71411-2

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No. 71411-2-I

COURT OF APPEALS OF THE STATE OF WASHINGTON
DIVISION I

BECKY S. ANDERSON, a single person,

Plaintiff-Appellant,

v.

DONALD R. PAUGH; WENATCHEE VALLEY MEDICAL CENTER, P.S.; LINDA K. SCHATZ; WENATCHEE ANESTHESIA ASSOCIATES; MEDTRONIC, INC.; MEDTRONIC XOMED, INC.,

Defendants-Respondents.

BRIEF OF RESPONDENTS MEDTRONIC, INC. AND MEDTRONIC XOMED, INC.

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I. INTRODUCTION

Appellant Becky Anderson was seriously injured during an elective throat surgery performed by surgeon Donald Paugh, M.D. and anesthesiologist Linda Schatz, M.D. Central Washington Hospital, the facility where the surgery occurred, settled Anderson's claims against it just weeks before trial. Anderson moved for summary judgment against Dr. Schatz, and the trial court found the undisputed facts established that Dr. Schatz breached the applicable standard of care as a matter of law. After a seven week trial, in which the jury heard testimony from over 30 witnesses, the jury found Dr. Paugh and Dr. Schatz liable for Anderson's injuries and awarded damages of $18,000,000.00 jointly and severally against the two doctors and the non-party hospital.[1]

There is no dispute that Anderson experienced a tragic outcome. But that outcome was not attributable to any action or inaction on the part of Medtronic Xomed, Inc.,[2] the manufacturer of the laser-resistant endotracheal tube used in Anderson's surgery, or Medtronic, Inc., the corporate parent of Medtronic Xomed, Inc. (collectively, "Medtronic"). Prior to trial, the court below ruled that Anderson's injuries were not proximately caused by the warnings that accompanied Medtronic's

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[1] Although Dr. Schatz and Dr. Paugh subsequently appealed the verdict and damages award, they withdrew their appeal on July 9, 2014. CP 5199.

[2] Anderson alleged Medtronic, Inc. "acted as a manufacturer or product seller as those terms are understood under the WPLA." Medtronic, Inc. denied these allegations.

endotracheal tube, a prescription medical device. The jury unanimously found that Medtronic complied with the applicable standard of care in its design of the endotracheal tube, and assigned no fault to Medtronic.[3]

Anderson's arguments on appeal are without merit. Her first assignment of error concerns the jury instructions on Anderson's negligent design claim. Anderson twice proposed and endorsed the very pattern instruction given by the court, thereby precluding appellate review. Regardless, the trial court properly refused to inject strict liability into a negligent design case, and the jury instructions, as given, allowed Anderson to argue her theory of the case and were otherwise proper.

Anderson's second argument, challenging the court's dismissal of her failure to warn claim on summary judgment, fares no better. Medtronic's Instructions for Use clearly, accurately, and consistently apprised physicians of the known risks and were adequate as a matter of law. Anderson also failed to prove that Medtronic's warnings proximately caused her injury. Neither Dr. Paugh nor Dr. Schatz read the Instructions for Use that accompanied Medtronic's endotracheal tube. The undisputed evidence established that additional warnings would not have altered the outcome, and any contrary claim is purely speculative.

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[3] The jury assigned 52.5% fault to Dr. Schatz and her practice, 42.5% fault to Dr. Paugh and his practice, and 5% fault to Central Washington Hospital, which was no longer a party at the time of the verdict. CP 2543-45.

II. STATEMENT OF FACTS

A. ANDERSON'S CLAIMS AND THE DISPOSITION BELOW

1. Anderson's Amended Complaint

Anderson's Amended Complaint alleged "Defendants Medtronic, Inc. and/or Medtronic Xomed, Inc. are liable under the Washington Products Liability Act R.C.W. Chapter 7.72. *See* WPI Chapter 110." CP 2232. It thus encompassed various theories, including design defect, failure to warn, manufacturing defect, and breach of warranty. Anderson also alleged negligence by Dr. Paugh, Dr. Schatz, their respective practices, and the hospital at which her surgery occurred. CP 2231-32.

2. The trial court granted Medtronic's motion for summary judgment and dismissed all of Anderson's claims against Medtronic—including failure to warn—except for her negligent design claim.

Prior to trial, Medtronic moved for summary judgment on all of Anderson's claims.[4] CP 3769-94. As to Anderson's failure to warn claim, Medtronic moved on the principal grounds that Medtronic's warnings were adequate as a matter of law and Anderson could not establish proximate causation. CP 3783-87. In her two paragraph opposition,

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[4] This appeal does not implicate any claim under a theory of (i) manufacturing defect or (ii) breach of warranty. Medtronic moved for summary judgment on both theories, CP 3787-89, and Anderson did not oppose Medtronic's manufacturing defect argument in her brief, CP 4423-46, or at oral argument; she also presented no evidence at trial that Medtronic's endotracheal tube was improperly manufactured. In addition, Anderson abandoned, and the trial court dismissed, any breach of warranty claim against Medtronic. RP 93:8-10 (09/20/13); RP 100:8-10 (09/20/13).

Anderson did not oppose Medtronic's argument that her failure to warn claim failed for lack of causation. *See* CP 4441. She also did not argue for application of strict liability. *Id.* Following oral argument, the trial court granted Medtronic's motion, dismissing the failure to warn claim:

> With all due respect to Mr. Leedom and Mr. Cunningham, I'm having a hard time with the notion that there's a proximate cause link when I have an affirmative statement from the learned intermediary that he didn't even bother to look. And I'm going to give the defense the nod on that and dismiss [the failure to warn] claim, because, frankly, what I see happening is if we were to go there, we'd get into an infinite loop of what could have fit on the box. . . . And if you put this much on the box, do you need to put the rest of it on the box. . . .
>
> . . . [T]hese folks are professionals. I think you have to assume that they're going to act in a professional manner, which would mean, in my mind, that they would make sure that they knew how to use the item before they used it.

RP 99:6-100:8 (09/20/13).

Pursuant to the court's summary judgment rulings, Anderson only proceeded against Medtronic at trial under a negligent design theory. Anderson conceded that she could only pursue that claim under a negligence theory: ". . . [O]n the record, I'm willing to accept a negligent standard in this case, because I don't want error." RP 80:17-81:15 (09/20/13). This statement confirmed her previously-stated position.[5]

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[5] *See* CP 4437 ("the WPI instruction on design defects involving comment k products adopts a negligence standard"); CP 4438 ("In order to avoid potential reversible error from an incorrect instruction, Plaintiff is presenting the design defect case under the WPI quoted above [WPI 110.02.01], and not under the consumer expectations test . . .").

3. Anderson proposed, and the trial court gave, a jury instruction that accurately described Anderson's negligent design claim against Medtronic.

At the start of trial, the parties prepared pre-instructions to be read to the jury before opening argument. Anderson and Medtronic submitted nearly identical pre-instructions describing Anderson's negligent design claim against Medtronic. CP 5194; *see also* Plaintiff's Proposed Jury Pre-Instructions.[6] Anderson agreed to these instructions on the record. RP 7:12-19 (10/24/13 PM). The parties' agreed-upon instructions were identical to WPI 110.02.01,[7] and a slightly modified WPI 110.21.

Following three days of hearings on pre-trial motions and four days of voir dire, trial began on October 25, 2013, and the court read pre-instructions to the jury on that date. With respect to Medtronic's duty of care, the court's pre-instruction was identical to Anderson's proposed pre-instruction under WPI 110.02.01. RP 25:21-26:16 (10/25/13). The trial court's instruction on the elements of Anderson's claim against Medtronic only slightly modified the instruction to which Anderson had expressly agreed. RP 25:8-21 (10/25/13). Anderson did not object or take written exception to the pre-instruction. RP 25:8-26:16, 28:8-19 (10/25/13).

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[6] A true and correct copy of Plaintiff's Proposed Jury Pre-Instructions is attached as Appendix A. Medtronic has filed a motion asking the Court to permit submission of Anderson's Pre-Instructions pursuant to RAP 9.11(a) and 10.4(c). Anderson failed to file her Pre-Instructions as required by CR 51(b), and the Pre-Instructions are necessary for the Court of Appeals to fairly resolve these issues on review.

[7] WPI 110.02.01 is titled "Manufacturer's Duty—Design—Unavoidably Unsafe Products—Negligence—Comment K."

The last witness testified on November 27, 2013. That afternoon Anderson submitted Plaintiff's Amended Proposed Jury Instructions. CP 2463. Anderson's proposed instructions as to her claim against Medtronic, CP 2476-77, were identical to the agreed-upon Pre-Instructions she submitted on October 24, 2013. Fn. 6, *supra*. Her instruction concerning Medtronic's standard of care, CP 2476, was again identical to the pre-instruction previously read by the Court. RP 25:8-26:16 (10/25/13 AM).

On December 2, 2013, the day before closing argument, Anderson submitted a proposed supplemental jury instruction wherein she requested an instruction on strict liability principles. CP 4463. As to Anderson's claim against Medtronic, the trial court instructed the jury in accordance with WPI 110.02.01 and WPI 110.21 (as modified). CP 2567-68. The jury returned its verdict on December 3, 2013, finding that Medtronic complied with the applicable standard of care in its design of the endotracheal tube, and assigned no fault to Medtronic. CP 2544-45.

B. THE LASER SHIELD II ENDOTRACHEAL TUBE

In August of 1990, the Food and Drug Administration ("FDA") cleared the Laser-Shield II, a Class II medical device, for market and sale through the 510(k) process. CP 3831. The FDA's primary mission is to protect the public health; it also has a role in promoting innovation in medical devices. RP 92:4-11 (11/26/13 PM). Consistent with both

functions, the FDA reviews the critical aspects of a manufacturer's 510(k) application for safety and effectiveness, RP 76:10-15 (11/26/13 PM); 36:17-37:1 (11/27/13 AM), and scrutinizes the manufacturer's proposed labeling. RP 105:8-14 (11/26/13 PM). The 510(k) review process is "certainly not a rubber stamp," RP 37:2-3 (11/27/13 AM), but rather a thorough and rigorous process for evaluating new medical devices. RP 76:7-9 (11/26/13 PM). In January of 2000, following a supplemental 510(k) application to reflect a design change involving an enhancement to its laser resistant wrapping, the FDA again reviewed the Laser-Shield II and its labeling and cleared it for marketing and sale. CP 3832.

The Laser-Shield II, like any standard endotracheal tube, is inserted into the trachea for the primary purpose of establishing and maintaining a patient's airway and to facilitate the adequate exchange of gases. Unlike standard endotracheal tubes, however, the Laser-Shield II is designed to be used in laser surgeries. CP 3812. Its main shaft is covered in a laser resistant overwrap made of aluminum and Teflon over the silicone shaft of the tube. *Id.* The Laser-Shield II has a dye-filled inflatable cuff near the distal end of the tube, which pursuant to its Instructions for Use, should be inflated with saline to seal the airway. *Id.*

As required by the FDA, every Laser-Shield II comes with "Instructions for Use," which include instructions and warnings for its safe

and proper use.[8] *Id.* The Instructions for Use, as reviewed and cleared by the FDA,[9] warn that the cuff part of the tube is not laser resistant and instructs users to protect the cuff area by placing wet cotton gauze around the cuff. CP 3812. As an additional safety feature, the cuff contains a powder blue methylene dye, which is designed to mix with the saline in the cuff. *Id.* In the event that the cuff is perforated by a laser strike, the blue-dyed saline is designed, assuming it is placed properly, to stain the wet cotton gauze to help the surgeon detect a cuff rupture. *Id.*

The Laser-Shield II's Instructions for Use specifically warn of the risk of fire and serious injury due to elevated oxygen levels. *Id.* For example, the second paragraph of the instructions warns:

> EXTREME CARE MUST BE TAKEN IN MAINTAINING . . . THE OXYGEN GAS MIXTURE CONCENTRATIONS FOR LASER APPLICATIONS.
>
> Failure to comply . . . will cause unnecessary risk to the health and safety of the patient.

