed consent, so was entitled to warnings under the WPLA, or alternatively as a learned intermediary.

The trial court also erroneously declined to instruct the jury on strict liability. The rule is strict liability, and the exception applies only when a product is accompanied by proper warnings. Thus, the exception cannot apply to an inadequate-warning claim.

This Court should reverse and remand for trial with proper instructions.

## STATEMENT OF THE CASE

### A. Overview.

The da Vinci robot is quite possibly the most complex medical device on the market. BA 5. It allows surgeons to perform laparoscopic surgery at a "viewing console" ten feet away from the patient, using what are essentially very sophisticated joysticks to control robotic arms holding surgical instruments that are manipulated inside the patient's body. *Id.* The FDA cleared the da Vinci for prostatectomy in May 2001.<sup>1</sup> Ex 502, RP 488.

Dr. Scott Bildsten completed ISI training in July 2008, and performed two proctored procedures on the 28<sup>th</sup> and 29<sup>th</sup>. BA 27-28. Following ISI's recommendations, Harrison credentialed Bildsten, who operated on Fred Taylor just five or six weeks after finishing ISI training. BA 1, 27. After proceeding robotically for 8 hours, Bildsten converted to an open procedure, lasting another five hours. BA 28.

The surgical complications and their aftermath are discussed in full at BA 28-33. It is undisputed that Fred suffered life-altering injuries, including chronic pain, incontinence, lost mobility, and lost

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<sup>1</sup> The FDA did not "approve" the da Vinci robot, but "cleared" it for prostatectomy, in a process that is far simpler, faster, and cheaper than obtaining approval. RP 469, 491, 2709, 2712, 2723, 2741. Clinical trials do not need to be as robust and there is "a lot less oversight." RP 491. ISI nonetheless marketed the robot as FDA approved. BA 17-18.

mental function. *Id.* The robotic surgery “destroyed [Fred’s] quality of life.” RP 2093. The parties dispute whether the surgery hastened his death four years later. RP 1451.

**B. Without any medical literature to support its claim, ISI representatives on Harrison’s credentialing committee recommended that two proctored procedures were sufficient to credential a doctor to use the robot.**

Credentialing is the process by which hospitals authorize surgeons to perform specific procedures in the hospital, in this case robotic prostatectomy. RP 956-57. Three ISI employees sat on the steering committee that recommended the credentialing requirements Harrison adopted. BA 25. ISI provided credentialing examples from other local hospitals purchasing robots, claiming the area average was two proctored procedures. RP 714-16. ISI also provided written materials recommending that two proctored procedures were sufficient to “ensure success in becoming a proficient robotic surgeon.” BA 25-26; Ex 511; RP 573, 711-12, 716, 840, 1036. No medical literature supports that claim. BA 26.

**C. ISI did not tell Harrison that it had dramatically reduced the training program used to obtain FDA clearance.**

After obtaining FDA clearance, but before selling a robot to Harrison, ISI reduced its Phase I-training 70-question test to a 10-question test that is “impossible to fail.” BA 13. ISI shortened Phase

2 off-site training from three days to one, where only one member of the surgical team trains on the console. BA 13-14. ISI did not use an "objective standard" to evaluate trainees or determine "mastery," despite promises to the FDA. *Id.*

It is unclear what, if anything, ISI did to evaluate surgeons in the Phase 3 dry-run, and ISI had little or no involvement in Phase 4, despite promises to the FDA. BA 14-15. Thus, when ISI sold Harrison a robot, it was foreseeable that ISI had not adequately assessed surgeons graduating from its training program to determine their readiness to operate using the robot. BA 15.

**D. ISI never disclosed to Harrison numerous articles, some published by its own consultants, showing that the learning curve was as high as 250 robotic prostatectomies.**

ISI instructed sales reps to tell potential purchasers that "[t]here is a fairly short learning curve," referring to the number of surgeries required to achieve "basic competency" on the robot. BA 19-20 (citing RP 546; Ex 14, p. 2; CP 5364-65). ISI claims that it "provided extensive materials" to purchasers, but never gave the following articles to Harrison (or Bildsten).<sup>2</sup> Answer at 4; BA 24.

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<sup>2</sup> Despite telling the FDA that surgeons should "meet basic and advanced laparoscopic requirements" (RP 1915; Ex 20, p. 55) ISI could not recall sharing this with Harrison (or any hospital). BA 15-16. (cont'd. next page)

The only study using “margin rates” – cancer removal – to measure the learning curve, showed that robotic-surgery results were not comparable to open-surgery results until 150 robotic prostatectomies. BA 21-22. “Surgeon comfort and confidence” was not comparable “until 250 robotic procedures.” *Id.*; RP 804, 1949-50.

