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SUPREME COURT OF THE STATE OF WASHINGTON

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

Petitioners,

VS.

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

Respondent.

INTUITIVE SURGICAL'S ANSWER TO PETITION FOR REVIEW

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A. INTRODUCTION

This is a product liability action arising out of the robotically-assisted surgery performed by Dr. Scott Bildsten using a system ("da Vinci System") manufactured by Intuitive Surgical, Inc. ("Intuitive"). In her petition for review, Josette Taylor, Fred Taylor's wife and personal representative ("Taylor"), misrepresents the actual facts at trial. In so doing, she also seeks to upend settled principles of Washington product liability law.

Dr. Scott Bildsten performed robotically-assisted surgery on Fred Taylor at Harrison Medical Center ("Harrison") in Bremerton to remove Taylor's prostate. Prior to the surgery, Dr. Bildsten specifically disclosed to Fred Taylor, and discussed with him, the possible risks of his surgical procedure, including risks specific to robotically-assisted surgeries using the da Vinci System. After this discussion, Fred Taylor insisted on robotically-assisted surgery and specifically consented to the surgery here. But Dr. Bildsten exercised poor medical judgment in selecting Taylor for such robotically-assisted surgery and performed the surgery negligently. As a result of Dr. Bildsten's negligence, Fred Taylor was injured. Taylor then sued Dr. Bildsten, his partner, his practice, and Intuitive. She also sued Harrison, and then settled any corporate negligence claims against it, a critical fact omitted from her petition for review.

Taylor now asserts that although the jury found Intuitive to have properly warned Dr. Bildsten as a "learned intermediary" under the Washington Products Liability Act, RCW 7.72 ("WPLA"), she is entitled to a new trial against Intuitive because Intuitive allegedly breached a separate duty to warn Harrison under WPLA. Taylor also contends that a strict liability standard governs the duty to warn learned intermediaries.

This Court should reject Taylor's bid to create a Supreme Court issue where none exists. Harrison is certainly not a learned intermediary under the WPLA because it did not prescribe or operate the da Vinci System for Fred Taylor's surgery. But, more to the point, Taylor has no standing to sue Intuitive under the WPLA for any alleged independent duty Intuitive might have had to warn Harrison about its da Vinci System, a point missed by Taylor and the Court of Appeals dissent. Further, there are significant prudential reasons why review of this issue is inappropriate in this case. Finally, controlling precedent applies a negligence standard to the duty to warn learned intermediaries under the WPLA, as the Court of Appeals unanimously determined. Taylor had a fair trial over six weeks and lost. This Court should deny review. RAP 13.4(b).

B. ISSUES PRESENTED FOR REVIEW

Taylor raises five issues for review by this Court, pet. at 2, and

then only discusses two of them in the petition.¹ Like the Court of Appeals, op. at 2 n.4, this Court should disregard the three issues Taylor failed to properly raise.

C. STATEMENT OF THE CASE

The Court of Appeals opinion discusses the facts here, op. at 2-7, but several factual points bear emphasis.

The da Vinci System translates the surgeon's natural hand movements, which are performed on instrument controls at a surgeon's console, into corresponding micro-movements of instruments positioned inside the patient through small incisions, or ports. CP 335. The da Vinci System provides the surgeon with intuitive control, range of motion, fine tissue manipulation capability, and high definition 3-D vision. *Id.* A surgeon perceives that his or her hands are immersed in the surgical field, even though they are outside the patient's body, and that the tools are in his or her own hands. CP 335. The da Vinci System may *only* be used by medical professionals upon a physician's order or prescription for its use.

Taylor later acknowledges that the other three issues "do not independently require this Court to grant review." Pet. at 20. Taylor is correct. Under RAP 13.7(b), merely listing issues in the fashion Taylor has done here in the petition, without articulating an actual rationale for review, does not "raise" those issues. RAP 13.4(c)(7) requires a petition to contain "a clear and concise statement of the reason why review should be accepted..." Just as the violation of RAP 13.4(c)(5) results in the denial of review on an issue, State v. Korum, 157 Wn.2d 614, 623-25, 141 P.3d 13 (2006), the same principle applies to a violation of RAP 13.4(c)(7).