Id. Under the heading "WARNINGS," the Instructions for Use also stated: "Do not use surgical lasers or thermal cautery power sources in the presence of elevated oxygen levels or other flammable gases, or damage to the tube may result in ignition and serious patient injury." *Id.*

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8 A true and correct copy of the Instructions for Use is attached as Appendix B.

9 RP 105:8-14 (11/26/13 PM),

In addition, the Instructions for Use explicitly direct: "Dilute oxygen or other flammable gases with Helium, Nitrogen or room air as needed. Dilute oxygen to the minimal inspired concentration compatible with satisfactory oxygen concentration." *Id.* They further provide: "RECOMMENDATION: Use 30% oxygen / 70% helium, or 30% oxygen / 70% room air." *Id.* Finally, the Instructions state that "equipment used must be capable of providing diluted gas mixture concentrations for the safe use of this endotracheal tube in laser surgery." *Id.*

The Instructions for Use plainly warn of the risk of striking the device, and particularly the cuff, with a laser beam. They warn users under the WARNINGS heading: "Do not impact the LASER-SHIELD II with a laser beam" and "Do not contact the cuff or distal end of the shaft with a laser beam or electrosurgical instrument. Contact may cause deflation of the cuff and result in combustion and fire." CP 3812. The Instructions for Use also specify in the very first paragraph that "[t]he proximal and distal end of the silicone elastomer shaft and cuff are not covered and therefore, are not laser resistant." *Id.*

C. ANDERSON'S FEBRUARY 3, 2012 SURGERY

On February 3, 2012 Anderson underwent an elective surgery to remove polyps from her vocal cords at Central Washington Hospital in Wenatchee. CP 4. When the surgery (which was expected to last around

ten minutes) was about 90% complete, a fire ignited in Anderson's airway, causing serious injury. CP 3880 (55:10-24); CP 4.[10]

Dr. Paugh, a board certified otolaryngologist, performed the procedure using a carbon dioxide laser to remove the polyps. CP 4; CP 3868 (8:17-21). Dr. Schatz, a board certified anesthesiologist, administered anesthesia to Anderson during the procedure, which included the administration and monitoring of oxygen. CP 3834 (8:3-6); CP 3850 (29:4-9). Dr. Paugh and Dr. Schatz utilized a Laser-Shield II, a laser-resistant endotracheal tube manufactured by Medtronic, to facilitate the administration of oxygen to Anderson. CP 4. Contrary to the warnings, instructions, and recommendations contained in the Instructions for Use, and despite her own knowledge and training concerning appropriate medical care, Dr. Schatz administered 100% oxygen to Anderson throughout the entire surgical procedure. CP 3812; CP 3850 (32:17-33:1). Anderson alleged that during the procedure Dr. Paugh contacted the cuff of the Laser-Shield II with a laser beam, which was warned against in the Instructions for Use, thereby perforating the cuff and causing the 100% oxygen to reach the surgical field and ignite. CP 4; CP 3812; CP 4424.

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[10] Among other allegations, Anderson alleged Dr. Paugh and Dr. Schatz breached the applicable standards of care in their response to the fire, because Dr. Paugh poured saline down Anderson's throat before Dr. Schatz removed the endotracheal tube, which exacerbated her injury by causing the tip of the tube and other debris to lodge in Anderson's throat and lungs. CP 5125-27.

Dr. Schatz admitted that although she did not know why she did not turn down the oxygen to a level lower than 100% during Anderson's surgery, her training required the oxygen level to be reduced and she should have done so. CP 3855 (51:20-24, 52:13-22). At no time either prior to or during Anderson's surgery did her physicians discuss the proper oxygen level to be administered. CP 3876 (39:1-9). It was not Dr. Paugh's practice to discuss oxygen levels with the anesthesiologist during his laser surgeries; rather, he relied on the anesthesiologist to determine and set the appropriate level. CP 3876 (38:3-8, 39:10-15).

Neither Dr. Paugh nor Dr. Schatz had performed a laser surgery using the Laser-Shield II prior to Anderson's procedure. CP 3846 (13:19-14:3); CP 3870 (13:24-14:5). Their previous surgical experiences involved a similar, but not identical, laser resistant endotracheal tube manufactured by a Medtronic competitor. Both Dr. Paugh and Dr. Schatz expected the competitor's tube to be available when they arrived at the operating room prior to Anderson's surgery, and both were surprised when only Medtronic's tube was available instead. CP 3846 (13:19-14:3, 15:12-16:16); CP 3878 (47:18-14). Dr. Paugh and Dr. Schatz asked operating room staff if the other tube was available, and were told it was not. *Id.*

Despite their inexperience with the Medtronic endotracheal tube, Dr. Paugh and Dr. Schatz elected to proceed with surgery. *Id.* The

Instructions for Use for the Laser-Shield II were in the operating room and available to Dr. Paugh, Dr. Schatz, and the rest of the operative team. CP 3861 (74:16-75:9). Dr. Schatz saw the box containing the Laser-Shield II in the operating room, with the Instructions for Use inside it. *Id.* Dr. Schatz did not testify that she saw or read any of the writing on the box. *Id.* Furthermore, all of Anderson's relevant healthcare providers—Dr. Paugh, Dr. Schatz, and Scott Vandoren, the attending laser safety nurse—affirmatively testified **they did not review the Instructions for Use**. CP 3857 (60:1-6) [Dr. Schatz]; CP 3888-89 (88:13–89:4) [Dr. Paugh]; CP 3911 (42:22–43:2) [Vandoren]. Dr. Paugh did visually inspect the Laser-Shield II prior to beginning the surgery, noting the laser-resistant and non-laser-resistant areas of the tube's design. CP 3891 (99:3-99:21).

Although Dr. Schatz, Dr. Paugh, and Nurse Vandoren did not review the Instructions for Use, they were all well trained and independently aware of **all** risks warned of in the Instructions for Use. They all knew of the risk of fire and that administering oxygen above 30% increased the risk of an airway fire and should be avoided except when medically necessary. CP 3848 (21:17-24); CP 3858 (61:13-19, 62:3-12); CP 3891 (97:8-16); CP 3903 (9:17-10:20). Dr. Paugh understood that laser airway surgery could result in a throat fire. CP 3890 (93:20-94:14).

In addition, even without reading the Instructions for Use, Dr.

Paugh was aware from inspecting the Laser-Shield II prior to the surgery that the proximal and distal ends of the shaft and the cuff are not protected and thus not laser-resistant. CP 3891 (99:3-99:21). Dr. Schatz was also aware that the distal end of the shaft was not laser-resistant and should not be contacted with the laser. CP 3858 (61:4-12, 61:20-62:2). Nurse Vandoren had previously attended a laser safety course where the importance of maintaining a low concentration of oxygen during laser airway surgeries was taught. CP 3903 (9:17-10:2).

Neither Dr. Paugh nor Dr. Schatz had any criticisms of Medtronic's Laser-Shield II. CP 3887 (82:4-7); CP 3893 (106:14-17); CP 3861 (75:13-16). Likewise, neither Dr. Paugh nor Dr. Schatz would render the opinion that Medtronic's endotracheal tube caused the fire in Anderson's airway. CP 3887 (83:4-12); CP 3858 (64:10-16).

III. SUMMARY OF THE ARGUMENT

This Court should affirm both the jury's verdict and the trial court's summary judgment ruling. Anderson's argument that the trial court gave an erroneous jury instruction fails for three reasons. First, Anderson explicitly accepted the instruction given and acknowledged both on the record and in written submissions that a negligence standard applied. She proposed and agreed to jury instructions using a negligence standard mirroring those ultimately given. That she belatedly proposed a

long-abandoned strict liability instruction should not provide the basis for appeal. Second, under Washington law, a negligence standard applies to a design claim asserted against the manufacturer of a prescription medical device like Medtronic's endotracheal tube, and the trial court did not err by refusing to charge the jury on strict liability tests. Third, the trial court's negligence instruction allowed Anderson to argue her theory of the case, was not misleading, and accurately informed the jury about the applicable law.

The trial court also correctly dismissed Anderson's failure to warn claim on summary judgment. As required by law, Medtronic's endotracheal tube was accompanied by written warnings to physicians in the form of Instructions for Use, which accurately and consistently described the very risks and injuries that Anderson could, and unfortunately did, suffer. Medtronic's warnings were thus adequate as a matter of law. Summary judgment was also proper because any alleged inadequacy in the warnings did not proximately cause Anderson's injuries. Although Dr. Schatz and Dr. Paugh had never used Medtronic's endotracheal tube, and despite their awareness that detailed written warnings typically accompany prescription medical devices, they did not review the product insert before Anderson's surgery. Consequently, there is no warning that would have altered Anderson's outcome. Moreover,

the physicians were independently aware of all risks associated with Medtronic's product, and there is no evidence they would have changed their behavior if presented with different or additional warnings.

Anderson's final two arguments cannot disturb the result in the trial court, and are, in any event, without merit. First, Anderson claims that strict liability, not negligence, should apply if her failure to warn claim is remanded. Anderson neither preserved this issue nor assigned error to it here, and the Court should decline to address an issue that was not litigated below. If the Court does address this issue, Anderson's argument is contrary to established Washington precedent. Anderson's final point ignores the trial court's inherent discretion to award costs. Regardless, Anderson's only remedy for an alleged abuse of that discretion is a reduction of her payable costs, not a new trial.

IV. ARGUMENT

A. THE COURT SHOULD AFFIRM THE JURY'S VERDICT BECAUSE THE TRIAL COURT PROPERLY REFUSED TO INSTRUCT THE JURY ON STRICT LIABILITY PRINCIPLES, AND ITS NEGLIGENCE INSTRUCTION ACCURATELY STATED THE APPLICABLE LEGAL STANDARD AND DID NOT PREJUDICE ANDERSON.

Anderson assigns error to the trial court's refusal to instruct the jury in accordance with WPI 110.02, which describes the risk-utility and consumer expectation tests under the Washington Product Liability Act (WPLA), RCW 7.72.030(1)(a) & (c). Although the term "strict liability"

never appears in her discussion of the first assignment of error, the risk-utility and consumer expectation tests define the standard for strict liability under Washington law. Thus, Anderson's argument is that trial court erred in refusing to instruct the jury on strict liability principles.