These results are consistent with a 2010 article in the New England Journal of Medicine, concluding that it took between 150 to 250 robotic procedures to become “adept.” BA 22; RP 984-85. Similar articles predating Fred Taylor’s surgery discuss the steep learning curve in robotic procedures. BA 22. Still another article directly questions ISI’s website claims, opining that the learning curve is at least 100 procedures, an insurmountable patient volume for many open surgeons. BA 22-23.

When the learning curve does not account for margin rates, it is much lower – though not as low as the two proctored procedures ISI recommended to Harrison. A former ISI consultant and highly respected leader in minimally invasive robotic surgery led an expert

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(cont’d. footnote) There is also no indication that ISI told Harrison that margin rates – the amount of cancer left behind after prostatectomy – are up to 19% higher in robotic prostatectomy, or that it can take a surgeon thousands of robotic prostatectomies to achieve margin rates comparable to an open procedure. BA 18-19. Nor did ISI tell Harrison about studies showing that robotic prostatectomy can increase some risks associated with robotic prostatectomy. BA 19-20.

surgical team whose learning curve was 20 to 25 cases. BA 23-24. This is consistent with ISI's decision to include only doctors who have completed at least 20 robotic procedures in the "surgeon locator" feature on its website. BA 24. Another expert surgical team led by another ISI consultant had a learning curve of 8 to 12 procedures when the learning curve accounted only for surgical time. *Id.* But they had a 22% complication rate, and 30% to 35% margin rates. *Id.*

The trial court declined to instruct the jury that ISI had a duty to warn Harrison. The appellate court affirmed in a 2-1 decision. This Court should reverse and remand for trial with proper instructions.

### **ARGUMENT**

**A. The trial court erroneously refused to instruct the jury that ISI had a duty to warn Harrison, the product purchaser.**

**1. ISI has a WPLA duty to warn Harrison.**

As it must, ISI acknowledges that it has a duty to provide "adequate warnings or instructions" "with the product" – the da Vinci robot. RCW 7.72.030(1)(b). ISI can provide warnings "with the" robot, only by warning Harrison, which purchased the robot, credentialed Bildsten (and others), and obtained Fred's informed consent. Thus, under the WPLA's plain language, the trial court erred in failing to instruct the jury that ISI had to warn and instruct Harrison.

ISI does not address the WPLA's plain language, claiming not to understand the "precise contour" of any duty to Harrison, and questioning the causal connection between any duty to warn and Fred's injuries. Answer at 10. ISI advised Harrison that two proctored procedures were sufficient, while omitting (a) the lack of medical literature supporting its claim; (b) its recommendation to the FDA that robotic surgeons have basic and advanced laparoscopic skills; and (c) the articles and studies finding that the learning curve was up to 250 procedures. ISI's failure to warn Harrison led it to credential Bildsten to use the robot, harming Fred.

ISI claims that Taylor lacks "standing," but there is no question that an injured party has standing. Answer at 11. And it is irrelevant that Taylor settled with Harrison, where the issue is that Fred was injured by ISI's failure to warn Harrison, leading to woefully inadequate credentialing requirements. *Id.*

ISI's "prudential" arguments are equally unavailing. Answer at 12-14. ISI asserts a lack of evidence supporting a duty-to-warn instruction, ignoring that Harrison purchased the robot, credentialed Bildsten, and obtained Fred's informed consent. And there is substantial evidence that ISI influenced Harrison's decision to buy the robot and its adoption of credentialing requirements. *Supra*,

Statement of the Case § B. ISI's harmless error argument fails for the same reasons – the robot reached Fred only through Harrison. Answer at 13-14. And ISI's assertion that the proposed instructions are incorrect is equally unavailing, where providing adequate warnings and instructions includes a duty to train, which ISI assumed in any event. *Compare* Answer at 13 *with* Reply at 2-3.

**2. The learned intermediary doctrine does not address, much less govern, whether a manufacturer owes a hospital a duty to warn.**

At odds with the WPLA's plain language, ISI argues, and the appellate majority held, that under the learned intermediary doctrine, ISI has a duty to warn Bildsten only, not Harrison. But the learned intermediary doctrine does not apply, where it provides only that a manufacturer need not warn patients directly if it adequately warns prescribing doctors. *Terhune v. A. H. Robins Co.*, 90 Wn.2d 9, 12-14, 577 P.2d 975 (1978) (discussing RESTATEMENT (SECOND) OF TORTS § 402A (1965) ("§ 402A"). The doctrine does not address third-party hospitals like Harrison, who purchase a dangerous medical device and credential physicians to use it on patients the hospital owes an independent duty of care. And limiting a manufacturer's duties as ISI suggests would frustrate the purpose of the doctrine by decreasing patient safety. This Court should hold that

the learned intermediary doctrine does not change ISI's WPLA duty to warn Harrison, and reverse for trial with proper instructions.

