Supreme Court No. 92416-3
Court of Appeals, Division I No. 71411-2-I

SUPREME COURT OF THE STATE OF WASHINGTON

DOROTHY L. PAYNE, Individually and as the personal representative of the Estate of BECKY S. ANDERSON, deceased,

Petitioner,

vs.

DONALD R. PAUGH; WENATCHEE VALLEY MEDICAL CENTER, P.S.; LINDA K. SCHATZ; WENATCHEE ANESTHESIA ASSOCIATES; LASER ENGINEERING, INC., a foreign corporation,

Defendants,

MEDTRONIC, INC.; MEDTRONIC XOMED, INC., and UNKNOWN JOHN DOES,

Respondents,

CENTRAL WASHINGTON HEALTH SERVICES ASSOCIATION d/b/a CENTRAL WASHINGTON HOSPITAL, a Washington corporation,

Defendant.

PETITION FOR REVIEW

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes and Rules

Other Authorities

A. IDENTITY OF PETITIONER

This petition for review is filed on behalf of Dorothy L. Payne, individually and as the personal representative of the Estate of Becky S. Anderson.

B. COURT OF APPEALS DECISION

Ms. Payne seeks review of the published Court of Appeals decision terminating review as to defendants/respondents Medtronic, Inc., and Medtronic Xomed, Inc. *See Payne v. Paugh*, — Wn. App. —, — P.3d —, 2015 WL 5682438 (Div. I, Sept. 28, 2015). A copy of the decision is in the Appendix at pages A-1 to A-16.

C. ISSUE PRESENTED FOR REVIEW

In this product liability action alleging defective design of a medical device, the superior court instructed the jury that the plaintiff has the burden of proving the manufacturer is negligent and that the device is not "reasonably safe," in accordance with the applicable pattern jury instruction. *See* WPI 110.02.01. However, the court declined to give an instruction containing the statutory tests to determine whether the product is reasonably safe.

The Washington Product Liability Act (WPLA) defines the phrase "reasonably safe" in terms of a risk-utility balancing test and a consumer expectations test. *See* RCW 7.72.030(1)(a) & (3). By

comparison, the ordinary meaning of the phrase "reasonably safe" is "fairly" or "moderately" safe.

In the absence of the WPLA definition of the phrase "reasonably safe," did the superior court's instructions properly inform the jury of the applicable law, allow Anderson to argue her theory of the case, and constrain the Medtronic defendants' closing arguments?

D. STATEMENT OF THE CASE

On February 3, 2012, Becky Anderson went to the hospital for minor elective surgery that was supposed to last ten minutes, using a laser to remove a polyp on her vocal cords so she would not get hoarse when she sang.[1] In the past, her surgeon had always used a special endotracheal tube with two "cuffs" to seal off the patient's trachea during this type of procedure, while the anesthesiologist administered oxygen through the lumen of the tube, thereby allowing the patient to breathe. The purpose of the double-cuff design is to protect the patient. The upper cuff is filled with saline, and, if struck by the laser, it acts like a shield, absorbing energy

[1] Regarding the nature of the surgery, *see* RP 98:12-17 (10/28/13 a.m.); RP 74:24-75:8 (10/30/13 p.m.); RP 49:5-15 (11/7/13 a.m.); RP 38:16-21 (11/12/13 p.m.); RP 77:21-78:1 (11/19/13 a.m.); RP 35:12-13 (11/20/13 p.m.). Because the report of proceedings is numbered discontinuously, citations parenthetically indicate the date of the cited portion of the transcript, and, where applicable, whether it is from the morning (a.m.) or afternoon (p.m.) session of court.

from the laser and preventing the lower cuff from being inadvertently struck by the laser. The lower cuff will continue to hold the seal on the airway, so the surgeon can stop the procedure and swap out the damaged endotracheal tube for a new one before continuing. The lower cuff prevents oxygen-enriched air from escaping from the lungs to the site where the laser is being used.