Anderson's first assignment of error fails for three reasons. First, it is barred by the invited error doctrine. On numerous occasions in the proceedings below, Anderson acknowledged her claim against Medtronic sounded in negligence, not strict liability, and she submitted jury instructions that properly stated the negligence standard. She should not be permitted to create an error because the trial court accepted her proposed instructions. Second, Anderson's claim against Medtronic could only sound in negligence by virtue of Washington's adoption of comment k to the Restatement (Second) of Torts § 402A. Because strict liability principles had no place in the jury's consideration of Anderson's negligence claim, it was not error for the trial court to refuse to give an instruction that incorrectly stated the applicable law. Finally, the negligence instructions as given were sufficient: they allowed Anderson to argue her theory of the case, they were not misleading, and they properly stated the applicable law. The trial court did not abuse its discretion or otherwise prejudice Anderson by declining to define "reasonably safe," particularly when her proposed definition would have misstated the law.

1. Anderson's concessions preclude review.

Anderson asserts that she properly preserved the alleged instructional error for appellate review. *See Brief of Appellant*, p. 13. She does not inform the Court, however, of the many instances when she conceded that negligence, not strict liability, applied to her claim against Medtronic. *E.g.*, CP 4438. Anderson similarly omits that before and during the trial, she not only endorsed, but herself submitted, the exact pattern negligence instruction that was subsequently given by the trial court. *E.g.*, CP 2476-77.

Anderson's support for the negligence standard began as early as her opposition to Medtronic's summary judgment motion. CP 4437 ("the WPI instruction on design defects involving comment k products adopts a negligence standard."). Anderson later affirmed her adherence to this position during the oral argument on Medtronic's motion:

> [The Court]: . . . I guess my only question of you, Mr. Cunningham, is I think that pursuant to the comment K that is interlaced through the briefing here, that the standard that would have to be applied is a negligent standard there. And do you concur with that? I think you do.
>
> [Mr. Cunningham]: Because I'm a member of the plaintiff's bar, and we argue very vehemently that the standard should be the strict liability even for prescription . . . That being said, **and on the record, I'm willing to accept the negligent standard in this case, because I don't want error.**

RP 80:17–81:15 (9/20/13) (emphasis supplied). Anderson's concessions continued throughout her pre-trial submissions. *See* CP 5134 (citing WPI 110.02.01 and stating "[f]or comment k products such as the Laser Shield II, this standard is modified to the extent that negligence is included within the legal standard"). Anderson's trial brief made no mention of the risk-utility test, the consumer expectations test, or WPI 110.02.[11] *Id.*

Anderson did not deviate from her position throughout the trial. She agreed to the pre-instructions concerning her claim against and burden of proof as to Medtronic, which were nearly identical to those given by the trial court at the close of evidence. *Compare* Anderson's Proposed Jury Pre-Instructions (citing WPI 110.21, WPI 110.02.01) [Appendix A] *with* CP 2567-68. Upon submitting these instructions, Anderson stated:

> These are now all agreed. . . . The two instructions dealing with the claim against Medtronic and the burden of proof on Medtronic are in there and agreed to by us.

RP 7:12-19 (10/24/13 PM). The trial court thereafter instructed the jury in

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[11] References to negligence pervade Anderson's arguments during other pre-trial proceedings. *See, e.g.*, RP 36:7-12 (10/17/13 PM) ("[U]ltimately what kind of care did Medtronic exercise in the design. Not only the design at the time but the design over time. Did they have some reason, things that they did or did not do, that they should have done or should not have done? Whatever it was that reflects on the reasonable care."); RP 51:13-18 (10/17/13 PM) ("I just wanted to outline for you our theory of the case. You're right. They were negligent in the way they managed their company, in terms of failing to design a reasonably safe product . . . That's – that's our case. Quite – quite simply stated."); RP 64:9-10 (10/17/13 PM) ("[I]t's not just about the product when I have to prove negligence, your Honor."); RP 12:24-13:17 (10/22/13 AM) ("Just to explain what we did. Because it's a negligence case, we had to add in some negligence concepts because the WPI is written primarily as a strict liability.").

accordance with Anderson's Pre-Instructions, *see* RP 25:8-26:16 (10/25/13), and Anderson did not object to the instruction as given or otherwise take written exception. It was not until December 2, 2013—the day before closing argument—that Anderson first renewed her previously abandoned proposal for a strict liability instruction. CP 4463.

Anderson is precluded from assigning error to jury instructions to which she expressly agreed and to which she never took exception under the invited error doctrine, *e.g.* CR 46; *State v. Bertrand*, 165 Wn. App. 393, 412 n. 19, 267 P.3d 511 (2011); *State v. Winings*, 126 Wn. App. 75, 89, 107 P.3d 141 (2005). It would be unjust to permit Anderson to appeal the trial court's acceptance of her own proposed instructions.

2. The trial court properly refused to give Anderson's requested instruction because strict liability principles are inapplicable to a negligent design claim.

Even if Anderson's concessions were not fatal to her argument on appeal, it was not error for the court to refuse to give her proposed instruction. The "clear rule is that a trial court need never give a requested instruction that is erroneous in any respect." *Crossen v. Skagit Cy.*, 100 Wn.2d 355, 360–61, 669 P.2d 1244 (1983) (internal citation and quotations omitted); *see also Kastanis v. Educ. Emp. Credit Union*, 122

Wn.2d 483, 499, 859 P.2d 26 (1993).[12] Anderson asked the trial court to instruct the jury on the tests for strict liability, but, as she herself admitted, her claim against Medtronic sounded in negligence. The court below thus properly refused Anderson's requested instruction.

Washington has adopted the Restatement of Torts (Second) § 402A (1965), which applies strict liability in claims against product manufacturers. *See, e.g., Terhune v. A.H. Robins Co.*, 90 Wn.2d 9, 12, 577 P.2d 975 (1978). Pursuant to this section, products are deemed to be unreasonably dangerous if an error was committed in the manufacturing or design process, or if the manufacturer failed to warn of a hazard associated with use of the product. *See Ruiz-Guzman v. Amvac Chem. Corp.*, 141 Wn.2d 493, 505, 7 P.3d 795 (2000). "[N]egligence focuses upon the conduct of the manufacturer while strict liability focuses upon the product and the consumer's expectations." *Davis v. Globe Mach. Mfg. Co., Inc.*, 102 Wn.2d 68, 72, 684 P.2d 692 (1984); *accord Young v. Key Pharms.*, Inc., 130 Wn.2d 160, 178, 922 P.2d 59 (1996); *Falk v. Keene Corp.*, 113 Wn.2d 645, 653, 782 P.2d 974 (1989).

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[12] The standard of review for a trial court's refusal to give a particular jury instruction turns on whether the refusal was based on a matter of fact, which are reviewed for an abuse of discretion, or a matter of law, which are reviewed de novo. *Compare State v. Lucky*, 128 Wn.2d 727, 731, 912 P.2d 483 (1996), *overruled on other grounds by State v. Berlin*, 133 Wn.2d 541, 947 P.2d 700 (1997), *with State v. Clausing*, 147 Wn.2d 620, 626-27, 56 P.3d 550 (2002). Here, the Court should review Anderson's first assignment of error for abuse of discretion because the trial court's refusal to give the instruction at issue was at least partially based on Anderson's representations.

The Restatement, however, recognizes an exception for "unavoidably unsafe products" such as prescription drugs and medical devices that "are quite incapable of being made safe for their intended and ordinary use." *Restatement (Second) of Torts* § 402A, cmt, k. Under this exception, a manufacturer or seller of such products "is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." *Id.* In such instances, negligence, not strict liability, applies. *Id.* There is no dispute that Washington has expressly adopted comment k. *Terhune*, 90 Wn.2d at 12; *Rogers v. Miles Labs.*, 116 Wn.2d 195, 203, 802 P.2d 1346 (1991); *Ruiz-Guzman*, 141 Wn.2d at 507-08.

Anderson claims the trial court erred by refusing to give Washington pattern jury instruction 110.02, which describes the risk-utility test and consumer expectation tests under the WPLA. *Brief of Appellant*, p. 13; *see also* CP 4463. These tests, however, define the strict liability standard under Washington law. *See Falk,* 113 Wn.2d at 653 (finding that consumer expectation and risk-utility tests of the WPLA were appropriate for strict liability claims, but not claims based on negligence); *Seattle-First Nat'l Bank v. Tabert*, 86 Wn.2d 145, 154, 542 P.2d 774 (1975) (adopting the consumer expectation test as an element of strict

product liability claims under Washington common law). As established above, Washington does not recognize strict liability claims against the manufacturer of a prescription medical device like the endotracheal tube at issue here.[13] The trial court thus correctly rejected Anderson's instruction.

Contrary to Anderson's arguments, *Soproni v. Polygon Apt*, 137 Wn.2d 319, 971 P.2d 500 (1999) and *Ayers v. Johnson & Johnson*, 117 Wn.2d 747, 818 P.2d 1337 (1991) are inapposite and do not support her position. *Brief of Appellant*, p. 20–22. Although in both cases the Supreme Court upheld the use of the consumer expectation and risk-utility tests, both cases were decided in the context of strict liability claims, and neither involved a prescription medical product to which comment k applied. *See Soproni*, 137 Wn.2d at 502 (claim for negligent design of a window); *Ayers,* 117 Wn.2d at 750 (failure to warn claim against manufacturer of baby oil, an over-the-counter product). Anderson's reliance on *Hub Clothing Co. v. City of Seattle*, 117 Wn. 251, 201 P. 6 (1921) is similarly misplaced. In *Hub Clothing*, the court held it was error to give an instruction that failed to fully define the applicable rule and standards by which the jury was to make its determination of liability. *Id.*

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[13] Medtronic's endotracheal tube is indisputably a prescription medical device that falls within the ambit of comment k. *Young*, 130 Wn.2d at 169–170 (no separate determination required for prescription drug or medical device). Like the device in *Terhune*, "the insertion of [the tube] requires a physician's services, his knowledge and skill . . . and it is he who supplies and inserts the device." 90 Wn.2d at 15.

at 252-54. Here, by contrast, Anderson's proposed instructions would have misstated, not clarified, the applicable rules and standards of liability.

In accordance with Washington's adoption of comment k, the trial court properly refused to give a strict liability instruction in a negligence case. *See Crossen*, 100 Wn.2d at 360–61; *Kastanis*, 122 Wn.2d at 499.

3. The trial court properly and sufficiently instructed the jury on Anderson's negligence claim against Medtronic.

It is well established that the number and language of jury instructions are matters left to the trial court's discretion. *Douglas v. Freeman*, 117 Wn.2d 242, 256, 814 P.2d 1160 (1991). In determining the sufficiency of jury instructions, the test is whether the instructions: (a) permit counsel to argue their theories of the case; (b) are not misleading; and (c) properly inform the trier of fact on the applicable law. *Id.* If the instructions meet these requirements, "[n]o more is required," *id.*, and it is not error to refuse to give an augmenting instruction. *See Havens v. C & D Plastics, Inc.*, 125 Wn.2d 158, 165-66, 876 P.2d 435 (1994); *see also Gammon v. Clark Equip. Co.*, 104 Wn.2d 613, 617, 707 P.2d 685 (1985).

The trial court's instructions complied with this standard, and Anderson was not prejudiced by the court's failure to include the definition of "reasonably safe" in its instructions on the elements of a defective design claim and burden of proof.

a. The trial court's instruction permitted Anderson to argue her theory of the case.