The learned intermediary doctrine acknowledges that manufacturers have a duty to warn patients, but shifts that duty to prescribing doctors, rationalizing that doctors act as gatekeepers standing in the manufacturer's place vis-à-vis the patient. *Terhune*, 90 Wn.2d at 14. The underlying assumptions are that doctors learn about the qualities and characteristics of the product, have superior knowledge of their patients, and exercise independent medical judgment. *Id.* The patient in turn relies primarily on his doctor, not whatever warnings the manufacturer may have included. *Id.*

Since these underlying assumptions do not apply here, no legal basis exists for applying the learned intermediary doctrine to cut off ISI's WPLA duty to warn Harrison. Dissent at 21. Doctors are not gatekeepers standing between manufacturers and credentialing hospitals – they have no duty to warn hospitals, and are not in a superior position to do so. *Id.* Harrison did not look to Bildsten for information about the robot, but to ISI, which sold itself as a “partner,” working closely with Harrison on credentialing. BA 16-17. ISI was well situated to give Harrison warnings “with the” robot.

Despite these distinctions between doctors and credentialing hospitals, the appellate court majority incorrectly held it irrelevant that Harrison purchased the robot, stating the “learned intermediary doctrine is not concerned with who pays for the product or who retains possession of the product.” Majority at 11. But Harrison is not comparable to a patient who ultimately pays for a drug or device he can acquire only through his doctor. Harrison is more comparable to the doctor in that it owes patients an independent duty of care, and exercises independent medical judgment regarding credentialing requirements. Again, the robot could not have reached Fred Taylor without Harrison's purchase and credential.

Using the learned intermediary doctrine to cut off the WPLA duty to warn Harrison also decreases patient safety, undermining the recognized goal of the learned intermediary doctrine. *Terhune*, 90 Wn.2d at 14. Without adequate warnings, Harrison could not safely establish credentialing requirements – the minimum threshold for performing robotic surgeries at Harrison. And ISI's failure to warn is exacerbated by its participation in the credentialing process, including its unfounded recommendation that two proctored procedures were sufficient. Adequate warnings are implicated even in Harrison's decision to purchase the robot, particularly where many

surgeons lack the patient volume required to ever become proficient robotic surgeons. *Supra*, Statement of the Case § D.

Even ISI agrees that Harrison owes an independent duty of care to its patients. Answer at 11.<sup>3</sup> Indeed, Harrison independently obtained Fred's informed consent. CP 250. Adequate warnings are vital to a hospital's ability to satisfy its duties to its patients.

**3. If this Court holds that the learned intermediary doctrine applies, then it should hold that Harrison is a second learned intermediary, where Harrison stands between the da Vinci robot and the patients it can harm.**

If this Court is convinced that manufacturers like ISI have to warn only learned intermediaries, then the Court should hold that Harrison is a learned intermediary, consistent with the doctrine's underlying purpose of ensuring that adequate warnings and instructions get to those most able to keep patients safe.<sup>4</sup> *Terhune*, 90 Wn.2d at 14. The appellate court majority incorrectly rejected this argument, holding that the "learned intermediary doctrine singles out the physician because it is he who finally controls the dispensing of

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<sup>3</sup> See, e.g., *Douglas v. Freeman*, 117 Wn.2d 242, 248, 814 P.2d 1160 (1991); *Pedroza v. Bryant*, 101 Wn.2d 226, 236, 677 P.2d 166 (1984).

<sup>4</sup> Since this is a question of first impression in this State, Taylor discusses foreign cases at BA 46-47; Reply 10-11.

the product.” Majority at 12 (quoting *Terhune*, 90 Wn.2d at 16). That is not a rational basis for requiring ISI to warn only Bildsten, where Harrison too controlled “the dispensing” of the robot through its credentialing process.

The majority’s (and ISI’s) comparison to *McKee* is similarly unpersuasive. Majority at 12-14; Answer at 9. In *McKee*, this Court declined to extend the learned intermediary doctrine to pharmacists, as they are not responsible for patient safety. *McKee*, 113 Wn.2d 701, 711-12 782 P.2d 1045(1989). But Harrison is responsible for patient safety, where it purchased an unavoidably unsafe medical device, obtained Fred’s informed consent, established credentialing requirements, and credentialed Bildsten. Credentialing surgeons to use a dangerous medical device ensures patient safety.

