No. 45052-6-II

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

JOSETTE TAYLOR as Personal Representative of the Estate of FRED E. TAYLOR, deceased; and on behalf of the Estate of FRED E. TAYLOR; and JOSETTE TAYLOR,

Appellants,

v.

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

Respondent.

REPLY BRIEF

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INTRODUCTION

The trial court erroneously refused to instruct the jury that ISI had a duty to warn and instruct Harrison, which purchased the da Vinci robot. It erroneously failed to instruct the jury that strict liability applies here, and erroneously excluded evidence to rebut ISI's false suggestion that there were no other similar incidents at Harrison. Because of these errors, the jury returned a defense verdict.

ISI spends an inordinate amount of time addressing Bildsten's negligence, an undisputed point. It points the finger at Fred, but his failure to mitigate, if any, is a jury question. It claims that Josette's product-liability claim failed even with the benefit of an erroneous duty-to-train instruction, but the WPLA imposes a duty to train, and ISI assumed that duty in any event.

Harrison is entitled to warnings and instructions under the WPLA as the product purchaser. ISI ignores this point. It instead argues that Harrison is not a learned intermediary entitled to warnings and instructions. But Harrison must be warned because it played an integral role in patient safety, obtaining Fred's informed consent, adopting credentialing requirements, and credentialing Bildsten to operate using the robot.

This Court should reverse and remand for trial.

REPLY ARGUMENT

A. ISI assumed a duty to train on its da Vinci robot.

ISI accuses Josette of "fundamentally misstat[ing]" the duties owed under the WPLA," arguing that the duty to provide "adequate warnings or instructions" does not include a duty to train. BR 20-25. But providing "instructions" means "to instruct," defined as "to train in some special field." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY, 1172 (1993). The WPLA unequivocally includes a duty to train.

ISI also assumed a duty to train as part of its 510(k) application for prostatectomy. ISI submitted to the FDA the "Intuitive Surgical Customer Training Program," detailing the four-phase training program it undertook to provide. Ex 24, p.30; RP 1913. This training program's express purpose was to familiarize surgeons with the robot and to "provide instruction for performance of general surgical tasks using the [da Vinci]." Ex 24, p.30. ISI promised that "surgeons will have received training and demonstrated proficiency" from the basic system to "Surgical Skills." *Id.*; *see also* RP 2605-06. ISI does not disagree that it dramatically reduced this promised training before Fred's surgery. BA 12-16.

ISI also marketed itself to Harrison (and others) as a "partner," "lead[er]," and "expert" in the field. RP 550, 679-80, 1669, 1688, 1694; CP 4584, 4587-88; Ex 48; Ex 281, p. 5. In short, ISI's argument rings hollow. The WPLA imposes a duty to train, and ISI promised to train Harrison, Bildsten, and others.

B. ISI ignores Josette's argument that ISI had a duty to warn Harrison, which purchased the robot and credentialed surgeons to use it.

ISI ignores Josette's first two arguments that ISI had a duty to warn Harrison because Harrison purchased the robot, mistakenly suggesting that Josette's sole argument on appeal is that ISI had a duty to warn Harrison because it is a "second learned intermediary." BR 16, 25-32. Josette was very clear that ISI's duty to warn Harrison flows from the WPLA, not the learned intermediary doctrine, and that by perverting that doctrine, ISI led the trial court into instructional error. BA 39-45. ISI apparently has no answer.

1. ISI has a duty to warn Harrison under the WPLA.

ISI had a duty to warn Harrison because ISI manufactured the da Vinci robot and sold it to Harrison. BA 39-42. As defined under the WPLA, the da Vinci robot is a "relevant product" giving rise to Josette's product liability claim, and ISI is the "product seller" and "manufacturer." BA 40; RCW 7.72.010(1)-(3). Josette is a

"[c]laimant" asserting a "[p]roduct liability claim." RCW 7.72.010(4), (5). As such, ISI is "subject to liability" to Josette if the da Vinci robot was not reasonably safe in that ISI failed to provide adequate warnings and instructions "with the product." RCW 7.72.030(1)(b).