One of the risks of laser surgery, especially in the presence of relatively high concentrations of oxygen, is fire in the patient's airway. The combination of a heat source (the laser), combustible material (the endotracheal tube and the patient's tissue), and the flow of highly concentrated oxygen creates a blowtorch effect.[2]

On the day of Ms. Anderson's surgery, the surgeon used a Laser Shield II endotracheal tube manufactured by Medtronic Xomed, Inc., and its parent company, Medtronic, Inc., a major manufacturer of medical devices (collectively "Medtronic").[3] The Laser Shield II employs a single-cuff design. Medtronic criticizes the double-cuff design as giving the surgeon a "false sense of security," contending that it may lead the surgeon to continue the surgery even though the second cuff is vulnerable to a laser strike

[2] Regarding the blowtorch effect, *see* RP 30:15-33:4 (10/29/15 p.m.); RP 32:15-19 (10/30/13 a.m.).
[3] The jury instructions did not distinguish between the Medtronic defendants.

and resulting airway fires.[4] However, since 2000, there is a history of eight airway fires with the single-cuff Laser Shield II, including two known reports in the State of Washington. During the same period of time, there is only one reported airway fire with the double-cuff design, occurring outside of Washington.[5]

During the operation on Ms. Anderson, the surgeon struck the cuff of the Laser Shield II with the laser, while the anesthesiologist was administering 100% oxygen. Without any protection from a second cuff, the oxygen leaked into the surgical site where the laser was being used. The endotracheal tube caught on fire, creating the blowtorch effect, and Ms. Anderson suffered horrific burns in her respiratory tract. Fragments of the Laser Shield II were embedded in her trachea, and the tip of the tube lodged in the lower left lobe of her lungs. She was hospitalized for more than five months, undergoing multiple surgeries, and ultimately placed in a nursing home.

Before the surgery, Ms. Anderson would simply get hoarse when she sang. Afterward, she was unable to speak or even breathe

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[4] Regarding Medtronic's claim that the double-cuff design creates a false sense of security, *see* RP 96:8-97:24 (11/21/13 p.m.); RP 16:23-17:14 (11/25/13 p.m.); RP 62:4-25 (11/25/13 p.m.).

[5] There is reason to believe adverse events are underreported. *See* RP 7:4-16 (11/4/13 p.m.); RP 50:24-52:1 (11/4/13 p.m.).

on her own for more than 30 minutes at a time without ventilator assistance.

Ms. Anderson filed suit against her health care providers for negligence and against Medtronic for defective design of the Laser Shield II endotracheal tube. Following trial, the jury returned a verdict against the health care providers, but in favor of Medtronic. Ms. Anderson appealed the judgment in favor of Medtronic.[6] During the appeal, Ms. Anderson died and Ms. Payne has been substituted as Personal Representative of her estate.

1. The superior court instructed the jury that Ms. Anderson had the burden to prove that Medtronic's Laser Shield II is not "reasonably safe," but declined her request to give the pattern jury instruction containing the statutory tests to determine whether a product is reasonably safe.

During trial, there was conflicting testimony regarding the safety of Medtronic's design for the Laser Shield II. The superior court gave Instruction No. 19, adapting the pattern jury instruction regarding the elements of a defective design claim, WPI 110.21. *See* CP 2567. The court also gave Instruction No. 20, adapting the pattern instruction regarding negligent design in the context of

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[6] *See* CP 4471-84 (notice of appeal); CP 4485-96 (amended notice). Ms. Anderson's appeal was styled as a cross-appeal because the health care providers filed two separate appeals of the judgment entered against them. The health care provider appeals later settled without a decision by the Court of Appeals.

medical devices, WPI 110.02.01. *See* CP 2568. The court did not give any other instructions regarding the design claim.[7]

The court's instructions to the jury required Ms. Anderson to prove "that the Medtronic defendants failed to exercise reasonable care in the design of the Laser-Shield II at the time the product left their control," and explained that "a medical device manufacturer has a duty to use reasonable care to design medical devices that are ***reasonably safe***." CP 2567-68 (emphasis added). The instructions further required Ms. Anderson to prove "that the ***unsafe condition*** of the product was a proximate cause" of her injuries. CP 2567 (emphasis added). The instructions did not define what constitutes a "reasonably safe" product.

Ms. Anderson brought the lack of definition of the phrase "reasonably safe" to the court's attention, and proposed an instruction based on WPI 110.02, stating the risk-utility and consumer expectations tests for determining whether a product is reasonably safe under the WPLA, RCW 7.72.030(1)(a) & (3).[8] When

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[7] Instructions Nos. 19 & 20 and WPI 110.02.01 & 110.21 are reproduced in the Appendix.