Unlike the pharmacist in *McKee*, Harrison exercised independent medical judgment. Majority at 12-14; Answer at 9-10. Harrison does not “simply enable[] a medical product to get to a patient” – it decides who qualifies to safely operate the robot – a decision vitally important to patient safety. *Id.*

**B. This matter is governed by a strict liability standard.**

The rule in Washington is that strict liability applies to product defect claims based on inadequate warnings. *Ayers v. Johnson &*

*Johnson Baby Prods. Co.*, 117 Wn.2d 747, 762-63, 818 P.2d 1337 (1992); § 402A. Comment *k* to § 402A creates a narrow exception to that rule, applying a negligence standard where an unavoidably unsafe product is “properly prepared and marketed,” and “accompanied by proper directions and warning”:

*k. Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. . . . **Such a product, properly prepared, and accompanied by proper directions and warning, is not defective**, nor is it *unreasonably* dangerous. . . . The seller of such products, **again with the qualification that they are properly prepared and marketed, and proper warning is given**, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use . . .

§ 402A, cmt. *k* (bold emphases added). Since “proper directions and warning” are a predicate to comment *k*’s application, comment *k* cannot apply to inadequate-warning claims:

By its express terms, comment *k* protection from strict liability is not available to a manufacturer who fails to adequately warn. Comment *k* does not state whether the adequacy of its required warning is measured under a negligence or strict liability standard. This is so because the comment is intended to apply to a claim of design defect and assumes that adequate warnings were given. Adequate warnings are a predicate to application of comment *k*, but the adequacy of those warnings is not governed by comment *k*. Rather, warnings are measured under the rule set forth in § 402A, and the exception to that rule, outlined in comment *k*, applies only after the trier of fact determines whether the known or knowable risk was disclosed.

*Rogers v. Miles Labs., Inc.*, 116 Wn.2d 195, 203-04 (Madsen, J., dissenting), 802 P.2d 1346 (1991). This Court should clarify *Rogers*, *supra*, and *Young v. Key Pharmaceuticals*, 130 Wn.2d 160, 168-71, 922 P.2d 59 (1996) in a manner consistent with comment *k*'s plain language.

In *Rogers*, this Court held that blood and blood products fell under comment *k*'s narrow exception.<sup>5</sup> 116 Wn.2d at 204. Although *Rogers* did not involve an inadequate-warning claim, this Court, in *dicta*, posed the hypothetical that to determine whether strict liability applies, a court must first resolve whether the manufacturer met its duty to warn under comment *k*. 116 Wn.2d at 207. Rejecting that hypothetical, the Court adopted the reasoning articulated in *Brown v. Superior Court*, a California case purporting to hold that comment *k* "is based on negligence," despite its plain language. *Id.* (citing 44 Cal.3d 1049, 751 P.2d 470 (1988)).

Relying heavily on the *Rogers dicta* and *Brown*, this Court's 4-4 *Young* decision held (without a constitutional majority) that comment *k* applies a negligence standard to inadequate warning

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<sup>5</sup> The WPLA excludes blood and blood products from coverage, RCW 7.72.010(3) – (5).

claims.<sup>6</sup> 130 Wn.2d at 168-71. Chief Justice Madsen's dissent, joined by three other Justices, disagreed with the plurality's refusal to apply strict liability. *Id.* at 204 (Madsen, J., dissenting). Faulting the plurality's reliance on **Rogers**, the dissent explains: (1) **Rogers** "departed from Washington precedent regarding failure to warn"; (2) **Rogers** is founded on **Brown**, "which the California Court subsequently explained did not hold that comment *k* alters the § 402A rule of strict liability when the claim is failure to adequately warn"; (3) **Rogers** is easily distinguishable (from **Young** and this matter) as it did not involve inadequate-warning claims; and (4) the portion of **Rogers** applying comment *k* to inadequate-warning claims is *dicta*, so "is simply not binding authority." *Id.* at 203-04 (Madsen, J., dissenting).

The **Rogers dicta** is also wrong. Applying comment *k* to inadequate-warning claims ignores its plain language requiring proper instructions and warnings. This *dicta* is contrary to numerous Washington cases holding that strict liability applies to inadequate warning claims. See **Little v. PPG Industries, Inc.**, 92 Wn.2d 118,

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<sup>6</sup> **Young** "has limited precedential value and is not binding." **Young**, 130 Wn.2d 160; **Lauer v. Pierce Cnty.**, 173 Wn.2d 242, 258, 267 P.3d 988 (2011) (quoting **In re Pers. Restraint of Isadore**, 151 Wn.2d 294, 302, 88 P.3d 390 (2004)).