The only way to provide those "with the product" was to give them to Harrison. Harrison, not Bildsten, purchased the da Vinci. Harrison credentialed Bildsten (and others) to use the robot and obtained Fred's informed consent. CP 250 (attached); RP 1151-52. Providing adequate warnings and instructions "with the product" meant giving them to Harrison, through whom the dangerous robot reached Fred.

ISI never addresses this argument. BR 25-32.

2. ISI perverted the learned intermediary doctrine to escape its duty to warn Harrison.

Objecting to Josette's proposed instructions on the duty to warn Harrison, ISI argued that under the learned intermediary doctrine, ISI had a duty to warn Bildsten only. BA 42-45; CP 4697, 4699-4702. Josette countered that ISI perverted the learned intermediary doctrine, but argued in the alternative that even if the doctrine applied, Harrison was a learned intermediary owed a warning. CP 4936-39, 5319-25; BA 46-48.

Under the learned intermediary doctrine, a medical device or prescription-drug manufacturer has no duty to warn the patient directly, 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." BA 42-45 (discussing ***Terhune v. A. H. Robins Co.***, 90 Wn.2d 9, 12-14, 577 P.2d 975 (1978)). The doctrine's rationale is that if the manufacturer adequately warns the doctor, the doctor will act in the patient's best interest and is better situated to do so. ***Terhune***, 90 Wn.2d at 14.

The learned intermediary doctrine addresses only a manufacture's duty to warn a patient. It has nothing do with a manufacturer's duty to provide necessary warnings and instructions "with the product" to the purchaser, where, as here, the purchaser is not the doctor or the patient, but a third entity. RCW 7.72.030(1)(b).

3. If the doctrine applies, then Harrison is a learned intermediary.

Ignoring Josette's first two arguments on ISI's duty to Harrison, ISI responds solely to Josette's "alternative" argument that if the learned intermediary doctrine applies, then it would require ISI to warn or instruct Harrison. BA 46-48; BR 25-32. This is consistent with ***Terhune***, which makes clear that the learned intermediary

doctrine is designed to get adequate warnings and instructions to those responsible for patient safety. 90 Wn.2d at 14. Harrison is plainly such an entity.

If, as ISI convinced the trial court, ISI has no duty to warn and instruct Harrison (or other purchasers), then hospitals cannot meaningfully obtain informed consent or credential surgeons to use the robot. Here, for example, ISI markets the robot as "[i]mprov[ing] cancer control," but failed to warn or instruct Harrison that the "positive margin rate" – that is the amount of cancer left behind – may be 16-to-19 times higher in a da Vinci robotic prostatectomy than in an open procedure. RP 557, 1720, 1965-66, 2054-55; Ex 177; Ex 509 p.4. As one author plainly stated, no clinical data supports ISI's claims. RP 1952.

Indeed, the only medical literature accounting for margin rates in the "learning curve" – *i.e.* "basic competency" – concludes that it took 150 robotic prostatectomies to achieve results comparable to an open procedure, and 250 robotic procedures to achieve "surgeon comfort and confidence." BA 21-22 (quoting RP 804, 1949-50). This article specifically warns that hospitals considering a robotics program must consider that most surgeons "may never overcome the learning curve" because they lack the required patient volume.

RP 805-06, 1949. But again, ISI did not warn Harrison. RP 565, 567, 1654-55.

When the learning curve does not account for margin rates, but surgical time, low blood loss, and few complications, medical literature available before Harrison's purchase put the learning curve at 20-25 robotic prostatectomies. BA 23-24. The expert surgical team involved in that study had a 22% complication rate and 30-35% margin rates. *Id.* The learning curve dropped below 20 robotic procedures only when it accounted **solely** for operating time. BA 24. Again, ISI did not warn Harrison. RP 565, 567, 1654-55.