Anderson introduced evidence at trial in accordance with the pre-instructions to which she previously agreed. *See* § A(1), *supra*. Those instructions informed the jury about Anderson's burden of proof, CP 2567, and defined the duty of care owed by a medical device manufacturer like Medtronic, including the duty to test, analyze, and inspect, and to keep abreast of scientific discovery, advances, and research. CP 2568.

These instructions did not constrain Anderson's ability to argue her theory of the case. To the contrary, the record demonstrates Anderson understood her negligence claim required proof of Medtronic's conduct and repeatedly argued and introduced evidence under that standard. In her opening statement, for example, Anderson told the jury that she had "to prove that the defendants acted negligently, and then [she also has] to prove that the negligence was a cause, a proximate cause of the fire and the injury . . ." RP 37:25-38:3 (10/25/2013). Similarly, Anderson did not ask the jury to find that Medtronic's endotracheal tube was not reasonably safe; rather, she focused on Medtronic's conduct. RP 52:8-10 (10/25/13) ("Again, if there are two ways to make a medical device, the manufacturer should choose the safest one possible").

Anderson's direct examination of George Samaras, M.D., her purported expert witness on medical devices, further demonstrates that she sought to elicit testimony establishing whether Medtronic's conduct was consistent with that of a reasonably prudent medical device manufacturer, i.e., testimony relevant to a negligence theory.[14] Anderson specifically asked Dr. Samaras "whether the Medtronic defendants acted as a reasonably prudent medical product company in this case." RP 40:22-25 (11/04/13 AM). She subsequently asked whether the Medtronic risk management process was "reasonably prudent" in addressing the endotracheal tube's potential dangers, RP 41:11-15 (11/04/13 AM), and whether Medtronic complied with the "basic safety rules that . . . are followed by reasonably prudent companies." RP 42:5-7 (11/04/13 AM). Throughout her examination of Dr. Samaras, Anderson repeatedly framed her questions in terms of a reasonably prudent manufacturer, not a reasonably safe medical device. RP 48:4-6; 48:12-13; 48:16-17; 48:19-20; 49:5-7; 49:10-11; 50:7-9; 50:11-13; 50:15-17; 50:21-23; 83:16-19 (11/04/13 AM). Furthermore, Anderson's closing argument framed the jury's decision in much the same terms. *See, e.g.*, RP 64:15-20 (12/03/13

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[14] During Anderson's direct examination of Dr. Samaras, Medtronic objected to her question regarding a reasonably prudent manufacturer's obligation to test for the "safest feasible solution to a problem." RP 46:21-47:7 (11/04/13). Anderson responded that Dr. Samaras was "just talking about how reasonably prudent companies act, and the instruction to the jury is that they have to determine whether this company worked as a reasonably prudent company." RP 47:10-14 (11/04/13).

AM) ("Did [Medtronic] take actions to try to make their product safer or did they close their eyes").[15]

At no time prior to the submission of her proposed jury instructions on December 2, 2013, did Anderson attempt to define the phrase "reasonably safe" to the jury. For over a month, Anderson elicited evidence concerning Medtronic's duty of care to design medical devices that are reasonably safe, and during that time she never referred to the risk-utility or consumer expectation tests or the balancing of the various factors those tests require. Rather, in accordance with established Washington law, Anderson focused the jury on Medtronic's conduct, and its alleged failure to anticipate or correct dangers inherent in the use of its product that were either known or knowable—a theory which "rings of negligence." *Rogers*, 116 Wn.2d at 207. The trial court's instructions clearly permitted Anderson to argue her theories of the case.

b. The trial court's instruction was not misleading and properly informed the jury on the applicable law.

Anderson argues it was error for the trial court to instruct the jury that Medtronic had "a duty to use reasonable care to design medical

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[15] *See* also RP 63:10-15 (12/03/13 AM) (asking the jury what Medtronic did to test and analyze its endotracheal tube to try to make it safer); 66:17-24 (12/03/13 AM) ("And reasonable care . . . is basically to design the medical devices that are reasonably safe, and their obligation is to act as a reasonably prudent medical device company."); 67:16-23 (12/03/13 AM) ("[Was Medtronic] trying to make the best and safest device possible for all reasonable foreseeable circumstances in the ten to twelve years between the launch of this product and [Anderson's injury]?").

devices that are reasonably safe" without also defining what constitutes a "reasonably safe" product. *Brief of Appellant*, pp. 12–13. But her proposed remedy—to instruct the jury on strict liability principles—would have misled the jury and misstated the applicable law, and Anderson identifies no case in the context of prescription medical products in which a court applied the strict liability tests described in WPI 110.02 in lieu of or in addition to the negligence standard set forth in WPI 110.02.01. As discussed above, the standard of liability as to Medtronic, a manufacturer of prescription medical products, is negligence, **not** strict liability.

To prove a negligence claim, a plaintiff must establish that: (1) that the defendant owed a duty of care to the plaintiff, (2) the defendant breached that duty, (3) the defendant's breach proximately caused the plaintiff's injury, and (4) damage. *See*, *e.g.*, *Davis*, 102 Wn.2d at 73. The trial court's instructions apprised the jury of these elements, *see* CP 2567-68, and Instruction No. 20 specifically defined the standard of care owed by a reasonably product medical device manufacturer. CP 2568. Both Instruction No. 19 and Instruction No. 20 followed the Washington Pattern Jury Instruction, and the "Note on Use" for WPI 110.02.01 specifically states that it should be used "in cases involving prescription drugs and medical devices." Accordingly, the trial court's instructions were not misleading and properly informed the jury on the applicable law. *See*

Young, 130 Wn.2d at 175-76 (upholding negligence instruction against prescription drug manufacturer); *see also State v. Bennett*, 161 Wn.2d 303, 307-08, 165 P.3d 1241 (2007) ("Washington has adopted pattern jury instructions to assist trial courts. . . . [P]attern instructions generally have the advantage of thoughtful adoption and provide some uniformity in instructions throughout the state").

The trial court's instructions also were proper because they were consistent with the pre-instructions. At the beginning of the case, the trial court instructed the jury on the law applicable to a negligence claim, which focuses on Medtronic's conduct. RP 25:21-26:16 (10/25/13). Anderson's last-minute proposed instruction, in contrast, would have required the jury to evaluate the consumer's expectations. Such an evaluation is inherently inappropriate in a negligence action, *e.g., Young*, 130 Wn.2d at 178, and it would have been highly confusing to the jury to have considered the evidence under one legal framework only to have the court introduce a new framework immediately before deliberations. *See Beville v. Ford Motor Co., Inc.*, 319 F. App'x 525, 528 (9th Cir. 2009) (finding no abuse of discretion where trial court refused proposed

instructions concerning claims "that were not presented at trial").[16] The trial court stressed the importance of consistent instructions, RP 7:21-8:1, RP 58:24-59:1 (11/27/13 PM), and it was not error to refuse Anderson's effort to inject a new standard at the close of the case.[17]

B. THE COURT SHOULD AFFIRM THE TRIAL COURT'S DECISION TO GRANT SUMMARY JUDGMENT ON ANDERSON'S FAILURE TO WARN CLAIM.

On review of an order granting summary judgment, the Court of Appeals applies a de novo standard of review, *Ruvalcaba v. Kwang Ho Baek*, 175 Wn.2d. 1, 6, 282 P.3d 1083 (2012), and performs the same inquiry as the trial court. *Hisle v. Todd Pac. Shipyards Corp.,* 151 Wn.2d 853, 860, 93 P.3d 108 (2004). To effectuate an identical de novo inquiry, the appellate court will only consider evidence and issues called to the

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[16] *See also Arnold v. Laird*, 94 Wn.2d 867, 870, 621 P.2d 138, 140 (1980). In *Arnold*, the Supreme Court affirmed trial court's refusal to give supplemental instructions on a negligence theory as proposed near the end of trial. The court "refused to instruct on the newly advanced theory on two alternate grounds: (1) the negligence theory was subsumed by the 'strict liability' theory and did not exist independently; and (2) no actionable negligence was established." *Id.* Similar reasoning should prevail here. Strict liability does not apply in this case, and Medtronic's duty to design a "reasonably safe" device is simply part of the applicable standard of care as defined by WPI 110.02.01.

[17] Anderson's other arguments lack merit. Anderson argues, for example, that she was prejudiced because Medtronic's closing arguments utilized the phrase "reasonably safe." *Brief of Appellant*, pp. 14-15, 23-24. As a starting point, the applicable jury instruction, WPI 110.02.01, includes the phrase "reasonably safe," and Medtronic did not commit misconduct by following the pattern. Even if Medtronic's closing arguments were improper, which Medtronic denies, Anderson failed to preserve the alleged error by requesting a curative instruction, *e.g.*, *Rasor v. Retail Credit Co.*, 87 Wn.2d 516, 532, 554 P.2d 1041 (1976) or making a timely objection. *E.g.*, *Loeffelholz v. Citizens for Leaders with Ethics and Accountability Now*, 119 Wn. App. 665, 708, 82 P.3d 1199 (2004).

attention of the trial court.[18] *Mithoug v. Apollo Radio of Spokane*, 128 Wn.2d 460, 462, 909 P.2d 291 (1996). Summary judgment is appropriate if "after viewing the pleadings and record, and drawing all reasonable inferences in favor of the non-moving party, [the court] finds there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law." *Mayer v. Pierce Cy. Med. Bur., Inc.*, 80 Wn. App. 416, 420, 909 P.2d 1323 (1996). The Court of Appeals may affirm on any basis supported by the record. *E.g.*, *Fabrique v. Choice Hotels Int'l, Inc.*, 144 Wn. App. 675, 682, 183 P.3d 1118 (2008).

A manufacturer of prescription drugs or medical devices owes a duty to warn of the known dangers and risks associated with such products. *E.g.*, *Estate of LaMontagne v. Bristol-Myers Squibb* ("*LaMontagne*"), 127 Wn. App. 335, 343-44, 111 P.3d 857 (2005) (citing *Restatement (Second) of Torts* § 402A, cmt. k (1965)). Because many

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[18] Anderson refers to an article authored by Kenneth R. Laughery to support her failure to warn argument. *See Brief of Appellant*, pp. 27 n. 31, 28. This article was not attached as an exhibit to or otherwise cited in either Medtronic's motion for summary judgment, *see* CP 3801-03, or Anderson's opposition. *See* CP 4159-61. Because the article was never called to the attention of the trial court before entry the summary judgment order, it may not be considered on appeal. *See State v. Young*, 62 Wn. App. 895, 899–900, 802 P.2d 829 (1991) (granting motion to strike medical journal articles that were not presented to the trial judge and were not part of the record), *opinion modified on reconsideration*, 62 Wn. App. 895, 817 P.2d 412 (1991); *see also Beaupre v. Pierce Cy.*, 161 Wn.2d 568, 576 n. 3, 166 P.3d 712 (2007) (granting motion to strike documents filed with appeal that were not before the trial court on summary judgment, were not attached to any filed motion or response, and were disallowed by the trial court in response to the proponent's motion to supplement). Even if the Court considers the Laughery piece, an opinion article can neither provide nor displace the legal standard established by the Washington courts.

drugs and medical devices are "available only on prescription or through the services of a physician, the physician acts as a 'learned intermediary' between the manufacturer or seller and the patient." *Terhune*, 90 Wn.2d at 14. Under the learned intermediary doctrine, a manufacturer fulfills its duty to warn by providing adequate warnings to the physician.[19] *LaMontagne*, 127 Wn. App. at 345 (quoting *Terhune*, 90 Wn.2d at 13). The physician, in turn, has a "duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product." *Terhune*, 90 Wn.2d at 14. At oral argument Anderson essentially concurred with this recitation of the law. RP 84:4-17 (9/20/13) ("[T]he manufacturer has . . . a duty to use reasonable care in regard to issuing warnings or instructions concerning any such danger. This duty is satisfied if the manufacturer exercises reasonable care to inform health care providers who prescribe or use the product.").