CP 364.2

Intuitive provided extensive materials regarding the da Vinci System to purchasers and surgeons.³

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 1017-18.⁴ Dr. Bildsten presented him with several

Open surgical procedures are still commonly used by surgeons, but the large incisions required for open surgery create trauma to the patient, resulting in longer recovery time, increased chance of blood loss, increased hospitalization time, and increased pain and suffering. CP 335. Over the past two decades, minimally invasive robotic surgery has reduced this patient trauma by allowing selected surgeries to be performed through small ports rather than large incisions, often resulting in shorter recovery times, fewer complications, and reduced hospitalization time. *Id.* Intuitive was founded in 1995 and three generations of da Vinci systems are currently in use. CP 139. Since its introduction, the da Vinci System has gained wide acceptance among surgeons, and is currently used, for example, in approximately 84% of prostatectomy surgeries in the United States. Op. at 2.

³ 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 "[1]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.

⁴ 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.

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, 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. Nowhere in the petition does Taylor acknowledge that Dr. Bildsten *knew* Fred Taylor was an exceedingly poor choice for robotically-assisted surgery, and was negligent in selecting him for such surgery *contrary to* Intuitive's unambiguous warnings.⁵

⁵ Not noted in the Court of Appeals' opinion or Taylor's petition is the fact that 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. Dr. Bildsten knew Fred Taylor was "severely obese," CP 173-74; RP 1140, or "morbidly obese" in clinical terms.

Nevertheless, Dr. Bildsten discussed da Vinci surgery with Fred Taylor, warning him of the 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 Taylor these risks, and that Fred Taylor insisted on surgery rather than radiation. RP 1067.

Dr. Bildsten was not only negligent in selecting Fred Taylor for robotically-assisted surgery,⁶ he was negligent in performing that surgery, and then the later open surgery, as Taylor's own urological expert, Dr. S. Adam Ramin, testified. CP 905-06, 977.

Prior to trial, Taylor settled with the doctors and their practice, CP 764-77, and settled any claim, including corporate negligence claims,

RP 1359. He had a history of multiple surgeries, including three abdominal surgeries (appendectomy, gall bladder removal, hernia surgery with mesh), which complicated his suitability for prostate surgery. CP 178. Taylor had been diagnosed with diabetes, coronary artery disease, hypertension, and high cholesterol. RP 1348-50, 1370. He had received treatment for those conditions, including a quintuple bypass heart surgery in 2002. RP 1348-57. Fred Taylor's physicians prescribed blood pressure, cholesterol, and diabetes medications, which he did not regularly take. *Id.* The medical records show that Taylor's diabetes and high blood pressure were out of control for many years before his death. RP 1376.

⁶ Dr. Bildsten ultimately determined, based upon his medical training, judgment, and experience, to proceed with robotically-assisted surgery, despite Intuitive's warnings, and despite Fred Taylor's complex medical history. RP 1134.

against Harrison. At trial, Taylor adduced no evidence from Harrison personnel regarding any distinct duty to warn owed by Intuitive to Harrison; no Harrison personnel were called to testify at trial.⁷

D. ARGUMENT WHY REVIEW SHOULD BE DENIED⁸

(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 upend settled Washington law on the duty to warn in product liability cases. The trial court's instructions on the duty to warn under the WPLA are found in Instructions 10-14. CP 5397-5400. In particular, Instructions 10 and 11 properly described the duty to warn Dr. Bildsten. CP 5397, 5398. See Appendix. Taylor's proposed

⁷ 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.

Were this Court to conclude that review is merited, Intuitive reserves the right to raise the conditional argument that the jury's verdict was also sustained because Dr. Bildsten's negligence was the superseding cause of Fred Taylor's injuries as a matter of law. Lewis River Golf, Inc. v. O.M. Scott & Sons, 120 Wn.2d 712, 714, 845 P.2d 987 (1993). Dr. Bildsten was negligent in his decision to use the da Vinci System in Fred Taylor's surgery, ignoring warnings from Intuitive about patient selection. Intuitive could not have foreseen that a trained, board-certified surgeon would ignore warnings about patient selection early in his learning curve on the robotic surgical system. Dr. Bildsten's negligent patient selection broke the causal chain. The difficulties Dr. Bildsten experienced during the robotic surgery were directly attributable to his poor selection of an obese patient as a candidate. RP 892, 1072, 1080, 1143. Moreover, Dr. Bildsten's surgical negligence caused Fred Taylor's injuries. RP 905-06. For example, Dr. Bildsten testified that he tore Taylor's rectum during an attempt to release an adhesion between Taylor's rectal wall and prostate. RP 1080. Again, such negligence broke the causal chain.

instructions 12 and 28 sought to extend the duty to warn and *train* to Harrison, despite the lack of evidence from anyone at Harrison.⁹ Review is not merited on this issue. RAP 13.4(b).