ISI claims that, if "pressed," it told surgeons the learning curve was 20 to 30 robotic prostatectomies. BA 8. But ISI's learning curve addresses only surgeon comfort, stating: (1) that surgeons should expect to feel "frustrated" for 5 cases; (2) that they "should begin to feel comfortable" at 10 cases; and that (3) ISI hopes they will feel "enthusiastic and committed" at 20 cases. CP 1694. This has nothing to do with patient safety. It is also at odds with studies showing it takes 250 procedures for surgeons to feel comfortable with a robotic approach. RP 804, 1949-50.

And contrary to even the sparse learning-curve information it provided, ISI recommended only two proctored procedures to

"ensure success in becoming a proficient robotic surgeon." BA 25-26; Ex 511; RP 573, 711-12, 716, 840, 1036. ISI admits that no clinical data supports its recommendation. BA 25-26; RP 573, 711-12.

In short, what ISI told Harrison was not only unsupported, but was contracted by the learning-curve information ISI withheld. What ISI failed to tell Harrison could have prevented it from credentialling Bildsten, or even from purchasing the robot, either of which would have prevented Fred's injuries.

ISI argues that Josette failed to preserve this instructional error because her proposed instructions erroneously included a duty to train. BR 26. As discussed above, the WPLA imposes a duty to train, and ISI plainly undertook a duty to train. *Supra*, Argument A. But in any event, Josette's proposed instructions would have fixed the error she asserts here. CP 4113-99.

ISI mistakenly claims that no one at Harrison ever "met with" Fred, or obtained his informed consent "separate from that obtained by Bildsten." BR 15, 28. Then misstating Josette's argument, ISI claims that if the treating physician gets informed consent, no Washington law supports the theory that a hospital has to obtain a second informed consent. *Id.* Josette never made such a claim. But

in any event, Harrison obtained its own distinct informed consent, so had the right and the responsibility to assess whether and when doctors could safely operate using the robot. CP 250 (attached); RP 1151-52. ISI deprived Harrison of that opportunity.

Apparently relying on ***McKee v. Am. Home Products Corp.***, ISI argues that the learned intermediary doctrine cannot apply to Harrison, which made no "medical judgment." BR 28-29 (citing 113 Wn.2d 701, 782 P.3d 1045 (1989)). ISI's reliance on ***McKee*** is misplaced. BR 28-29. There, our Supreme Court declined to extend the learned intermediary doctrine to pharmacists, who (unlike prescribing doctors) are not responsible for patient safety. ***McKee***, 113 Wn.2d at 711-12. A pharmacist filling a doctor's prescriptions is not equivalent to a hospital who obtains patients' informed consent and credentials doctors to use a dangerous medical device. Harrison plainly exercised judgment bearing on patient safety when it adopted credentialling requirements, credentialed Bildsten (and others), and obtained Fred's informed consent. CP 211, 250; RP 956-58, 1150-52.

True, no Washington law directly addresses whether the learned intermediary doctrine applies to a hospital that obtains informed consent and credentials surgeons to use an unavoidably

unsafe robot. BR 29-30. This is precisely why Josette cited the following foreign cases ISI attempts to distinguish. BA 46-47.

In ***Ellis v. C. R. Bard, Inc.***, the 11th Circuit held that a morphine-pump manufacturer sufficiently warned hospital physicians and nurses. 311 F.3d 1272, 1283 (11 Cir. 2002). ISI agrees that ***Ellis*** suggests that a hospital can be a learned intermediary, but argues that under ***Ellis***, only the physician has responsibility to warn the patient. BR 30. Again, Harrison obtained its own informed consent and takes responsibility for patient safety in the credentialling process. Thus, it too must be warned.