Washington has adopted comment k to the Restatement (Second) of Torts § 402A. *See* § A(2), *supra*. In accordance with "Washington

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[19] Manufacturers of prescription medical products most commonly warn physicians of risks and dangers via the Physicians' Desk Reference and "the manufacturer's formal warning in the package insert." *Martin v. Hacker*, 83 N.Y.2d 1, 9, 628 N.E.2d 1308 (1993). Such warnings are "to be read and understood by physicians, not laypersons . . ." *Id.* at 10.

case law interpreting comment k," whether Medtronic "satisfied its duty to warn physicians of known dangers raises an issue of negligence, not strict liability." *Young*, 130 Wn.2d at 169. Consequently, summary judgment is appropriate if Anderson failed to prove either that the warning was inadequate *or* that lack of adequate warning proximately caused her alleged injuries. *See, e.g., Adams v. Synthes Spine Co., LP.*, 298 F.3d 1114, 1118 (9th Cir. 2002) (applying Washington law and affirming summary judgment because warnings were adequate as a matter of law).

Here, Anderson's negligent failure to warn claim fails both because Medtronic's warnings were adequate as a matter of law and because Anderson did not—and cannot—establish that any alleged inadequacy proximately caused her injuries. Although Anderson's failure to prove causation was at the heart of the court's dismissal of her warning claim, RP 99:6-100:8 (9/20/13), this Court can affirm for either reason.

1. The Court should affirm summary judgment because Medtronic's warnings were adequate as a matter of law.

"A warning for a prescription drug may be adequate as a matter of law if it provides specific and detailed information about the risks of using the drug." *LaMontagne*, 127 Wn. App. at 344 (citation omitted). To evaluate the adequacy of a particular warning, courts must analyze:

> the warnings as a whole and the language used in the package insert. The court must examine the meaning and context of the

> language and the manner of expression to determine if the warning is accurate, clear and consistent and whether the warning portrays the risks involved in taking the prescription drug.

Id.

Summary judgment is appropriate when a medical device manufacturer provides plain and unequivocal instructions and warnings related to the use of the device, and the physician's failure to heed those instructions is not sufficient to support a claim of inadequacy. *See*, *e.g.*, *Adams*, 298 F.3d at 1118 ("There isn't any evidence in the record from which reasonable jurors could conclude that the warning was inadequate. It plainly said that the plate could break and that the manufacturer recommended removal. That physicians didn't follow the recommendation doesn't show that they couldn't or didn't read it and understand it, just that in their medical judgment, it wasn't wise to follow it."). Rather, if the manufacturer provides instructions and warnings that apprise the physician of the proper procedures and the dangers involved, it "may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient." *Terhune* 90 Wn.2d at 14.

a. Medtronic's warnings are accurate, clear, and consistent.

Medtronic accurately, clearly, and consistently portrayed on its product the risks associated with use, including the specific risks and

injuries that tragically occurred in this case. In particular, the Instructions for Use expressly described the device as:

> an endotracheal tube with a laser resistant overwrap of aluminum and a fluoroplastic covering the silicone elastomer shaft. The white wrap area, excluding the most distal 2mm of white wrapping is laser resistant . . . The proximal and distal end of . . . shaft and cuff are not covered and therefore are not laser resistant.

CP 3812. Dr. Paugh admits that he did not read the Instructions for Use. *See* § B(3)(a), *infra*. If he had, the Instructions for Use would have informed him of what he knew already from his own observation: only part of the device is laser resistant, while the remainder is not.

The Instructions for Use also expressly instruct physicians to avoid contact between the laser and the device and further identifies the risks associated with such contact:

> Do not impact the LASER-SHIELD II with a laser beam. The reflect aluminum wrapping is exposed and energy of the laser beam may be reflected onto the patient's tissue causing injury.
>
> Do not contact the cuff or distal end of the shaft with a laser beam or electrosurgical instrument. Contact may cause deflation of the cuff and result in combustion or fire.

CP 3812. Had Dr. Paugh read the Instructions for Use, and had he not already known, he would have learned that he should avoid contact between the laser and the device to minimize risk, including the risk of fire, to his patient.

The Instructions for Use also address the importance of appropriate

oxygen levels and the perils associated with elevated oxygen:

> EXTREME CARE MUST BE TAKEN IN MAINTAINING THE APPROPRIATE POWER DENSITY OF THE LASER AND THE OXYGEN GAS MIXTURE CONCENTRATIONS FOR LASER APPLICATIONS.

Id. The "WARNINGS" section of the insert also instructs physicians that they should "not use surgical lasers or electro or thermal cautery power sources in the presence of elevated oxygen levels or other flammable gases, or damage to the tube may result in ignition and serious patient injury." *Id.* The "INSTRUCTIONS FOR USE" section states that "oxygen or other flammable gases" should be diluted with Helium, Nitrogen or room air as needed" and that oxygen should be diluted "to the minimal inspired concentration compatible with satisfactory oxygen saturation." CP 3813. Additionally, the Instructions for Use recommend a mixture of 30% oxygen and 70% helium or room air. *Id.*

Medtronic's warnings are indisputably accurate, clear, and consistent. The Court should affirm the dismissal of Anderson's failure to warn claim for this reason alone.

b. Anderson's arguments are legally invalid and factually unpersuasive.

Anderson does not argue that the warnings contained in the Instructions for Use were inadequate or did not accurately and comprehensively warn of all of the risks of her surgery. Instead, she

claims that the exterior of the box in which the product was packaged should have reminded physicians "of the need to review the [Instructions for Use] before use." *Brief of Appellant*, p. 28. Anderson made the same argument to the trial court, *see* RP 87:1-4, 88:18-20, 89:5-7 (9/20/13), and the trial court properly rejected it.[20]

Anderson's contentions are not supported by Washington law, particularly in the context of prescription drugs and medical devices.[21] For example, the plaintiff in *Adams*, much like Anderson here, argued "basically that the warning wasn't clear enough for a doctor to notice or understand," and was inadequate because, according to the plaintiff, physicians never followed the warning. *Adams*, 298 F.3d at 1118. In awarding summary judgment to the defendant, the court focused not only on the substance of the labeling itself but on the unique nature of medical devices: "[t]he words in the warning are perfectly clear. What's more, this isn't something where the physicians just mail away for it, read the

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[20] Anderson's opposition to Medtronic's arguments on this issue focused exclusively on the name of Medtronic's product. CP 4441.

[21] For example, Anderson relies on *Little v. PPG Indus., Inc.*, 92 Wn.2d 118, 122, 594 P.2d 911 (1979), for the proposition that the proper question is whether the warning was "sufficient to catch the attention of persons who could be expected to use the product; to apprise them of its dangers and to advise them of the measures to take to avoid those dangers?" *Brief of Appellant*, p. 26. The product at issue in *Little*, however, was a cleaning solvent, a consumer product. *Little*, 92 Wn.2d at 119. The Supreme Court therefore appropriately applied a strict liability standard, not the negligent standard that is applicable here. Moreover, the opinion in *Little* does not turn on an evaluation of the warnings at issue, and the Court framed the operative question not to answer it but to explain why the defendant's conduct, and the concept of reasonableness, were not relevant to the adequacy of warnings under a strict liability theory. *Id.* at 122-24.

directions, and start screwing these things into patients' spines." *Id.* Even outside the medical context, a manufacturer who provides adequate warnings in an instruction booklet or operator's manual is not required to inform the product's user that he or she must read the manual before using the product. *Stepp v. Takeuchi Mfg. Co. (U.S.) Ltd.*, No. C07-5446 (RJB), 2008 WL 4460268, *8-9 (W.D. Wash. Oct. 2, 2008) (affirming summary judgment in defendant's favor on failure to warn claim).

Anderson's reliance on New York law, specifically *Baker v. St. Agnes Hosp.*, 70 A.D.2d 400, 421 N.Y.S.2d 81 (2d Dep't 1979), is equally unpersuasive. *Brief of Appellant*, p. 27 n. 32. In *Baker*, the Second Department found a factual issue even though the physician had not read the package insert. Such inserts, noted the court, "are included within the drug package when it is shipped to the pharmacy. The pharmacist, however, often removes and discards the insert . . ." 70 A.D.2d at 406. Thus, the manufacturer established "no system for insuring, or even making it likely, that physician sees the insert." *Id.*

Here, in contrast, the physicians opened the box that contained the Instructions for Use just moments before the surgery, and Dr. Schatz knew the Instructions for Use were in the box. CP 3861 (74:25-75:9). Moreover, no Washington court has adopted a similar legal standard, and *Baker's* holding is unique to its facts and hardly representative of New

York law. *See, e.g., Wolfgruber v. Upjohn Co.*, 72 A.D.2d 59, 61-62, 423 N.Y.S.2d 95, 97 (1979) ("We consider *Baker* distinguishable since in that case the warnings were furnished at one time in the Physician's Desk Reference and then later discontinued") *aff'd on opn below,* 52 N.Y.2d 768, 417 N.E.2d 1002 (1980); *Eiser v. Feldman*, 123 A.D.2d 583, 584, 507 N.Y.S.2d 386 (1st Dep't 1986) ("[w]here, as here, express warnings have been given against the complained-of harm, bare allegations of inadequacy . . . are not sufficient to defeat . . . summary judgment."). Here, as in *Wolfgruber*, "not only were the warnings fully descriptive and complete, but they were communicated to the prescribing physician . . ." 72 A.D.2d at 61-62. And, as in *Eiser*, Anderson's "bare allegations of inadequacy" were insufficient to create an issue of fact.[22]

Finally, Anderson's argument, if taken to its logical conclusion, would effectively preclude any defendant from establishing that its warnings were adequate as a matter of law. Even if the Instructions for Use described the precise risk that the plaintiff experienced, the plaintiff

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[22] Anderson also states that "*Baker* is cited with approval in *Martin v. Hacker*, 83 N.Y.2d 1, 8, 628 N.E.2d 1308 (1993), which is in turn cited with approval in *LaMontagne*, 127 Wn. App. at 344." *Brief of Appellant*, p. 27 n. 32. This representation is misleading. To the extent *Baker* is approved by *Martin*, it is for a different and unrelated proposition. In fact, the decision in *Martin*, rendered by New York's highest appellate court, is unequivocal, directly contrary to *Baker*, and supports Medtronic's position here: the adequacy of warnings provided in connection with prescription drugs can be determined as a matter of law such that summary judgment is warranted when the "package insert contains language, which on its face, warns against the precise risk in question . . ." *Martin*, 83 N.Y.2d at 15-16.

could say that the warning should have been placed on the box. Even if some warnings were provided on the box, a plaintiff could say that the manufacturer prioritized the wrong warnings in the limited space on the packaging. The trial court identified the fallacy of this argument, and properly rejected Anderson's contention. RP 99:6-21 (9/20/13).