Taylor now argues, in effect, that although the jury found Intuitive was not negligent in its warnings to Dr. Bildsten, the learned intermediary who actually used the da Vinci System, she had a claim against Intuitive for its alleged negligence in failing to provide what would presumably be identical warnings to Harrison.¹⁰ She does not, and her argument would upend Washington law on product liability.

(a) Harrison Is Not a Learned Intermediary to Which a Duty to Warn is Owed

Plainly, Dr. Bildsten, not Harrison, was the learned intermediary to whom a WPLA duty to warn was owed.¹¹ Dr. Bildsten, not Harrison,

⁹ 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.

¹⁰ 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.

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.

stood in Fred Taylor's shoes to receive Intuitive's warnings 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.

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), a case not even mentioned by Taylor. This Court there emphasized that the learned intermediary doctrine applies in connection with pharmaceuticals to professionals exercising *medical judgment* as to their use for a patient, *id.* at 709-10, emphasizing the education, knowledge, and judgment of the physician upon which the patient relies for the patient's treatment. *Id.* at 711-12.¹²

This analysis applies with equal force to the application of the learned intermediary principle to a hospital where a physician, not the hospital, prescribes the use of the da Vinci System to treat a particular patient. This is a matter of medical judgment not exercised by the

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. Here, Dr. Bildsten, not Harrison, bore the responsibility under RCW 7.70 to exercise professional judgment, and to prescribe and then properly utilize the da Vinci System in Fred Taylor's case. To the extent that Taylor's proposed instructions 12 and 28 seek to expand the learned intermediary principle beyond the professional actually prescribing the product, they are an incorrect statement of law and were properly rejected by the trial court. *Havens v. C&D Plastics, Inc.*, 124 Wn.2d 158, 167, 876 P.2d 435 (1994).

(b) Intuitive Owed No Independent Duty to Warn
Harrison upon Which Taylor Was Entitled to Sue
Intuitive

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.

No Washington case has held that multiple duties to warn are required under RCW 7.72.030(1)(b). The precise contour of this duty to warn is not specified anywhere by Taylor; 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. 13

No Washington case has held that a party like Taylor may invoke the breach of the duty to warn another as the basis for recovery. Indeed, 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. The da Vinci System might well fall within such a duty, including the obligation to properly credential staff using it. But Taylor has resolved any claim by Fred Taylor against Harrison for an improperly credentialed staff by settling with Harrison. Intuitive owes no duty to Taylor to assure that Harrison fulfills its nondelegable 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 Vinci System and the credentialing of physicians using it; instead, Taylor seeks what amounts to a double recovery against Intuitive.

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 Renta-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).

(c) <u>Prudential Reasons Dictate that Review Is</u> <u>Inappropriate in This Case</u>

In addition to the fact that Taylor lacks standing to raise an issue of an independent duty to warn that might be owed by Intuitive to Harrison, there are significant prudential reasons that should deter this Court from granting review.

First, there is no evidence supporting Taylor's proposed instructions on a duty to warn Harrison. ¹⁴ 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 controlled Harrison's credentialing program. ¹⁵ Taylor

¹⁴ 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.

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.

Taylor also repeats the blatantly false assertion that Intuitive allegedly told Harrison that two proctored cases would suffice for credentialing. Pet. at 7-8. Intuitive

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. Taylor's argument ultimately is mere speculation, which is another reason why the trial court properly rejected the theory.

Second, the proposed instructions on an independent duty to warn Harrison are incorrect statements of Washington law in any event. 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. A duty to train by the manufacturer is nowhere recognized in WPLA, and specifically rejected in other jurisdictions. Br. of Resp't at 25-32. These instructions incorrectly expanded the WPLA's duty to warn, and the trial court was not obligated to give them as they erroneously stated the law. Havens, supra.