Contrary to ISI's assertion, the remaining cases Josette cites do not turn on who prescribes the product, but on who affects patient safety (BR 31-32):

- In ***Wright v. Abbott Labs., Inc.***, the 10th Circuit held that the manufacturer sufficiently warned the hospital, where a hospital nurse accidentally administered the wrong drug. The 10th Circuit rejected Wright's claim that Abbott Labs owed a duty to warn against storing medications in close proximity, holding that the other warnings provided to the hospital were sufficient. 259 F.3d 1226, 1233-34 (10th Cir. 2001).
- In ***Brown v. Drake-Willock Int'l., Ltd.***, the Court rejected the application of the learned intermediary rule to a dialysis machine technician, holding that "the hospital or physician was the proper recipient of necessary information or warnings" under the learned intermediary doctrine. 209 Mich. App. 136, 149, 530 N.W.2d 510, 516 (1995).

- And in ***McEwen v. Ortho Pharm. Corp.***, the Court held that the learned intermediary doctrine extends to "all members of the medical profession who come into contact with the patient in a decision-making capacity." 270 Or. 375, 388, 528 P.2d 522, 529 (1974)).

ISI next claims that any error was harmless, misstating the burden of proof and the standard of review. BR 32 & 32 n.19. This Court reviews *de novo* claimed instructional errors depending, as here, on statutory interpretation. BA 39. And if, as Josette claims, omitting Harrison is a legal error, then the instructions are "presumed to be prejudicial" and will be reversed unless ISI proves they were harmless. ***Thompson v. King Feed & Nutrition Serv., Inc.***, 153 Wn.2d 447, 453, 105 P.3d 378 (2005); ***Mackay v. Acorn Custom Cabinetry, Inc.***, 127 Wn.2d 302, 311, 898 P.2d 284 (1995).

ISI also mischaracterizes Josette's argument as being that ISI should have warned Harrison not to credential Bildsten or controlled Harrison's credentialling program.[1] BR 32-33. The (missed) point is that ISI possessed considerable information that it would take 150 robotic procedures to achieve cancer-removal rates comparable to an open procedure, 250 robotic procedures to achieve comparable

[1] ISI claims that the court rejected its strawman theory as speculative. BR 33. The trial court does not say why it elected not to give Josette's proposed instructions, but it appears that ISI's mischaracterization of the learned intermediary rule led the court into error.

surgeon confidence and comfort, and 20 to 25 procedures just to achieve basic competency in terms of surgical time, blood loss, and complication rates. BA 21-26. But ISI withheld that information and recommended only two proctored procedures. *Id.* ISI does not have a duty to tell Harrison who to credential, but to provide warnings relevant to Harrison's credentialling decisions, and to avoid providing materially misleading information. BR 32-33.

Finally, ISI attempts to place all of the blame on Bildsten. BR 33. ISI again misses the point – with proper warnings, Harrison may not have credentialed Bildsten, or even have purchased a robot, preventing the surgery altogether.

C. Strict liability, not negligence, governs the inadequate-warning claims.

ISI does not disagree that strict liability is typically the standard for inadequate-warning claims. BR 34. Nor does it disagree that our courts must sparingly apply comment *k* to RESTATEMENT (SECOND) OF TORTS § 402A (1965), which creates an exemption from strict liability only for "unavoidably unsafe products" that are "properly prepared, and accompanied by proper directions and warnings." ***Ruiz-Guzman v. Amvac Chem. Corp.***, 141 Wn.2d 493, 505-06, 7 P.3d 795 (2000). Rather, ISI argues that the

negligence standard applies, despite comment *k*'s plain language. BR 34-38. This Court should reject ISI's assertion, and enforce comment *k*'s plain statement that its narrow exemption from strict liability applies only if the product is accompanied by adequate warnings and instructions.

1. Our Supreme Court has left open whether strict liability applies to inadequate-warning claims.

As discussed in the opening brief, the four major Washington cases addressing comment *k* do not compel the application of a negligence standard. BA 50-57 (discussing ***Terhune*** and ***Ruiz-Guzman***, *supra*, and ***Rogers v. Miles Labs., Inc.***, 116 Wn.2d 195, 802 P.2d 1346 (1991), and ***Young v. Key Pharmaceuticals***, 130 Wn.3d 160, 922 P.2d 160, 922 P.2d 59 (1996)). ISI does not convincingly argue otherwise.