594 P.2d 911 (1979). And this *dicta* is contrary to this Court's warning: "[b]ecause comment *k* was not expressly provided for in the WPLA, we must be sparing in its application lest we defeat the letter or policy of the WPLA." ***Ruiz-Guzman v. Amvac Chem. Corp.***, 141 Wn.2d 493, 505, 7 P.3d 795 (2000).<sup>7</sup>

**C. This Court should hold in the alternative that comment *k* applies only on a case-by-case basis.**

Alternatively, this Court should hold that comment *k* does not apply unless and until the jury finds that at the time of Fred's procedure, the da Vinci robot's social utility greatly outweighed its inherent risk. Regarding pesticides, this Court held that comment *k* applies only where the manufacturer proves: (1) that the product's utility greatly outweighs its risk; (2) that the risk is known; (3) that there is no other way to achieve the product's benefit; and (4) that there is no known way to avoid the risk. ***Ruiz-Guzman***, 141 Wn.2d at 509-10. While this Court declined to address whether the product-by-product approach should also apply to prescription drugs (a question that was not properly before the Court on certification) the

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<sup>7</sup> This Court should overrule ***Estate of LaMontagne v. Bristol Meyers Squibb***, applying a negligence standard to inadequate-warning claims. 127 Wn. App. 335, 343, 111 P.3d 857 (2005). ***LaMontagne*** misplaces reliance on ***Ruiz-Guzman*** and fails to address ***Young*** and ***Rogers***.

Court noted that a blanket exemption for prescription drugs is “incongruent with the social utility reasoning in *Terhune* and *Rogers*.” *Id.* The same is true for medical devices.

**D. The trial court erred in prohibiting any evidence to rebut the false assertion that Fred Taylor’s procedure was the only incident at Harrison.**

Though the trial court had reserved ruling on Josette’s motion *in limine* to exclude evidence of other robotic surgical outcomes at Harrison (CP 2628), ISI’s O’Connor gave testimony strongly suggesting that Fred’s complications were unique and caused solely by Bildsten. That is false, but the trial court refused to allow Josette to put on contradictory evidence, instead giving a curative instruction. The damage could not be undone. This Court should reverse.

O’Connor testified on direct and cross that he had concerns about the robotics-program launch at Harrison, but said nothing, per ISI instructions. BA 62; RP 731-33, 795-96, 811; Ex 116. When asked about those concerns on re-cross, O’Conner did not stick to the robotics-program launch, but broadly stated that Harrison’s robotics program was a success “outside this incident,” that Bildsten was the only surgeon who quit the program, and that Harrison was purchasing another robot. RP 855. This falsely suggested that Fred’s procedure was an outlier and that Bildsten’s performance was

unique, when a number of robotic surgeons at Harrison experienced the same complications as in Fred's procedure. Josette's proposed exhibit 304; RP 1416-18; CP 4482.

The appellate court affirmed the trial court's ruling that it would have been confusing and unduly prejudicial to admit Josette's proposed exhibit 304. Unpub. Op. at 18. But the court ignored that Josette was seeking any opportunity to rebut O'Connor's testimony – exhibit 304 or otherwise. RP 1423-24, 1426-27.

An instruction could not cure the prejudice caused by O'Conner's testimony, which was "inherently prejudicial and of such a nature as to be most likely to impress itself upon the minds of the jurors." *State v. Suleski*, 67 Wn.2d 45, 51, 406 P.2d 613 (1965). Prohibiting contradictory evidence deprived Josette of any meaningful opportunity to argue her case theory that ISI's inadequate warnings were a cause of Fred's injuries. RP 1418.

**E. Two additional instructions were erroneous.**

**1. The court erred in giving a superseding cause instruction.**

The trial court erred in giving a superseding cause instruction, where: (1) the intervening act alleged – Bildsten's negligence – did not create a different type of harm than otherwise would have resulted from the negligence alleged – ISI's failures to warn Bildsten

and Harrison; and (2) Bildsten's negligence was not extraordinary and did not operate independently of ISI's failures to warn. See **Campbell v. ITE Imperial Corp.**, 107 Wn.2d 807, 812-13, 733 P.2d 969 (1987). The harm caused by Bildsten's negligence and the harm resulting from the failure to warn Harrison is identical: Fred's catastrophic injuries. **Campbell**, 107 Wn.2d at 815. And Bildsten's intervening negligence "did not operate independently of the situation created by [ISI's] failure to warn" Harrison: inadequate credentialing requirements that allowed doctors, like Bildsten, to operate independently before they were ready to do so. *Id.*

In short, with adequate warnings, Harrison likely would not have credentialed Bildsten, who would have then been unable to operate on Fred using the robot. Bildsten's negligence cannot be a superseding cause.