Finally, any alleged error in this case as to an independent duty to warn Harrison was ultimately harmless where Dr. Bildsten warned Fred

has repeatedly noted in pleadings in the Court of Appeals that this is false. 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 did not state that two proctored surgeries were sufficient. Instead, Intuitive recommended two proctored surgeries or hospital protocol. RP 1036, 1656, 1729.

Taylor in detail regarding the risks of robotically-assisted surgery and secured his informed consent to the surgery. In turn, 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 in specific; 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. There was no evidence at trial that any different or additional warnings to Harrison would have changed the outcome. Such a theory is mere speculation, and the trial court properly rejected Taylor's proposed jury instructions regarding a failure to warn or train Harrison. Review is not merited. RAP 13.4(b).

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

Taylor claims that strict liability, rather than negligence, ¹⁷ governs Intuitive's duty to warn, contending that this Court has somehow "left

¹⁶ Br. of Resp't at 32-33; 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.").

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.

open" the question of whether a negligence standard applies. Pet. at 15-20. The Court of Appeals here unanimously disagreed. Taylor misrepresents Washington law that clearly provides that negligence, not strict liability, governs the duty to warn a learned intermediary about a medical product. 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.

Taylor suggests that this Court has not yet decided whether the Restatement's comment k applies to "defective warning" claims. Taylor is simply wrong. It has. The holding in Rogers v. Miles Labs., Inc., 116 Wn.2d 195, 802 P.2d 1346 (1991) is clear and is the basis for a pattern instruction, WPI 110.02.01. 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. Taylor's attempt to argue that Rogers' holding was dictum because it only addressed design defects actually concedes that this Court

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).

Instruction 11 is also incorrectly stated that Intuitive had a duty to train, which again is unsupported in law. Despite this error, Intuitive prevailed at trial.

there impliedly determined that warnings were at issue.

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.²⁰ The *Rogers* holding has been good law for 23 years.

In addition to discounting *Rogers'* holding as dictum, Taylor tries to avoid *Rogers* on multiple other grounds. Pet. at 17-19. *None* of these arguments is persuasive as to why review is warranted.

Taylor references the fact that *Rogers* adopted the reasoning of a California case, and *incorrectly* claims that the adopted reasoning was later "clarified" in California. Pet. at 18. That California case is still good law there.²¹

When an interpretation of a rule of law is essential to a court's decision, it is not dictum. Wagg v. Estate of Dunham, 146 Wn.2d 63, 73, 42 P.3d 968 (2002). The term "dictum" refers to statements that have no bearing on the court's decision. In the Matter of the Marriage of Rideout, 150 Wn.2d 337, 354, 77 P.3d 1174 (2003).

²¹ In fact, 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 has reaffirmed the case that Taylor says is no longer the law in California, Brown v. Superior Court, 44 Cal.3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988). In Anderson, the court noted that confusion had surrounded Brown about whether its holding was limited to prescription drug cases, in which negligence is the controlling principle of liability. Id. at 999. The Anderson court also clarified that "Brown clearly implied that knowledge is also a

Seeking another method to discount *Rogers*, Taylor references this Court's decision in *Young v. Pharmaceuticals*, 130 Wn.2d 160, 168, 922 P.2d 59 (1996) which *affirmed Rogers*. Pet. at 17-18. Taylor tries to discount the controlling opinion in *Young* as "not binding" and of "limited precedential value," but nevertheless, relies on the Young dissent repeatedly. *Id.* at 18.