Terhune and ***Ruiz-Guzman*** are inapposite – neither addresses the standard applicable to inadequate-warning clams. BA 50, 53-54. Although ***Young*** is on point, it is a 4-4 plurality decision, so "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)). There, the 4-judge "majority" held

that plaintiff Young's inadequate-warning claims were governed by a negligence standard under comment *k*, relying in large part on ***Rogers***. ***Young***, 130 Wn.2d at 168-71. As discussed at length in Chief Justice Madsen's dissent, the ***Young*** majority misplaced reliance on ***Rogers*** *dicta* based on a foreign case since held inconsistent with ***Rogers***:

- ***Rogers*** did not address medical devices or drugs, but blood products, which are exempt from coverage under the WPLA;
- The ***Rogers*** plaintiffs did not claim inadequate warnings, but design defects only;
- Thus, the part of ***Rogers*** addressing inadequate-warning claims is *dicta*, so is not binding; and
- ***Rogers*** is at odds with the foreign precedent it is based on. ***Rogers*** purports to follow a California Supreme Court decision 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.

116 Wn.2d at 203-07 (Madsen, J., dissenting).

ISI ignores that ***Young*** is not binding and has little precedential value. BR 35. It relies chiefly on ***Rogers***, ignoring that it is no longer good law, and was improvidently relied on by the ***Young*** plurality in any event. *Id.*

2. This Court should hold that strict liability applies to inadequate-warning claims.

Where, by its plain language, comment *k* creates an exception to strict liability only when the manufacturer provides adequate

warnings and instructions with the product, and where no binding authority compels a different conclusion, Josette asked this Court to disagree with Division One's holding in ***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). Again, ***LaMontagne*** provides no analysis, fails to address ***Young*** and ***Rogers***, and misplaces reliance on ***Ruiz-Guzman***. BA 57. Thus, this Court should reject ISI's invitation to assume that the Legislature agrees with ***LaMontagne***, and hold that strict liability applies. BR 36.

3. Alternatively, this Court should hold that comment *k* applies only on a product-by-product basis.

Alternatively, this Court should hold that comment *k* does not apply unless and until the jury finds that the da Vinci robot's social utility greatly outweighs its inherent risk. Our Supreme Court adopted this product-by-product approach for pesticides in ***Ruiz-Guzman***, holding 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. 141 Wn.2d at 509-10. This analysis is consistent with both ***Terhune*** and ***Rogers***. 141 Wn.2d at 510.

ISI argues that ***Ruiz-Guzman*** "*resolved this issue*," holding that the product-by-product approach applies to pesticides "*as opposed to a blanket exemption like that for medical products.*" BR 37 (quoting ***Ruiz-Guzman***, 141 Wn.2d at 511, emphasis ISI's). But the Court specifically refused 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. 141 Wn.2d at 508. The Court noted, however, that a blanket exemption for prescription drugs despite their "*vastly differing* social utility," is "incongruent with the social utility reasoning in ***Terhune*** and ***Rogers***." *Id.* (emphasis in original). The same is true for medical devices.

ISI also faults Josette for being "imprecise" about ***Ruiz-Guzman***, claiming that it "only addressed the predicate issue to the application of comment *k* . . . not the consequence of such a determination." BR 37. This argument makes no sense. Whether comment *k* applies determines the applicable standard, where comment *k* is an exception to the rule that strict liability generally governs products-liability claims. *Id.*

At the time of Fred's surgery, the da Vinci's "utility" did not "greatly outweigh" its risks. ***Ruiz-Guzman***, 141 Wn.2d at 510. According to ISI, the robot's "utility" is that with smaller incisions comes shorter recovery times, shorter hospitalizations, and fewer complications. BR 4-5. The same is true of a traditional laparoscopic approach, so there is no need for a robot to accomplish these goals. ISI's claims of improved cancer control are unsupported and likely untrue. Ex 509 p.4; BA 21-22; RP 1952. The benefits of a robotic procedure are minimal. RP 1950-51.