## **2. The mitigation instruction was improper.**

The trial court erroneously instructed the jury not to include in its total damages award any amount Fred could have avoided by exercising ordinary care (Instruction 20), while also instructing the jury to account for any failure to mitigate by assigning a percentage of fault to Fred (verdict form). CP 5323, 5407, 5629. Taking Instruction 20 and the verdict form together, the court instructed the

jury to reduce damages twice – first by omitting off the top any damages Fred could have avoided by exercising ordinary care (Instruction 20), and again by allocating fault to Fred for any failure to mitigate (verdict form). CP 5323, 5407, 5629. That is error.

Allocating fault to Fred is also an improper way to account for any failure to mitigate. CP 5407. Failure-to-mitigate instructions are appropriate only when the defendant can meet its burden to segregate the damages resulting from the failure to mitigate. WPI 33.02 (attached). Allowing the jury to allocate a percentage of fault to Fred impermissibly reduced ISI's burden. CP 5323, 5407.

### **CONCLUSION**

With proper warnings and instructions, Harrison could have kept Fred Taylor safe. This Court should reverse and remand.

RESPECTFULLY SUBMITTED this 11th day of April, 2016.

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

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

**CERTIFICATE OF SERVICE BY MAIL AND/OR EMAIL**

I certify that I caused to be emailed/ or mailed a copy of the foregoing **PETITIONER'S SUPPLEMENTAL BRIEF** this 11th day of April, 2016, to the following counsel of record at the following addresses:

Co-counsel for Appellants

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

U.S. Mail  
 E-Mail  
 Facsimile

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

U.S. Mail  
 E-Mail  
 Facsimile

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

U.S. Mail  
 E-Mail  
 Facsimile

Counsel for Respondent

Phillip Talmadge  
Talmadge/Fitzpatrick  
2775 Harbor Ave SW  
Seattle, WA 98126

U.S. Mail  
 E-Mail  
 Facsimile

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

U.S. Mail  
 E-Mail  
 Facsimile

Allen J. Ruby  
Skadden, Arps, Slate, Meagher & Flom

U.S. Mail  
 E-Mail

525 University Ave.  
Palo Alto, CA 94301

Facsimile

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

U.S. Mail  
 E-Mail  
 Facsimile

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

U.S. Mail  
 E-Mail  
 Facsimile

  
\_\_\_\_\_  
Kenneth W. Masters, WSBA 22278  
Attorney for Petitioner

## RCW 7.72.010

### Definitions.

For the purposes of this chapter, unless the context clearly indicates to the contrary:

(1) Product seller. "Product seller" means any person or entity that is engaged in the business of selling products, whether the sale is for resale, or for use or consumption. The term includes a manufacturer, wholesaler, distributor, or retailer of the relevant product. The term also includes a party who is in the business of leasing or bailing such products. The term "product seller" does not include:

(a) A seller of real property, unless that person is engaged in the mass production and sale of standardized dwellings or is otherwise a product seller;

(b) A provider of professional services who utilizes or sells products within the legally authorized scope of the professional practice of the provider;

(c) A commercial seller of used products who resells a product after use by a consumer or other product user: PROVIDED, That when it is resold, the used product is in essentially the same condition as when it was acquired for resale;

(d) A finance lessor who is not otherwise a product seller. A "finance lessor" is one who acts in a financial capacity, who is not a manufacturer, wholesaler, distributor, or retailer, and who leases a product without having a reasonable opportunity to inspect and discover defects in the product, under a lease arrangement in which the selection, possession, maintenance, and operation of the product are controlled by a person other than the lessor; and

(e) A licensed pharmacist who dispenses a prescription product manufactured by a commercial manufacturer pursuant to a prescription issued by a licensed prescribing practitioner if the claim against the pharmacist is based upon strict liability in tort or the implied warranty provisions under the uniform commercial code, Title 62A RCW, and if the pharmacist complies with recordkeeping requirements pursuant to chapters 18.64, 69.41, and 69.50 RCW, and related administrative rules as provided in RCW 7.72.040. Nothing in this subsection (1)(e) affects a pharmacist's liability under RCW 7.72.040(1).