It is understandable that Taylor would like to ignore Young, because it reaffirms Rogers that under comment k, inadequate warning claims are negligence claims. 130 Wn.2d at 168. However, 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). Taylor concedes that Young holds that negligence is the test for warning cases. Pet. at 17. 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

component of strict liability for failure to warn in cases other than prescription drug cases." Id. at 1000 (emphasis added). Anderson did not overrule Brown, or even call it into question. Anderson relied on Brown's reasoning that even in strict liability failure to warn cases, the plaintiff must prove that the manufacturer knew of the risks. Id. Moreover, Anderson is not a comment k case, and Brown is. Anderson, 53 Cal.3d at 1008 (Mosk, A.J., concurring and dissenting) ("We emphatically declared in Brown that 'there is an important distinction between prescription drugs and other products..."). Any difference in the analysis between Anderson and Brown is not a product of a change in the California Supreme Court's reasoning, but the difference between comment k cases and traditional strict liability cases. Id.

particular conclusion was reached unanimously by the Young court.²²

Finally, Division I in Estate of La Montagne v. Bristol-Meyers Squib, 127 Wn. App. 335, 343-44, 111 P.3d 857 (2005) had no difficulty in understanding that the rule in Rogers and Young applied.²³ Taylor concedes that La Montagne applies a negligence standard by asking this Court to overrule it. Pet. at 19.²⁴

Although Rogers, Young, and La Montagne have long interpreted the WPLA to apply a negligence standard in duty to warn cases under comment k of the Restatement (Second) of Torts § 402A, the Legislature has taken no steps to override such an interpretation, acquiescing in that interpretation of its statute.²⁵

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.

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).

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). The Legislature has not seen fit to change the common law or to amend the WPLA to reverse the rule that comment k inadequate warning claims sound in negligence since this Court decided

Taylor finally 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). 26 Taylor neglects to reference Terhune on this point, and the case Taylor cites in support of her contention, this Court's decision in 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. This Court's decisions in Terhune and Guzman say that it does. Apparently, Taylor wants to overrule Terhune and Guzman.

There is no factual dispute that the da Vinci System is an

Rogers and Young, and Division I decided La Montagne, confirming the applicability of that rule.

²⁶ 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 (9th Cir. 2002) (surgically implanted spinal plate).

unavoidably unsafe product as described in comment k and *Terhune*. Taylor seeks a general ruling regarding medical devices and comment k, when the specific medical device at issue here undisputedly qualifies. This Court should deny review. RAP 13.4(b).

E. CONCLUSION

The Court of Appeals correctly determined that the trial court did not commit prejudicial error in its instructions to the jury on Intuitive's duty to warn under the WPLA. The trial court properly rejected Taylor's proposed instructions designed to allow her a claim for Intuitive's alleged breach of a duty to warn or train Harrison. The trial court also properly instructed the jury to apply a negligence standard, rather than strict liability.

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

This Court should deny review.

DATED this 21st day of October, 2015.

Respectfully submitted,

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APPENDIX

KITBAP UROLOGY ASSOCIATES 2500 CHERRY AVE SUITE 301 BREMERTON, WA 98310 (360) 377-0049

Physician's Surgical Procedure Discionure and Patients Consent

- TO THE PATIENT: You have the right to be informed about your condition and the recommended surgical, medical or diagnostic procedure so that you may make the decision whether or not to undergo the procedures after knowing the risks involved and any treatment alternatives available to you. This information is not meant to alarm you; it is an effort to make you better informed so that you may give or withhold your consent to the procedure. If you do not understand any of the information provided, ask your physician to explain it.
- 1. PATIENT NAME TAYLOR, FRED
- 2. PRACTITIONER PERFORMING THE TREATMENT/PROCEDURE SCOTT A. BILDSTEN, D.O.
- 3. SUPERVISING PRACTITIONER (IF APPLICABLE)
- 4. OTHER PRACTITIONERS PERFORMING THE TREATMENT/PROCEDURE (IF APPLICABLE)
 JOHN C. HEDGES, M.D.
- 5. COUNSELING PROVIDER (IF APPLICABLE)
- 6. WHAT IS THE CONDITION OR DIAGNOSIS FOR WHICH THIS TREATMENT/PROCEDURE IS RECOMMENDED?

 Prostate Cancer
- 7. WHAT DOES THIS TREATMENT/PROCEDURE INVOLVE?
 Removal of entire prostate & seminal vesicles and regional pelvic lymph nodes.
 (radical retropublic prostatectomy)using the Da Vinci Robotic System
- 8. ON WHAT PART OF THE BODY WILL THIS TREATMENT/PROCEDURE BE

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PERFORMED?