In sum, this Court should hold that comment *k* does not apply to inadequate-warning claims, or alternatively applies only on a product-by-product basis. The Court should reverse and remand.

D. The trial court erred in prohibiting any evidence to rebut the false assertion that the robotics program at Harrison was very successful outside Fred's procedure.

The testimony at issue began when Josette asked ISI's O'Connor about an email that circulated immediately before Harrison started its robotics program, in which ISI instructed O'Connor not to tell Harrison about his concerns regarding the "potential quality" of Harrison's impending robotics program. BA 62; RP 731-33, 811; Ex 116. O'Conner answered that he had never expressed his concerns

to Harrison. RP 733, 811. On cross-examination, O'Connor acknowledged that his concern had been that someone would drop the ball as they were "getting ready to implement and launch the program." RP 795-96. His concern, and the email, were plainly related to the time before Harrison's robotics program began.

But on re-cross, when ISI again asked O'Connor why he "did not express doubts about the quality," O'Conner did not opine about the timeframe right before the robotics-program launch, but broadly stated that "outside this incident . . . it's been a very successful program." RP 855. He then divulged that Harrison was purchasing another robot, and concluded that Harrison too had no concerns about the robotics program. *Id.*

This incredibly damaging testimony created the false impression that the problems in Fred's procedure were isolated. CP 4482; RP 1414, 1629. In truth, there were a number of other incidents at Harrison, including, as with Fred's procedure, problems with the robot and robotic instruments, excessive console time, leaky anastomosis, and unintended lacerations and conversions to open procedures. RP 911, 1107, 1111, 1287, 1416-18 (discussing proposed Ex 304); CP 4482.

ISI inaccurately claims that Josette did not contemporaneously object. BR 39. After a few short questions, ISI rested and Josette asked for a sidebar, noting her objection to O'Connor's testimony. RP 855-56, 878-89. Two-days later, after obtaining a transcript, Josette argued that O'Connor's testimony plainly – and falsely – implied that Fred's procedure was the only "incident[]" at Harrison, opening the door to rebuttal. RP 855, 878-79, 1221, 1229-30. The court deferred ruling, and Josette again asked for rebuttal the next day. RP 1232-33, 1423-24, 1426-27; CP 4482-85.

ISI mistakenly suggests that the only rebuttal at issue was proposed exhibit 304, a record of the first 233 robotic procedures at Harrison, documenting other similar incidents. BR 39, 41, 43, 44; RP 1412-15; CP 4482. The trial court plainly understood Josette to be seeking an opportunity to rebut O'Connor's testimony period, not only by admitting exhibit 304 RP 1423-24, 1426-27.

Here, as below, ISI misleadingly argues that Josette "admittedly raised the subject of the general quality of the robotic surgery program." BR 42 (citing BA 62); CP 4477, 4488-89. Josette admitted no such thing, but clearly explained that her questions

specifically addressed the robotics-program launch and the "potential" program at Harrison. BA 62-63; RP 731-33, 811; Ex 116.

Josette's inquiry did not, as ISI claims, open the door to testimony about the general success of the program years later, much less to O'Connor's gratuitous comment that all surgeons other than Bildsten remained in the robotics program. BR 39-40. Rather, O'Connor's broad testimony elicited by ISI opened the door, so ISI had to expect that Josette could inquire. ***Ang v. Martin***, 118 Wn. App. 553, 562, 76 P.3d 787 (2003), *aff'd*, 154 Wn.2d 477, 114 P.3d 637 (2005).[2]

Rebuttal would not have been "confus[ing]" or only "marginally relevant," where O'Connor's inaccurate and unrebutted testimony furthered ISI's principal defense – that Bildsten was the sole cause of Fred's injuries. BR 39. Prohibiting rebuttal evidence deprived Josette of any meaningful opportunity to argue her case theory that ISI's inadequate warnings were also a cause of Fred's injuries. RP 1418. The court's error deprived the jury of the truth.