(2) Manufacturer. "Manufacturer" includes a product seller who designs, produces, makes, fabricates, constructs, or remanufactures the relevant product or component part of a product before its sale to a user or consumer. The term also includes a product seller or entity not otherwise a manufacturer that holds itself out as a manufacturer.

A product seller acting primarily as a wholesaler, distributor, or retailer of a product may be a "manufacturer" but only to the extent that it designs, produces, makes, fabricates, constructs, or remanufactures the product for its sale. A product seller who performs minor assembly of a product in accordance with the instructions of the manufacturer shall not be deemed a manufacturer. A product seller that did not participate in the design of a product and that constructed the product in accordance with the design specifications of the claimant or another product seller shall not be deemed a manufacturer for the purposes of RCW 7.72.030(1)(a).

(3) Product. "Product" means any object possessing intrinsic value, capable of delivery either as an assembled whole or as a component part or parts, and produced for introduction into trade or commerce. Human tissue and organs, including human blood and its components, are excluded from this term.

The "relevant product" under this chapter is that product or its component part or parts, which gave rise to the product liability claim.

(4) Product liability claim. "Product liability claim" includes any claim or action brought for harm caused by the manufacture, production, making, construction, fabrication, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging, storage or labeling of the relevant product. It includes, but is not limited to, any claim or action previously based on: Strict liability in tort; negligence; breach of express or implied warranty; breach of, or failure to, discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation, concealment, or nondisclosure, whether negligent or innocent; or other claim or action previously based on any other substantive legal theory except fraud, intentionally caused harm or a claim or action under the consumer protection act, chapter 19.86 RCW.

(5) Claimant. "Claimant" means a person or entity asserting a product liability claim, including a wrongful death action, and, if the claim is asserted through or on behalf of an estate, the term includes claimant's decedent. "Claimant" includes any person or entity that suffers harm. A claim may be asserted under this chapter even though the claimant did not buy the product from, or enter into any contractual relationship with, the product seller.

(6) Harm. "Harm" includes any damages recognized by the courts of this state; PROVIDED, That the term "harm" does not include direct or consequential economic loss under Title 62A RCW.

[1991 c 189 § 3; 1981 c 27 § 2.]

#### NOTES:

**Preamble—1981 c 27:** "Tort reform in this state has for the most part been accomplished in the courts on a case-by-case basis. While this process has resulted in significant progress and the harshness of many common law doctrines has to some extent been ameliorated by decisional law, the legislature has from time to time felt it necessary to intervene to bring about needed reforms such as those contained in the 1973 comparative negligence act.

The purpose of this amendatory act is to enact further reforms in the tort law to create a fairer and more equitable distribution of liability among parties at fault.

Of particular concern is the area of tort law known as product liability law. Sharply rising premiums for product liability insurance have increased the cost of consumer and industrial goods. These increases in premiums have resulted in disincentives to industrial innovation and the development of new products. High product liability premiums may encourage product sellers and manufacturers to go without liability insurance or pass the high cost of insurance on to the consuming public in general.

It is the intent of the legislature to treat the consuming public, the product seller, the product manufacturer, and the product liability insurer in a balanced fashion in order to deal with these problems.

It is the intent of the legislature that the right of the consumer to recover for injuries sustained as a result of an unsafe product not be unduly impaired. It is further the intent of the legislature that retail businesses located primarily in the state of Washington be protected from the substantially increasing product liability insurance costs and unwarranted exposure to product liability litigation." [1981 c 27 § 1.]

## RCW 7.72.030

### Liability of manufacturer.

(1) A product manufacturer is subject to liability to a claimant if the claimant's harm was proximately caused by the negligence of the manufacturer in that the product was not reasonably safe as designed or not reasonably safe because adequate warnings or instructions were not provided.

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

(b) A product is not reasonably safe because adequate warnings or instructions were not provided with the product, if, at the time of manufacture, the likelihood that the product would cause the claimant's harm or similar harms, and the seriousness of those harms, rendered the warnings or instructions of the manufacturer inadequate and the manufacturer could have provided the warnings or instructions which the claimant alleges would have been adequate.

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

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

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

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

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

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

[1988 c 94 § 1; 1981 c 27 § 4.]

## **WPI33.02 Avoidable Consequences—Failure to Secure Treatment**

### **Washington Practice Series TM Washington Pattern Jury Instructions--Civil**

6 Wash. Prac., Wash. Pattern Jury Instr. Civ. WPI 33.02 (6th ed.)

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Part IV. Damages

Chapter 33. Damages—Mitigation—Avoidable Consequences

#### **WPI 33.02 Avoidable Consequences—Failure to Secure Treatment**

A person who is liable for an injury to another is not liable for any damages arising after the original *[injury] [event]* that are proximately caused by failure of the injured person to exercise ordinary care to avoid or minimize such new or increased damages.