Prostate

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

10. WHAT ARE THE KNOWN RISKS OF THIS TREATMENT/PROCEDURE?

- Impotence (inability to achieve adequate erections)
- Incontinence (inability to maintain urinary control)
- Strictures of bladder and/or urethra requiring stretching or further procedures.
- Damage to ractal wall (possibly requiring temporary colostomy).
- No guarantee of cancer cure and need for further cancer treatment such as radiation or hormone therapy.
- Infection of incision requiring further treatment.
- · Emboli (blood clots) from veins into the lung
- · Ansathetic or cardiovascular problems during or after surgery
- Pain or hernia formation in area of incision
- Significant blood loss, possibly requiring transfusions
- Urinery infection
- Death
- Renal (kidney) failure
- Decreased penile length
- Urinary fistula
- Urinary retention
- 11. WHAT ARE THE ALTERNATIVES TO THIS TREATMENT/PROCEDURE? Radiation therapy, radioactive implant, removal of all male hormones, observation (no immediate treatment), cryotherapy, different surgical approaches.
- 12. WHAT WILL HAPPEN IF THE TREATMENT/PROCEDURE IS NOT DONE? Continued growth and possible spread of malignant (cancerous) tumor, making tumor incurable or later removal impossible; urinary retention, pain, bleeding, renal (kidney) failure, death
- 13. IS IT EXPECTED THAT AN ANESTHESIA PRACTITIONER WILL BE INVOLVED IN THIS TREATMENT/PROCEDURE?

IT IS EXPECTED that an anesthesia practitioner will be involved in this treatment/procedure.

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

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

Types of anesthesis include:

General anesthesia: Drug injected into the bloodstream, breathed into the lungs, or by other routes with possible placement of a tube into the windpipe.

Anticipated benefit: Total unconscious state, assistance with breathing.

Possible risks: Pain where injection is given, mouth or throat pain, hourseness, injury to mouth or teeth, awareness under anesthesia, nausea, injury to blood vessels, pneumonia.

Spinal or epidural analgesia/anesthesia: Drug injected through a needle/catheter placed either directly into the spinal canal or immediately outside.

Anticipated benefit: Temporary decreased feeling and/or movement to lower part of the body.

Possible risks: Pain where injection is given, headache, backache, buzzing in the ears, convulsions, injection, persistent weakness, numbrees, residual pain, injury to blood vessels, total spinal.'

Majoriminor nerve block: Drug injected near nerves providing loss of sensation to the area.

Anticipated benefit: Temporary loss of feeling and/or movement of a specific limb or area.

Possible risks: Pain where injection is given, infection, convuisions, weakness, persistentnumbness, residual pain, injury to blood vessels.

14. IS IT EXPECTED THAT BLOOD PRODUCTS MAY BE NEEDED IN THIS TREATMENT/PROCEDURE?

IT IS EXPECTED that blood products may be used in this treatment/procedure.

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

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

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

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Period: TAYLOR, FRED (Procedure:						
16. CONSENT TO BLOOD PRODUCTS (IF APPLICABLE) The patient (or surrogate) consents to the use of blood products.						
16. TREATMENT LIMITATIONS: I impose no specific limitations or prohibitions regarding treatment other than those that follow:						
17. DISPOSAL OF TISSUE: I authorize the disposal of any surgically removed tissue or parts resulting from the procedure according to accustomed practice.						
18. CONSENT TO TREATMENT OF UNFORESEEN CONDITIONS: I understand that my physician may encounter or discover other or different conditions which require additional or different procedures than those planned. I authorize my physician, and associated technical assistants, and other health care providers to perform such other procedures which are advisable in their professional judgment.						
19. OUTCORE: I understand that the practice of medicine is not an exact science, and that no warranty or guarantee has been made to me as to result or cure.						
20. CONSENT TO TRAINING PARTICIPATION: This facility may have an educational role in the training of paramedical personnel.						
Admittance of students and/or technical representatives [] i consent to the admittance of students and/or technical representatives for the purpose of advancing medical education and/or product usage.						
[] I do not consent to the admittance of students and/or technical representatives for the purpose of advancing medical education and/or product usage.						
Participation of students and/or technical representatives [] consent to the participation of students and/or technical representatives for the purpose of advancing medical education and/or product usage.						
 I do not consent to the participation of students and/or technical representatives for the purpose of advancing medical education and/or product usage. 						
17. ADDITIONAL INFORMATION understand that during the treatments/procedures, the doctor or dentist may need to place a medical device in my body. If a medical device is implanted in my body, personal information (such as my name, social security number, and medical						

information) will be given to the maker of the device for quality control purposes.