[8] Ms. Anderson's proposed instruction, CP 2238 & 4463, the pattern instruction, WPI 110.02, and the statute on which they are based, RCW 7.72.030, are reproduced in the Appendix. At one point, Medtronic proposed an instruction based on WPI 110.02, containing a form of the risk-utility test, but not the consumer expectations test. *See* CP 4896. A copy of Medtronic's proposed instruction is also reproduced in the Appendix.

the court declined to give the instruction, she took formal exception.[9]

2. During closing argument, Medtronic focused almost entirely on whether its product is "reasonably safe."

Counsel for Medtronic began closing argument by emphasizing what she believed to be the dispositive issue: "I want to start by saying that this case is complex, but I think what's clear is that the plaintiffs cannot prove that the Laser Shield II was not ***reasonably safe, which is the standard***." RP 83:9-12 (12/3/13 p.m.) (emphasis added).[10] "I am focusing on this first question, that is, did the plaintiff's [sic] prove, have they proven that the Laser Shield II is not ***reasonably safe***." RP 84:11-13 (brackets & emphasis added).

Counsel pointed out that the verdict as to Medtronic hinged on this single issue:

> did the plaintiffs prove, did they meet their burden of proving negligent design? ***Here's what it is, did the plaintiff prove through expert testimony to a reasonable degree of scientific probability that the Laser Shield II modified was not reasonably safe***? Okay. And the answer — if the answer is no, then you stop there, and I will show you the verdict form as we go. You check no for

[9] The written exception, CP 4468-69, is reproduced in the Appendix. *See also* RP 10:11 (12/3/13 a.m.) (incorporating written exceptions by reference).

[10] All citations to Medtronic's closing argument are from the 12/3/13 p.m. session of court.

> no negligence and you stop. And it's a defense verdict for Medtronic/Xomed. No need to even proceed beyond the first question.

RP 90:5-15 (emphasis added); *accord* RP 85:8-10 ("if you find that the Laser Shield II, first question, question one, negligence. Is reasonably safe, then deliberations must end [sic]").

Throughout closing, counsel continually returned to the issue of whether Medtronic's Laser Shield II is reasonably safe. *See, e.g.,* RP 88:23-24, 92:21-93:1, 93:13-14, 96:9-12, 97:22-98:2, 98:20-22, 99:4-15, 100:1-24, 101:7-9, 102:10-15, 103:23-104:1, 109:2-9, 112:19-21, 123:2-14, 128:14-16, 133:11-16, 134:12-17. Counsel emphasized that the issue is "the heart of our case" and "the heart of our defense." RP 111:2-3. She concluded:

> Was this a reasonably safe design? I think we have covered that extensively. I told you I wanted to spend the majority of my time on that and I have.

RP 116:7-10. As requested, the jury returned a special verdict in Medtronic's favor, finding no negligence. CP 2544 (question no. 7).

3. The Court of Appeals held that the statutory tests to determine whether a product is reasonably safe are limited to product liability claims involving strict liability and inapplicable to cases, such as this one, involving negligence.

On appeal, Anderson argued that the superior court erred in failing to instruct the jury regarding the statutory tests to determine

whether a product is "reasonably safe."[11] The parties and the appellate court agreed that this case is governed by the Restatement (Second) of Torts § 402A cmt. *k* (1965) (hereafter "Comment *k*"), which provides that manufacturers of products deemed to be "unavoidably unsafe" to one extent or another are not subject to strict liability. This category of products generally includes medical products prescribed by a physician. *See Payne*, 2015 WL 5682438, at *15.

The parties and the appellate court also agreed with the pattern jury instruction for claims subject to Comment *k*, which requires proof that the manufacturer of a medical product was negligent as well as proof that the product itself is not "reasonably safe." *See id.* at *15-16. However, the court rejected Anderson's contention that the phrase "reasonably safe" as used in the pattern instruction should be defined in accordance with the statutory tests for determining whether a product is reasonably safe, reasoning that:

> the risk utility and consumer expectations tests are used to determine whether a manufacturer is strictly liable and do not apply to a negligence design defect claim under comment k.

[11] Although Ms. Anderson's appeal initially included dismissal of a failure-to-warn claim against Medtronic on summary judgment, the failure-to-warn claim is no longer subject to review.

Id. at *16.

At one point in its opinion, the court questioned whether an "unavoidably unsafe" product could ever be considered "reasonably safe." *See id.* at *15.[12] However, in the final analysis, the court approved the pattern instruction requiring Anderson to prove that Medtronic's product was not "reasonably safe" without a definition of the phrase:

> The instruction the court gave to the jury correctly describes the duty of a manufacturer of unavoidably unsafe products in designing reasonably safe medical devices under comment k of the *Restatement (Second) of Torts* section 402A.

Id. at *17.

From this decision, Ms. Payne seeks review.

E. ARGUMENT WHY REVIEW SHOULD BE ACCEPTED

1. The decision below alters the definition of a "reasonably safe" product in claims against medical product manufacturers, and presents a substantial issue of public interest that should be determined by this Court under RAP 13.4(b)(4).