2. The trial court properly found Anderson failed to prove Medtronic's warnings proximately caused her injuries.

It is axiomatic that Anderson bears the burden of proving the lack of adequate warnings proximately caused her injuries. *E.g.*, *Soproni*, 137 Wn.2d at 325 ("In a product liability action, the plaintiff must prove that his or her injuries were proximately caused by a product . . . because adequate warnings or instructions were not provided."). Because the undisputed evidence established that any additional or different warnings would not have impacted the outcome, the trial court properly granted summary judgment in Medtronic's favor based on Anderson's inability to prove proximate cause. *E.g.*, *Davis,* 102 Wn.2d at 74 ("If an event would have occurred regardless of defendant's conduct, that conduct is not the proximate cause of the plaintiff's injury"). On appeal, Anderson fails to even address her inability to establish causation. This failure, in and of itself, supports the dismissal of her failure to warn claim.

Anderson cannot establish proximate causation for three reasons.

First, her physicians did not read the written instructions provided by Medtronic despite knowing that the product insert existed. Second, her physicians were independently aware of the risks associated with using an endotracheal tube in laser surgery. Third, the undisputed facts demonstrate that no amount of additional warnings would have altered the behavior of Anderson's physicians.

a. Anderson cannot establish proximate causation because neither Dr. Paugh nor Dr. Schatz reviewed the Instructions for Use.

A physician's failure to review or read available warnings breaks the causal chain because the plaintiff cannot prove additional information would have altered the outcome. *E.g.*, *Hiner v. Bridgestone/Firestone, Inc.*, 138 Wn.2d 248, 257-58, 978 P.2d 505 (1999) (finding no proximate cause as a matter of law because plaintiff failed to either read the provisions in the product's owner's manual or otherwise examine product for warnings); *Douglas v. Bussabarger*, 73 Wn.2d 476, 477-78, 438 P.2d 829 (1968) (affirming jury verdict for drug manufacturer because "even if we assume [additional] labeling should have taken place, [the physician] testified that he relied on his own knowledge of anesthetics and, in fact, did not read the labeling which was on the container"). Courts in other jurisdictions have reached the same conclusion in the context of prescription medical devices. *See*, *e.g.*, *Jones v. C. R. Bard, Inc.*, No.

2:11-cv-00114, 2013 WL 5591948, *6 (S.D. W. Va. Jun. 4, 2013) ("Simply put, because Dr. Williams did not review the [Instructions for Use], no amount of warnings contained in it would have caused Dr. Williams to act any differently"); *Sosna v. Am. Home Prod.*, 298 A.D.2d 158, 748 N.Y.S.2d 548 (1st Dep't 2002) (same); *Motus v. Pfizer, Inc.*, 196 F. Supp. 2d 984, 999 (C.D. Cal. 2001) (same).

Here, none of Anderson's medical providers actually read the Instructions for Use that accompanied the Laser-Shield II.[23] *See* CP 3857 (60:1-6) [Schatz Dep.]; CP 3888 (88:13-89:4) [Paugh Dep.]. Thus, other or additional warnings would not have yielded a different result. *E.g.*, *Hiner*, 138 Wn.2d at 257-58.

Anderson may attempt to argue that a jury was entitled to decide whether additional warnings on the box would have altered the conduct of her physicians. If this is her argument, it fails for lack of evidentiary support: neither Dr. Paugh nor Dr. Schatz testified that any additional warnings would have convinced them to read the Instructions for Use that they chose not to review. Even drawing every inference in Anderson's favor, as the Court must do, it is "purely speculative" to claim that Dr. Paugh and Dr. Schatz would have acted differently—and prevented the

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[23] Dr. Schatz unequivocally testified that the Instructions for Use were in the box and available to both her and Dr. Paugh had they wanted to review them prior to Anderson's surgery. CP 3861 (74:25-75:9).

injury to Anderson—had the tube been in a different box. *Baughn v. Honda Motor Co., Ltd.*, 107 Wn.2d 127, 144, 727 P.2d 655 (1986).

To the extent Anderson maintains her argument that the box specifically should have warned physicians to reduce the oxygen level, *see* RP 87:1-4, 88:18-20, 89:5-7 (9/20/13), that argument is unsupported by any competent evidence. Dr. Schatz, the anesthesiologist, saw the box containing Medtronic's endotracheal tube, but she did not testify that she saw or read any of the writing on the box. CP 3861 (74:16-75:9). Regardless, Dr. Schatz did not criticize the box in any way, and she already knew about the combustion risk associated with high oxygen levels. *See* § B(3)(b), *infra*. The only physician testimony about the box came from Dr. Paugh, the surgeon. Dr. Paugh, however, does not participate in, let alone make, decisions regarding the level of oxygen administration, CP 3876 (38:3-8), and he has no recollection of doing so in this case. CP 3882 (64:7-9); CP 3892 (102:12-22). Prior to Anderson's surgery, it was not Dr. Paugh's practice to address the level of oxygen administration with the anesthesiologist. CP 3876 (39:10-15). Because Dr. Paugh played no role in setting the oxygen level, his testimony cannot establish that Anderson's injury would have been avoided even if the box

had "reminded" physicians to use reduced oxygen levels.[24]

For all of these reasons, Anderson's claim fails for lack of proof of causation. *Hiner*, 138 Wn.2d at 257-58; *Stepp*, 2008 WL 4460268 at *8-9.

b. Anderson cannot establish proximate causation because her physicians were independently aware of the risks associated with the endotracheal tube.

An alleged failure to provide adequate warnings does not proximately cause an injury if the product user is independently aware of the risks and dangers associated with the product. *See Baughn*, 107 Wn.2d at 143-44; *Soproni*, 137 Wn.2d at 326 (affirming summary judgment dismissal of failure to warn claim against window manufacturer where plaintiff was aware that an open window presented a danger and that her child had easily opened the window just prior to his fall). The same is true in the context of prescription drugs and medical devices. *See, e.g.*, *Ellis v. C. R. Bard, Inc.*, 311 F.3d 1272, 1280 (11th Cir. 2002) (affirming summary judgment for manufacturer of medical device where plaintiff's healthcare providers had actual knowledge of risks that were not identified in product literature).

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[24] At most, Dr. Paugh testified that he thought Medtronic's tube could be struck by the laser because of the name "LASER SHIELD II." CP 3890 (93:10-19). He certainly did not testify that he struck the tube on purpose or that he would not have struck the tube had its box borne the trade name "LASER RESIST II" or otherwise warned him to avoid contact between the laser and the tube. Dr. Paugh knew from his own inspection that the cuff was not laser resistant. CP 3891 (99:3-21). Dr. Paugh also acknowledged that the laser can strike any endotracheal tube, and he's "certain [he's] struck the tube that [he] had use[d] for years on the other cases." CP 3890 (96:15-20).

Anderson's failure to warn claim fails for lack of proof of causation because her medical providers admitted they were independently aware of the dangers associated with the product. Based on his general training and experience, Dr. Paugh was aware that it was dangerous to use surgical lasers in the presence of elevated oxygen levels. CP 3891 (97:8-16). He generally knew there was an inherent risk of fire when using a laser in a surgical procedure, CP 3894 (111:11-14), and he specifically knew that using an endotracheal tube during laser surgery could result in a fire within a patient's throat. CP 3890 (94:7-14). Based on his own firsthand observation, he knew that certain parts of the Medtronic endotracheal tube, including the cuff, were not laser resistant. CP 3891 (99:3-21). Dr. Schatz, too, knew that laser surgery required "extreme care" to retain the appropriate "oxygen gas mixture concentration," CP 3858 (61:13-19), because "high oxygen supports combustion." CP 3855 (51:19); *see also* CP 3848 (21:17-24). Dr. Schatz also knew only some parts of the tube were laser resistant, CP 3858 (61:6-12), and that striking the cuff with the laser could result in fire. CP 3858 (61:20-62:2).

Because Dr. Paugh and Dr. Schatz were independently aware of all the risks associated with use of the Medtronic product, Anderson cannot establish that allegedly inadequate warnings caused her injury. *See Baughn*, 107 Wn.2d at 143-44; *Anderson v. Weslo, Inc.*, 79 Wn. App. 829,

840, 906 P.2d 336, 341 (1995) (a "manufacturer does not have a duty to warn of obvious or known dangers").

c. Anderson cannot establish proximate causation because no amount of warnings would have changed her physicians' behavior.

If the evidence reflects that additional warnings "would have made no difference," Anderson cannot prove proximate causation. *See Kauffman v. Manchester Tank & Equip. Co.*, 203 F.3d 831 (9th Cir. 1999); *see also Anderson,* 79 Wn. App. at 839 (no proof of causation because "when a person is aware of the risk and chooses to disregard it, the manufacturer's warning serves no purpose in preventing the harm").

The undisputed testimony established that Dr. Paugh expressed concern when he was presented with the Medtronic endotracheal tube in lieu of the device he customarily used. *See* CP 3846 (15:17-21); *see also* RP 88:4-7 (9/20/13). Under these circumstances a reasonably prudent physician would have reviewed the Instructions for Use for any unique instructions or warnings.[25] Yet despite his lack of familiarity with the product, and notwithstanding his independent awareness of the attendant risks and dangers, Dr. Paugh declined to avail himself of the information contained in the Instructions for Use. CP 3888-89 (88:13-17, 88:25-89:4).

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[25] Dr. Schatz also admitted that a reasonably prudent physician should be aware of the warnings and instructions associated with a medical device the physician had never used before. CP 3856 (54:5-10, 55:3).

Dr. Paugh thus "paid so little attention to the warnings that were given, [that] it is unlikely that he would have changed his behavior in response to even more detailed warnings." *Anderson*, 79 Wn. App. at 839.

C. THE COURT SHOULD DECLINE TO PROVIDE AN ADVISORY OPINION ON AN ISSUE THAT WAS NOT RAISED BELOW; ALTERNATIVELY, THE COURT SHOULD RULE THAT NEGLIGENCE APPLIES TO A WARNINGS CLAIM IN THE MEDICAL CONTEXT.

Although the issue is not labeled as an assignment of error, *Brief of Appellant*, p. ii, Anderson asks this Court to provide guidance for the benefit of the trial court on remand by ruling that "strict liability," as opposed to negligence, "is the standard for failure-to-warn claims in the medical context." *Brief of Appellant*, p. 29. The Court should decline to address this issue because Anderson seeks relief that she did not request in the court below. Even if Anderson's request were properly before the Court, negligence, not strict liability, applies to a failure to warn claim against manufacturers of prescription medical products.

1. Anderson failed to preserve this issue for review and seeks an improper advisory opinion.

Anderson's apparent challenge to the standard for her failure to warn claim is not adequately preserved for review, and improperly asks the Court to render an advisory opinion. *See* RAP 2.5(a) (an appellate court "may refuse to review any claim . . . not raised in the trial court.").