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

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If you have questions concerning the scheduling of your procedure, call 1-800-556-1111.

18. COMMENTS

SIGNING PRACTITIONER:

By signing below, I attest to the following:

- All relevant aspects of the treatment/procedure, including indications, benefits, risks, and alternatives including no treatment have been discussed with the patient (or surrogate) in language that sine could understand, and the patient (or surrogate) indicated comprehension of the discussion.
- I have given the patient (or surrogate) an opportunity to sak quastions.
- I did not use threats, inducements, misleading information, or make any attempt to coarse the patient/surrogate to consent to this treatment/procedure.
- I have given the patient (or surrogate) the opportunity to review a printed copy of the consent form.

- I have reviewed and approved the progress note.

PATIENT OR SURROGATE:

By signing below, I attest to the following:

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

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Pens 6

WITNESS(ES):

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

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

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000250			
Padent FEED Torcar			
i hereby authorize Dr. Bildsten	• • • • • • • • • • • • • • • • • • •		
and/or such especialise of essistants as may be selected by said physician to parlotin the following procedure(s) which has (have) been explained to ma:	attending physician, by an enestive-inlogist, or other		
RADICAL ROBETIC	may result in paralysis, duriduc arrest and/or brain death from both known and unknown causes.		
	Any liesues or parts surgicelly removed may be disposed of by the hospital or physician in accordance with accustomed practice.		
The treatment(s) plumed for my condition(s) has (have)	Full/Limited Disclosure		
been explained to me by my physician. I understand them to be:	described to me by my physicism the following points: a) the nature and character of the proposed treatment; b) the anticipated results of the proposed treatment; c) the afteredive 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 mon- treatment.		
### (recognize that, during the ocurse of the operation, post operative care, medical treatment, americals or other procedure, Unforces conditions may recessitate	(check one) My physician has informed me of the above points to my satisfaction prior to my suthorization of the proposed treatment.		
edditional or different procedures than those above set forth. I therefore suiffedize my above named physician, and his or her assistants or designees, to perform such surgical or other procedures as one in the expenses of his, her or their professional	I have decided that I do not want to be told of the above points. I commute to the use of transferior of blood and blood products as deemed reseasery. JSYES [] NO		
judgement necessary and desirable. (a) I have been informed that there are algorithment risks such as severe loss of blood, infection and cardiac surest that can lead to death or permanent or partial disability, which may occur from the performance of any procedure. I soknowledge that no warranty or guarantee has been made to me as to result or ours.	■ I give permission for pertinent data including my name and social security number to be released to manufacturers or the Food and Drug Adminishation upon their request to track certain medical devices. (This tracking is done in compliance with the Safe Medical Device Act.)		
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SPECIAL CONSENT TO OPERATION, POST	MR#: 210219 AGB:67Y		
OPERATIVE CARE, MEDICAL TREATMENT, ANESTHESIA, OR OTHER PROCEDURE	SEX:M DOB:12/14/1940 TAYLOR, FRED B		
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	HARRISONING 00238		

INSTRUCTION NO. 12

Issues

Mrs. Taylor claims that ISI was negligent because it engaged in improper and misleading marketing of the robotic surgical system, provided inadequate and misleading warnings, and inadequately trained Dr. Bildsten and the Harrison Medical Center staff.

Mrs. Taylor claims that ISI's conduct was a proximate cause of injuries and damage to her husband, her, and her husband's estate.

ISI denies these claims and asserts that Dr. Bildsten and Fred Taylor are the proximate cause of any injuries and damages suffered by plaintiffs.

ISI further denies the nature and extent of the claimed injuries and damage.

The foregoing is merely a summary of the claims of the parties. You are not to consider the summary as proof of the matters claimed and you are to consider only those matters that are admitted or are established by the evidence. These claims have been outlined solely to aid you in understanding the issues.