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[2] ISI also attempts to sow confusion about the motion in limine related to O'Connor's testimony. BR 41-42. Josette moved *in limine* to exclude evidence like O'Connor's testimony, but ISI countered that Josette's motion was premature. CP 2626, 2716. The court reserved ruling, granting the motion only after O'Connor's testimony. 3/12/13 RP 31-32.

ISI argues that exhibit 304 or other evidence of "complications" does not truly contradict O'Connor's testimony. BR 43-44. Again, this is not just about exhibit 304. And O'Connor's testimony that "outside of this incident . . . it's been a very successful program," plainly creates the impression that Fred's procedure was an outlier. RP 855. The jury could agree or disagree with O'Connor's definition of "success[]," but should have heard the truth and drawn its own conclusion.

ISI next argues that any error is harmless, questioning the correlation between inadequate warnings and surgical complications. BR 44-45. ISI should have told Harrison that depending on its definition, the learning curve is between 20 and 250 procedures. BA 22-24. ISI should have told Harrison that the foremost experts in the nation needed 20 to 25 cases to achieve "basic competency" when cancer removal was discounted. *Id.* ISI should **not** have told Harrison that two proctored procedures was sufficient, admitting that no medical literature supports that recommendation. BA 25-26. The fact that many other patients experienced serious complications like those Fred suffered demonstrates the need for the warnings ISI omitted and the falsity of its explicit claims.

Finally, a limiting instruction cannot cure the admission of evidence "which is 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); BR 45-46. O'Connor's testimony was plainly "inherently prejudicial" – he strongly suggested that Fred's were the only serious complications at Harrison, implying that Bildsten was the sole cause of Fred's injuries. ***Suleski***, 67 Wn.2d at 51. That is impossible to forget when assessing ISI's fault.[3]

E. Two additional instructions were erroneous.

1. The court erroneously gave a superseding cause instruction.

ISI argues that the superseding cause instruction was appropriate because ISI could not foresee that Bildsten would "ignore" the "warnings" ISI provided.[4] BR 47-48, 51-58. What ISI

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[3] ISI complains that Josette's argument that the limiting instruction cannot cure the prejudice caused by O'Connor's testimony "stands in stark contrast to Taylor's initial claims that evidence of other surgical complications 'has no bearing on any issue in this trial.'" BR 46 n.28 (quoting CP 2628). Josette moved to exclude evidence of all surgical outcomes, good or bad, with the understanding that neither side would address the topic. CP 2628. ISI crossed that line.

[4] ISI misrepresents ***Anderson v. Weslo, Inc.***, which does not, as ISI claims, "note[]" that "the causal chain is broken when the prescribing physician is 'aware of the risk and choses to disregard it.'" BR 54 (quoting 79 Wn. App. 829, 839, 906 P.2d 336 (1995)). ***Anderson*** is about a child's failure to follow warnings accompanying a trampoline.

refers to are not "warnings" at all, but its self-titled "[u]seful guidelines for early patient selection." Ex 509 p.3. Bildsten did not "ignore" these "guidelines," but correctly understood them to be "recommendation[s]." RP 1067, 1134.

As ISI repeatedly asserts, Bildsten exercised his "medical judgment" that ISI's training had sufficiently prepared him to operate on Fred. BR 11, 27, 29, 31-32, 54. ISI acknowledges that selecting Fred for robotic surgery was "negligence." BR 51-52, 56. Negligence is foreseeable. ***Campbell v. ITE Imperial Corp.***, 107 Wn.2d 807, 812-13, 733 P.2d 969 (1987).