Anderson never asked the trial court to apply a strict liability

standard to her failure to warn claim, and she admits that "[t]he superior court below did not address the standard of liability." *Brief of Appellant*, p. 29. She also did not raise this issue in her summary judgment opposition, *see* CP 4441, or at oral argument. *See* RP 83-93 (09/20/13). She likewise never asked the trial court to adopt the dissent in *Young*, 130 Wn.2d at 179-89, which is now the basis of her argument. *See Brief of Appellant*, pp. 29-31. To the contrary, Anderson repeatedly acknowledged that negligence was the appropriate standard for all her claims, including failure to warn. RP 81:8-10 (9/20/13). As such, Anderson did not preserve this issue for appellate review. *E.g.*, *State v. Davis*, 175 Wn.2d 287, 344, 290 P.3d 43 (2012) (declining to review unpreserved argument in part because motion "did not mention . . . the case around which [appellant's] argument here is based"); *Foster v. Gilliam*, 165 Wn. App. 33, 49, 268 P.3d 945 (2011) (appellant abandoned issue and "cannot raise it now for the first time on appeal" because he did not make argument in memorandum of law or oral argument in trial court).[26]

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[26] Furthermore, although Anderson challenges the *evidentiary* basis of the trial court's ruling on Medtronic's summary judgment motion, she does not claim the trial court erred by applying a negligence standard to her failure to warn claim. *Brief of Appellant*, pp. 25-28. Although she contends *Caruso v. Local Union No. 690*, 100 Wn.2d 343, 352, 670 P.2d 240 (1983) authorizes the Court to provide guidance to the trial court on remand, the Court in that case addressed instructional errors identified and properly preserved by the petitioner. By contrast, Anderson is essentially requesting an improper advisory opinion, and "[b]ecause this issue has not been litigated below and may never be, [the Court should] decline to address it." *Commonwealth Ins. Co. of Amer. v. Grays Harbor Cy.*, 120 Wn. App. 232, 245, 84 P.3d 304 (2004).

2. In the context of prescription medical products, a negligence standard applies to any claim that the manufacturer provided inadequate warnings.

If the Court is inclined to address this issue, it should hold that a negligence standard applies to Anderson's failure to warn claim. Anderson assertion that "it is not settled" whether strict liability or negligence governs a failure to warn claim in the context of prescription drugs and medical devices is based entirely on two dissenting opinions. It thus ignores over twenty years of Washington decisions in which courts have held that a negligence standard applies to claims that a manufacturer of prescription medical products failed to adequately warn the patient's physician. *Rogers*, 116 Wn.2d at 207; *accord Young*, 130 Wn.2d at 169 (holding that whether a medical device manufacturer "satisfied its duty to warn physicians of known dangers raises an issue of negligence, not strict liability."); *LaMontagne*, 127 Wn. App. at 335 (same).[27]

Anderson's suggestion that the Court overrule *LaMontagne* for policy reasons, *see Brief of Appellant*, p. 31-32, misunderstands the Court's role. The Legislature is presumptively aware of the state of the law generally and judicial construction of its enactments specifically.

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[27] *See also Ruiz-Guzman*, 141 Wn.2d at 516 (Talmadge, J., dissenting) ("In general, the rationale for imposing strict liability . . . does not apply in the context of imposing liability for . . . defects based on inadequate instruction or warning. Consumer expectations as to . . . warnings are typically more difficult to discern than in the case of a manufacturing defect.").

Soproni, 137 Wn.2d 319, 327 n.3, 971 P.2d 500 (1999). The Legislature has not amended the WPLA in light of *LaMontagne* and the pattern jury instructions, and this Court thus should conclude that the courts are applying a negligence standard in accordance with the Legislature's intent.

D. THE TRIAL COURT DID NOT ABUSE ITS DISCRETION BY AWARDING DEPOSITION COSTS TO MEDTRONIC.

It was within the trial court's discretion to award Medtronic the full cost of the depositions. *See Citizens for Clean Air v. City of Spokane*, 114 Wn.2d 20, 40, 785 P.2d 477 (1990).[28] Here, two of the depositions were played almost in their entirety, and the others were all published in open court and used for cross-examination and impeachment purposes. It is reasonable to assume the depositions were necessary to achieve a successful result, and it was within the court's discretion to award the full costs of the depositions.[29]

V. CONCLUSION

Anderson's first assignment of error is barred by her own endorsement of the instructions given by the trial court. In the alternative, the trial court correctly refused to give a strict liability instruction, and its

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[28] *See also Herried v. Pierce Cy. Pub. Transp. Benefit Auth. Corp.*, 90 Wn. App. 468, 476, 957 P.2d 767 (1998); *Tombari v. Blankenship-Dixon Co.*, 19 Wn. App. 145, 150, 574 P.2d 401 (1978).

[29] Even if the trial court erred in its award of costs, that error has no impact on the underlying verdict in Medtronic's favor and gives rise to no basis for ordering a new trial. At most, the Court should reduce the costs Anderson must pay to Medtronic.

negligence instructions were otherwise proper in all respects.

The trial court also properly dismissed Anderson's failure to warn claim. The Instructions for Use were clear, accurate, and consistent, and were therefore adequate as a matter of law. Summary judgment also was proper because Anderson could not prove Medtronic's warnings caused her injuries. Anderson's physicians did not read the Instructions for Use, and they were independently aware of the risks and dangers. Anderson's remaining arguments do not afford a basis for a new trial.

In sum, the trial court properly dismissed Anderson's failure to warn claim and properly instructed the jury on Anderson's negligent design claim. Thereafter, the jury unanimously rendered its verdict in favor of Medtronic. Both the rulings and the verdict should stand.

RESPECTFULLY SUBMITTED THIS 21st day of July, 2014.

LANE POWELL PC
Attorneys for Appellees Medtronic, Inc. and Medtronic Xomed, Inc.

By _____
Stephania Camp Denton
WSBA No. 21920

Of counsel:

Lori G. Cohen (*pro hac vice*)
Victoria Lockard *pro hac vice*)
Evan Holden (*pro hac vice* pending)
Daniel I.A. Smulian (*pro hac vice*)

CERTIFICATE OF SERVICE

I hereby certify that on July 21, 2014, I caused to be served a copy of the attached document on the following person(s) in the manner indicated below at the following address(es):

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Helen Van Buren

APPENDIX A

HON. MICHAEL TRICKEY

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

BECKY S. ANDERSON, a single person, Plaintiff, vs. DONALD R. PAUGH; WENATCHEE VALLEY MEDICAL CENTER, P.S.; LINDA K. SCHATZ; WENATCHEE ANESTHESIA ASSOCIATES; MEDTRONIC, INC.; and MEDTRONIC XOMED, INC., Defendants.	NO. 12-2-17928-0 SEA PLAINTIFF'S PROPOSED JURY PRE-INSTRUCTIONS [CITED]

COMES NOW Plaintiff Becky Anderson, by and through her attorneys of record, and respectfully submits the following jury pre-instructions for presentation to the jury.

DATED this 24th day of October, 2013.

LUVERA, BARNETT,
BRINDLEY, BENINGER & CUNNINGHAM

/s/ Joel D.Cunningham
PAUL N. LUVERA, WSBA #849
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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was sent to the following parties in the manner indicated below:

Jennifer L. Moore Bennett, Bigelow & Leedom Two Union Square 601 Union Street, Suite 1500 Seattle, WA 98101-1355 *Attorneys for Defendants Paugh & Wenatchee Valley Med Ctr*	☒ Electronic Mail ☐ Fax Transmission ☐ First Class Mail ☐ Messenger Service ☐ Overnight Delivery
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I declare under penalty of perjury, under the laws of the State of Washington that the foregoing is true and correct.

Executed this 24th day of October, 2013, in Seattle, Washington.

/s/ Dee Dee White
Dee Dee White

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PRE-INSTRUCTION NO. _____

It is the duty of the court to instruct you as to the measure of damages. 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 the plaintiff, then you must determine the amount of money that will reasonably and fairly compensate plaintiff for such damages as you find were proximately caused by the negligence of the defendants.

If you find for plaintiff, Becky Anderson, you should consider the following past economic damages:

1. The reasonable values of necessary medical care, treatment, and services received.

2. The reasonable value of domestic services and non-medical expenses that have been required.

In addition you should consider the following future economic damages elements:

1. The reasonable value of necessary medical care, treatment, and service with reasonable probability to be required in the future.

2. The reasonable value of necessary nonmedical expenses that will be required with reasonable probability in the future.

In addition you should consider the following noneconomic damages elements:

1. The nature and extent of the injuries;

2. The disability, disfigurement, and loss of enjoyment of life experienced and with reasonable probability to be experienced in the future;

3. The pain and suffering, both mental and physical, experienced and with reasonable probability to be experienced in the future.

The burden of proving damages rests upon the plaintiff. 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.

WPI 30.01.01; 30.04; 30.05; 30.06; 30.07.01; 30.07.02; 30.08.02; 30.09.01; 30.09.02; RCW 4.56.250(1)(b)(defining noneconomic damages as "subjective, nonmontetary losses, including but not limited to pain, suffering, inconvenience, mental anguish, disability or disfigurement incurred by the injured party, emotional distress . . .)

PRE - INSTRUCTION NO. _____

The plaintiff has the burden of proving each of the following propositions:

First, that the defendant manufacturer failed to exercise reasonable care in supplying a product that was not reasonably safe as designed at the time the product left the defendant's control;

Second, that plaintiff was injured; and

Third, that the unsafe condition of the product was a proximate cause of plaintiff's injury.

If you find from your consideration of all the evidence that each of these propositions has been proved, your verdict should be for the plaintiff. On the other hand, if any of these propositions has not been proved, your verdict should be for the defendant.

WPI 110.21 (modified)

PRE-INSTRUCTION NO. _____

A medical product manufacturer has a duty to use reasonable care to design medical products that are reasonably safe. "Reasonable care" means the care that a reasonably prudent medical product manufacturer would exercise in the same or similar circumstances. A failure to use reasonable care is negligence.

The question of whether a medical product manufacturer exercised reasonable care is to be determined by what the manufacturer knew or reasonably should have known at the time the product left the defendant's control.

In determining what a medical product manufacturer reasonably should have known in regard to designing its product, you should consider the following:

A medical product manufacturer has a duty to use reasonable care to test, analyze, and inspect the products it sells, and is presumed to know what such tests would have revealed.

A medical product manufacturer has a duty to use reasonable care to keep abreast of scientific knowledge, discoveries, advances, and research in the field, and is presumed to know what is imparted thereby.

PRE-INSTRUCTION NO. _____

Wenatchee Valley Medical Center, Wenatchee Anesthesia Associates, Central Washington Hospital, Medtronic, Inc. and Medtronic, Xomed, Inc. are corporations. A corporation can act only through its officers and employees. Any act or omission of an officer or employee is the act or omission of the corporation.