CONTROL OF THE PROPERTY OF THE

It is the duty of the Court to instruct you as to the measure of damages on Mrs. Taylor's claim for losses suffered by Mrs. Taylor as a result of Fred Taylor's death. By instructing you on damages, the Court does not mean to suggest for which party your verdict should be rendered.

If your verdict is for Mrs. Taylor, and you have determined that Intuitive proximately caused Fred Taylor's death, then you must determine the amount of money that will reasonably and fairly compensate Mrs. Taylor for such damages as you find were proximately caused by the death of Fred Taylor.

If you find for Mrs. Taylor, you should consider the following items:

What Fred Taylor reasonably would have been expected to contribute to

Mrs. Taylor in the way of marital consortium. "Marital consortium" means
the fellowship of husband and wife and the right of one spouse to the
company, cooperation, and aid of the other in the matrimonial relationship.

It includes emotional support, love, affection, care, services,
companionship, including sexual companionship, as well as assistance
from one spouse to the other.

In making your determinations, you should take into account Fred Taylor's age, health, life expectancy, occupation, and habits. In determining

the amount that Fred Taylor reasonably would have been expected to contribute in the future to Mrs. Taylor in the way of marital consortium, you should also take into account the amount you find Fred Taylor customarily contributed to Mrs. Taylor.

The burden of proving damages rests upon Mrs. Taylor. It is for you to determine, based upon the evidence, whether any particular element has been proved by a preponderance of the evidence.

Your award must be based upon evidence and not upon speculation, guess, or conjecture.

The law has not furnished us with any fixed standards by which to measure noneconomic damages. With reference to these matters you must be governed by your own judgment, by the evidence in the case, and by these instructions.

DECLARATION OF SERVICE

On said day below I emailed a courtesy copy and deposited in the U.S. Mail for service a true and accurate copy of Intuitive Surgical's Answer to Petition for Review in Supreme Court Cause No. 92210-1 to the following parties:

William S. Cummings Richard Friedman Peter J. Mullenix Friedman Rubin 1126 Higland Avenue Bremerton, WA 98337	Carol N. Johnston Jane Morrow Otorowski, Johnston, Morrow & Golden PLLC 298 Winslow Way West Bainbridge Island, WA 98110
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Original efiled with:

Washington Supreme Court

Clerk's Office

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: October 2/s+, 2015, at Seattle, Washington.

Kelley Carroll, Legal Assistant
Talmadge/Fitzpatrick/Tribe

OFFICE RECEPTIONIST, CLERK

To: Kelley Carroll

Cc: Phil Talmadge; Chandra.Russell@skadden.com; Nicky.Espinosa@intusurg.com;

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bdurbin@riddellwilliams.com

Subject: RE: Josette Taylor, et al. v. Intuitive Surgical Inc. No. 92210-1

Received on 10-21-2015

Supreme Court Clerk's Office

Please note that any pleading filed as an attachment to e-mail will be treated as the original. Therefore, if a filing is by e-mail attachment, it is not necessary to mail to the court the original of the document.

From: Kelley Carroll [mailto:assistant@talmadgelg.com]

Sent: Wednesday, October 21, 2015 3:18 PM

To: OFFICE RECEPTIONIST, CLERK < SUPREME@COURTS.WA.GOV>

Cc: Phil Talmadge <phil@tal-fitzlaw.com>; Chandra.Russell@skadden.com; Nicky.Espinosa@intusurg.com;

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bshickich@riddellwilliams.com; bdurbin@riddellwilliams.com

Subject: Josette Taylor, et al. v. Intuitive Surgical Inc. No. 92210-1

Good afternoon:

Attached please find the following document for filing with the Supreme Court:

Document to be filed: Intuitive Surgical's Answer to Petition for Review

Case Name: Josette Taylor, et al. v. Intuitive Surgical Inc.

Case Cause Number: 92210-1

Attorney Names and WSBA#s: Philip A. Talmadge, WSBA #6973 and Sidney Tribe, WSBA #33160

Contact information: Kelley Carroll, (206) 574-6661, assistant@tal-fitzlaw.com

Hard copies to the parties will follow by U.S. Mail. Thank you.

Kelley Carroll, Legal Assistant Talmadge/Fitzpatrick/Tribe PLLC 2775 Harbor Avenue SW Third Floor, Suite C Seattle, WA 98126
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