But ISI misses the point in any event. If ISI had adequately warned and instructed Harrison, then Harrison likely would not have credentialed Bildsten. Dr. Bildsten's negligence was not independent of ISI's failure to warn Harrison – he never could have operated on Fred without Harrison's credential.[5]

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[5] ***Minert v. Harsco, Corp.***, is inapposite. BR 47 (citing 26 Wn. App. 867, 874-75, 614 P.2d 686 (1980)). There, the scaffolding manufacturer adequately warned the employer/purchaser who failed to warn its employees. The court affirmed, holding that a jury could conclude that the purchaser's failure to pass on the manufacturer's warnings was a superseding cause.

For the same reasons, this Court should reject ISI's meritless assertion that Bildsten's negligence was a superseding cause as a matter of law. BR 51-58.

2. The mitigation instruction was improper.

Taking Instruction 20 and the verdict form together, the jury was impermissibly asked 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 (the verdict form). CP 5323, 5407, 5629. Allowing the jury to allocate a percentage of fault to Fred also impermissibly reduced ISI's burden to prove the amount of damages, if any, that Fred's exercise of ordinary care could have minimized or avoided. CP 5407. This Court should address these errors.

ISI ignores Josette's argument that when read together, Instruction 20 and the verdict form improperly state the law. BR 49-50. As to Josette's second argument, ISI claims that assigning a percentage to each parties' fault is an appropriate way to calculate damages. BR 50 (citing ***ESCA Corp. v. KPMG Peat Marwick***, 135 Wn.2d 820, 830, 959 P.2d 651 (1998)). While this may be true for comparative fault, at issue in ***ESCA Corp.***, it is not true for a failure to mitigate. Rather, failure-to-mitigate instructions can be given only

when the defendant can meet its burden to segregate the damages resulting from the failure to mitigate. Wash. Pattern Instruction 33.02 (attached).

CONCLUSION

For the reasons stated, this Court should reverse and remand for trial under proper instructions.

RESPECTFULLY SUBMITTED this 31st day of July, 2014.

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CERTIFICATE OF SERVICE BY MAIL

I certify that I caused to be mailed, a copy of the foregoing **REPLY BRIEF**, postage prepaid, via U.S. mail on the 31st day of July, 2014, to the following counsel of record at the following addresses:

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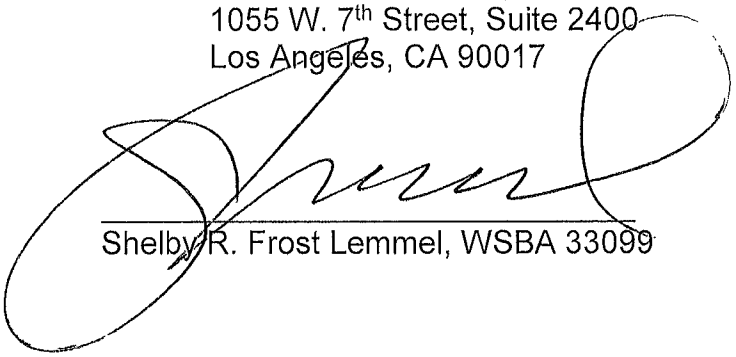

Shelby R. Frost Lemmel, WSBA 33099

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: agreed/accepted

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
Fred E Taylor	9/5/02	3:45	[signature]
Other Responsible Person	Date	Time	Witness

Relationship of Other Responsible Person

HARRISON MEDICAL CENTER
BREMERTON, WASHINGTON
PHONE 360.377.3911
FORM NO. 716 REV. 2-98

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 CANARY – PHYSICIAN PINK – PATIENT

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.

MASTERS LAW GROUP

July 31, 2014 - 2:43 PM

Transmittal Letter

Document Uploaded: 450526-Reply Brief.pdf

Case Name: Taylor v. Intuitive Surgical, Inc.
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: __Reply__

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: Shelly Windsby - Email: shelly@appeal-law.com