APPENDIX B

Medtronic

LASER-SHIELD® II Endotracheal Tube

Tube endotrachéal / Tubo Endotracheale / Endotrachealtubus / Tubo endotraqueal / Endotracheale slang / Endotrakealtube / Kurkkutorviletku / Endotrakealrör / Tubo endotraqueal / Ενδοτραχηλιακός σωλήνας / Rurka dotchawicza / Endotracheální trubice / Endotrachealis tubus / Endotrakealtube / Endotrakeal Tüp

Product Information and Instructions

Informations et instructions concernant le produit / Informazioni sul prodotto ed istruzioni per l'uso / Produktinformation und Gebrauchsanweisung / Instrucciones e información sobre el producto / Productinformatie en instructies / Produktoplysninger og vejledning / Tuotetta koskevat tiedot ja käyttöohjeet / Produktinformation och instruktioner / Informação do produto e instruções / Πληροφορίες προϊόντος και οδηγίες / Informacje o produkcie i instrukcje / Údaje o výrobku a pokyny / Termék információ és használati utasítás / Produktinformasjon og instruksjoner / Ürün Bilgileri ve Talimatlar

Rx Only

EXHIBIT 2

MDT-ANDB-00000005

English

DESCRIPTION

The LASER-SHIELD II is an endotracheal tube with a laser resistant overwrap of aluminum and a fluoroplastic covering the silicone elastomer shaft. The white wrap area, excluding the most distal 2mm of white wrapping, is laser resistant per the values in the section below titled, Test Results Summary and Power Recommendations. The proximal and distal end of the silicone elastomer shaft and cuff are not covered and therefore, are not laser resistant. The smooth, low traumatizing endotracheal tube is fitted with a cuff designed to provide an effective tracheal seal under multiple anatomical variations. The cuff inflation valve has been equipped with dry methylene blue to enable the detection of cuff ruptures. The tube and cuff are non-wetting, which allows for easy insertion and removal and reduces secretion accumulation during intubation. The tube is flexible and adapts easily to changes in airway position. The tubes are provided sterile and intended for single use only.

EXTREME CARE MUST BE TAKEN IN MAINTAINING THE APPROPRIATE POWER DENSITY OF THE LASER AND THE OXYGEN GAS MIXTURE CONCENTRATIONS FOR LASER APPLICATIONS.
Failure to comply with the Indications and Usage, Contraindications, Warnings, Product Usage Recommendations and Laser Power Recommendations will cause unnecessary risk to the health and safety of the patient.

INDICATIONS FOR USE

The LASER-SHIELD II is intended for endotracheal intubation. It is indicated for use for all types of surgical procedures involving carbon dioxide (10.60 microns) or KTP (532 nm) laser use (normal pulsed or continuous beam delivery in the non-contact mode), when endotracheal intubation is required to administer anesthetic gases or to overcome emergency obstruction of an airway.

CONTRAINDICATIONS

The LASER-SHIELD II should not be used in patients with narrow airways which could restrict ventilation inspiration and expiration, and result in excessive elevation of intratracheal pressures.

WARNINGS

- Do not use with any ND:YAG Laser or argon laser, or any laser type other than CO2 or KTP.
- Do not use any contact tip style laser delivery instrument with this product.
- Do not impact the LASER-SHIELD II with a laser beam. The reflective aluminum wrapping is exposed and energy of the laser beam may be reflected onto the patient's tissue causing injury.
- Do not contact the cuff or distal end of the shaft with a laser beam or electrosurgical instrument. Contact may cause deflation of the cuff and result in combustion and fire.
- Do not use surgical lasers or electro or thermal cautery power sources in the presence of elevated oxygen levels or other flammable gasses, or damage to the tube may result in ignition and serious patient injury.
- Do not use nitrous oxide for dilution of oxygen. Nitrous oxide is a flammable gas and may result in ignition and serious patient injury.
- Do not overinflate the cuff. Overinflation may result in tracheal damage, cuff rupture with subsequent deflation, or cuff distortion leading to herniation and airway blockage.
- Do no modify the LASER-SHIELD II by trimming, removing or adding additional metal foil wrapping on the main shaft, or patient injury may occur.
- Do not use sharp instruments in close proximity to the ventilation tube, to avoid damage to the tube and compromise ventilation of the patient.
- Do not re-sterilize the device. Medtronic assumes no liability for products which have been re-sterilzed by health care facilities.
- In the event of an AIRWAY FIRE, IMMEDIATELY:
  - TURN OFF THE OXYGEN FLOW
  - OCCLUDE THE CIRCUIT TUBING WITH A CLAMP
  - DISCONNECT THE BREATHING CIRCUIT
  - EXTINGUISH THE FIRE WITH STERILE WATER OR SALINE
  - REMOVE THE TUBE FROM THE PATIENT
  - PROVIDE IMMEDIATE CARE TO THE PATIENT

INSTRUCTIONS FOR USE

The surgeon must exercise best medical judgment in selecting patients as candidates for use of this device. The associated complications due to inappropriate patient selection, incorrect tube placement or improper connection of the Laser Shield II is essential for the safe and effective ventilation of the patient.

The surgeon must be trained in laser surgery techniques and the anesthesiologist must be trained in laser safety protocols to be followed and equipment used must be capable of providing diluted gas mixture concentrations for the safe use of this endotracheal tube in laser surgery.

Prior to Intubation

1. The risk of damaging an endotracheal tube is greater under extreme operating conditions, such as a very long procedure, repeated manipulation and movement of the endotracheal tube. A spare LASER-SHIELD II tube of the correct size should be readily available.
2. Before use, the cuff should be tested with 5 to 10 cc of air. Thoroughly evacuate all air before intubation. Replace with a new tube as determined.

Intubation

3. The cuff should be slowly inflated with the minimum volume of sterile, normal saline necessary to provide an effective seal. The saline will act as a heat sink.
4. To obtain maximum coloration of Methylene Blue, add approximately 3 cc of sterile, normal saline to the cuff. Slowly aspirate and reinject the normal saline. Repeating will further enhance coloration.
5. Monitor the cuff volume and pressure during the surgical procedure for changes due to the permeability of the thin silicone membrane cuff to nitrous oxide.
6. Place a wet cotton gauze around the cuff (and kept moist during the entire procedure) as an additional heat sink. If the cuff is penetrated and ruptures, the methylene blue solution will stain the wet cotton gauze. Wet cotton gauze will not withstand the laser power levels described in the Power Recommendations and must not be relied on for cuff protection.
7. Immediately discontinue use of the laser if cuff deflation occurs, or is suspected, and do not resume until the LASER-SHIELD II is removed and replaced with a new tube.

During procedure

8. Dilute oxygen or other flammable gases with Helium, Nitrogen or room air as needed. Dilute oxygen to the minimal inspired concentration compatible with satisfactory oxygen saturation.
9. RECOMMENDATION: Use 30% oxygen / 70% helium, or 30% oxygen / 70% room air. Closely monitor the patient for any signs of hypoxemia. Immediately reposition the tube, adjust the oxygen gas mixture or rate of delivery, or intubate the patient with a conventional tracheal tube if hypoxemia occurs.

Extubation

10. Fully deflate the cuff prior to extubation. Exercise caution while extubating the patient.

REFERENCES

- Duncavage, James A., et al. "Laser Surgery of the Larynx." Phonosurgery: Assessment and Surgical Management of Voice Disorders. Ed. Charles N. Ford and Diane M. Bless. New York: Raven Press, 1991.
- McGoldrick, Kathryn E. Anesthesia for Opthalmic and Otolaryngologic Surgery. Philadelphia: W.B. Saunders Company, 1992.
- Schramm, Victor L., et al. "Acute Management of Laser-Ignited Intratracheal Explosion," The Laryngoscope 91 (1981), 1417-1426.

PERFORMANCE TESTING

CO2 Laser Testing

Each tube was held in a horizontal position by clamps hooked onto a chemistry stand. A Vernatrol anesthesia machine was used to deliver 100% oxygen at a flow rate of 3 liters/minute. A Sharplan 1060 CO2 laser with a 400 mm lens microspot attachment coupled to a Zeiss operating microscope was used to deliver the laser beam. The distance from the delivery system to the target tube was held constant at 35.5 cm with a constant spot size of 0.38 mm (spot size was verified with measurements of power transmittance through a pinhole). An Ophire power meter was used to calibrate and record the wattage output. Omega calibrated thermocouple probes were used to measure the temperature rise on the extraluminal surface 1 cm from the point of beam impact and of the oxygen gas exiting the distal end of the tube. All tests were performed under a continuous beam for 3 minutes, with the laser delivering maximum power (40-45 watts). The endotracheal tube was curved to the recommended ANSI position and the beam was directed at the aluminum tape overlap juncture at an angle of incidence approximately 90° relative to the proximal end of the tube, always at a distance greater than one inch from the end of the tube wrapping. Each of the ten tubes was irradiated five times in this manner. Each tube was then subjected to 3-4 flexures from the straight position to the recommended ANSI curvature in order to simulate repeated intubation. Each tube was irradiated once following this manipulation at an incidence angle of 30° relative to the proximal end of the tube. The aluminum tape overlap juncture was again the prime target.

Results of CO2 Testing

Each of the ten tubes tested withstood 180 seconds of continuous irradiation with the CO2 laser before and after repeated ANSI flexures. There were no extra or intraluminal fires and no evidence of penetration through the tube. The average temperature rise on the tube surface during the 3 minute exposures was 43.2°C and the average temperature rise of the oxygen exiting the distal end of the tube was 11.9°C.

Protocol for KTP Laser Testing

The tube was positioned with oxygen flowing through it, as described above. A KTP laser (Laserscope, 532 nm) with a 400 mm lens microbeam coupled to a Storz operating microscope was used. The distance from the delivery system to the target tube was held constant at a distance 35.0 cm, delivering a focused spot of 380 micron (verified by measuring pinhole transmittance). Omega calibrated thermocouple probes were used to measure the temperature rise on the extraluminal surface 1 cm from the point of beam impact and the oxygen gas exiting the distal end of the tube. The endotracheal tube was directed at the aluminum tape overlap juncture at an angle of incidence approximately 90° relative to the proximal end of the tube, always at a distance greater than one inch from the end of the tube wrapping. Each of the five impacts was performed at different sites on the same tube under a continuous beam for 3 minutes, with the laser delivering maximum power (15 watts).

Results of KTP Testing

The tube withstood 180 seconds of continuous irradiation with the KTP laser delivering maximum power. There were no extra or intraluminal fires and no evidence of tube penetration. The average temperature rise on the extraluminal surface of the tube was 86.1°C and the average temperature rise of the oxygen exiting the distal end of the tube was 12.45°C.

TESTING RESULTS SUMMARY AND POWER RECOMMENDATIONS

Under the test conditions described above, in the area wrapped with the laser reflective wrap, proximal to the cuff and proximal to the most distal 2.5 mm of the white wrapping, the maximum power density (watt per cm2) that the LASERSHIELD II is able to withstand for three minutes without tube penetration is approximately 35,000 watts per cm2 for the CO2 laser and 11,900 watts per cm2 for the KTP laser. Based on these power density figures, the following recommendations listed in the table below are made for maximum power settings for these lasers when utilizing the specific beam diameters indicated. Data available upon request.

Testing of the LASER-SHIELD II and other reflective tubes indicates that if blood or a combination of blood and lubricant is present on the surface of the tube at the exact point of laser impact, resistances of the tube to penetration by the CO2 laser can be negatively affected and this negative effect can be significant (up to a 60% reduction recommended maximum power settings). All endotracheal tubes, regardless of the material of which they are composed, will combust under certain conditions if they are contacted by a laser beam.

CO2 Laser, Maximum Power Settings

Beam Diameter (mm)	0.4	0.5	0.6	0.8
Wattage	35	45	50	50

KTP Laser, Maximum Power Settings

Beam Diameter (mm)	0.4
Wattage	12

Test results on mainshaft, proximal to the cuff, and proximal to the most distal 2.5 mm of the white wrapping.

Based on testing performed by the Department of Otolaryngology, Laser Research Laboratory, Vanderbilt University Medical School, Nashville, TN.