In determining whether, in the exercise of ordinary care, a person should have secured or submitted to medical treatment, as contended by (insert name of applicable party), you may consider *[the nature of the treatment,] [the probability of success of such treatment,] [the risk involved in such treatment,]* [ (other factors in evidence),] and all of the surrounding circumstances.

(Insert name of applicable party) has the burden to prove (insert name of other party's) failure to exercise ordinary care and the amount of damages, if any, that would have been minimized or avoided.

#### **NOTE ON USE**

Use this instruction only if (1) there is evidence creating an issue of fact as to the injured person's failure to exercise ordinary care in receiving or submitting to medical treatment, and (2) the evidence permits a segregation of the damages resulting from that failure to exercise ordinary care.

Use bracketed material as applicable. For issues about avoidable consequences other than failing to secure or submit to medical treatment, see WPI 33.01, Avoidable Consequences—Personal Injury Generally, or WPI 33.03, Avoidable Consequences—Property or Business.

#### **COMMENT**

RCW 4.22.005 and RCW 4.22.015.

RCW 4.22.005 provides that contributory fault proportionately diminishes the amount of a claimant's recovery. RCW 4.22.015 defines "fault" as including "unreasonable failure to avoid an injury or to mitigate damages."

Whether or not reasonable care requires an injured person to submit to the treatment is a jury question. *Martin v. Foss Launch & Tug Co.*, 59 Wn.2d 302, 367 P.2d 981 (1962). The principles relating to the duty of an injured person in the securing of treatment are considered in *Dahl v. Wagner*, 87 Wash. 492, 151 P. 1079 (1915); *Hoseth v. Preston Mill Co.*, 49 Wash. 682, 96 P. 423 (1908); and *Rowe v. Whatcom County Ry. & Light Co.*, 44 Wash. 658, 87 P. 921 (1906). Also see, *Duty of Injured Person to Submit to Surgery to Minimize Tort Damages*, 62 A.L.R.3d 9.

The opinion in *Cox v. Keg Restaurants U.S., Inc.*, 86 Wn.App. 239, 935 P.2d 1377 (1997), contains an extended discussion of the sufficiency of evidence required to submit to a jury the issue of a plaintiff's unreasonable failure to secure treatment. The court noted that where causation turns on "obscure medical factors," expert testimony is required. "Submitting the issue to the jury without such testimony is improper because the jury is thus invited to reach a result based on speculation and conjecture." *Cox v. Keg Restaurants U.S., Inc.*, 86 Wn.App. at 244. The court further stated that the issue "should also not be submitted if the evidence shows that a proposed treatment might not be successful or if there is conflicting testimony as to the probability of a cure because it is not unreasonable for a plaintiff to refuse treatment that offers only a possibility of relief." 86 Wn.App. at 244.

Similarly, in *Hawkins v. Marshall*, 92 Wn.App. 38, 962 P.2d 834 (1998), although there was evidence the plaintiff had failed to follow her doctor's advice, there was no evidence presented that this omission aggravated her condition or delayed her recovery. Accordingly, it was not error to refuse to give this instruction.

Where, however, evidence is presented from which the jury could conclude that plaintiff's failure to secure treatment was unreasonable and that treatment would have improved or cured plaintiff's condition, the giving of an instruction on mitigation of damages is proper. *Fox v. Evans*, 127 Wn.App. 300, 111 P.3d 267 (2005), review denied at 156 Wn.2d 1017, 132 P.3d 734 (2006).

For additional discussion, see the Comments accompanying WPI 33.01, *Avoidable Consequences—Personal Injury Generally*, and WPI 33.03, *Avoidable Consequences—Property or Business*.

*[Current as of June 2009.]*

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**To:** Jaimie O'Tey  
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Attached please find Petitioner's Supplemental Brief for filing with the Supreme Court.

**Case Name:** Josette Taylor; Estate of Fred E. Taylor v. Intuitive Surgical, Inc.

**Case Number:** 92210-1

**Attorneys Name & WSBA#:** Kenneth W. Masters, WABA 22278, and Shelby R. Frost Lemmel WSBA 33099

Thank you,  
Jaimie

Jaimie M.L. O'Tey  
Appellate Paralegal  
Masters Law Group, PLLC  
241 Madison Avenue North  
Bainbridge Island, WA 9810  
(206) 780-5033

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