With the adoption of the WPLA, the liability of a product manufacturer hinges upon whether its product is not "reasonably safe." *See generally* 16A Wash. Prac., Tort Law & Practice § 17.8 (4th

[12] Similar questions were raised in oral argument. *See* Transcript of Oral Arg., Mar. 3, 2015, at 15:10-17:21. The transcript is reproduced in the Appendix.

ed.). There are several different approaches by which a plaintiff can show that the product was not reasonably safe: (1) it was "not reasonably safe as designed," (2) "not reasonably safe because adequate warnings or instructions were not provided," (3) "not reasonably safe in construction," or (4) "not reasonably safe because it did not conform to the manufacturer's express warranty or to the implied warranties under Title 62A RCW." RCW 7.72.030(1) & (2).

With respect to design claims, there are two tests for determining whether the product was "reasonably safe." The first test, which is specific to design claims, involves a balancing of risk versus utility. It provides:

> A product is not reasonably safe as designed, if, at the time of manufacture, the likelihood that the product would cause the claimant's harm or similar harms, and the seriousness of those harms, outweighed the burden on the manufacturer to design a product that would have prevented those harms and the adverse effect that an alternative design that was practical and feasible would have on the usefulness of the product[.]

RCW 7.72.030(1)(a) (brackets added). The second test, which applies to all of the different approaches for determining whether a product was reasonably safe, including, but not limited to design, is based on consumer expectations. It provides:

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

RCW 7.72.030(3). These tests are independent and alternative means of establishing the product was not reasonably safe. *See Soproni v. Polygon Apartment Partners,* 137 Wn. 2d 319, 326-27, 971 P.2d 500 (1999).

Normally, proof that a product is not reasonably safe as designed results in imposition of strict liability, without consideration of fault on the part of the product manufacturer. *See Falk v. Keene*, 113 Wn. 2d 645, 782 P.2d 974 (1989). In a series of cases decided both before and after adoption of the WPLA, this Court has recognized an exception to strict liability for unavoidably unsafe products covered by Comment *k*. *See Terhune v. A.H. Robins Co.*, 92 Wn. 2d 9, 577 P.2d 975 (1978); *Rogers v. Miles Labs.*, 116 Wn. 2d 195, 802 P.2d 1346 (1991); *Young v. Key Pharm., Inc.*, 130 Wn. 2d 160, 922 P.2d 59 (1996) (4-4 plurality); *Ruiz-Guzman v. Amvac Chem. Corp.*, 141 Wn. 2d 493, 7 P.3d 795 (2000). However, the Court has cautioned that "the comment *k* exception to strict liability was not expressly provided for by the Legislature in adopting the WPLA" and "we must be sparing in its

application lest we defeat the letter or policy of the WPLA." *Ruiz-Guzman,* 141 Wn. 2d at 506.

Although Comment *k* liability is premised on negligence, *see Rogers*, 116 Wn. 2d at 207, this Court has never addressed whether the plaintiff must also show that the product is not "reasonably safe" or what that showing might entail. In keeping with the WPLA's focus on reasonable safety of the product, the applicable pattern jury instruction requires the plaintiff to show that the product was not reasonably safe, but the instruction does not specifically indicate whether the statutory risk-utility and consumer expectations tests should be used to define the phrase. *See* WPI 110.02.01.

In the absence of definition, it is presumed that the jury ascribes the ordinary meaning to the phrase "reasonably safe" in the pattern jury instruction. *See State v. Meneses,* 169 Wn. 2d 586, 592, 238 P.2d 495 (2010). The ordinary meaning of "reasonably safe" is "moderately" or "fairly" safe. *See Merriam-Webster Online, s.v.* "reasonable" (available at www.m-w.com; viewed Oct. 26, 2015). This definition is less detailed and precise than the WPLA tests for determining whether a product is not reasonably safe as designed. It does not identify the relevant factors or the required balancing

involved in the risk-utility test, nor does it prompt the jury to consider the perspective of the consumer expectations test. It implies a less exacting standard of safety than would otherwise be imposed under these tests, and threatens the balance struck by the Legislature between consumers and product manufacturers in enacting the WPLA, unduly impairing the rights of consumers to recover for injuries sustained as a result of unsafe products. *See* Laws of 1981, Ch. 26, § 1.

In rejecting application of the risk-utility and consumer expectations tests to claims under Comment *k* because they sound in negligence, the Court of Appeals decision is problematic on several levels. *First,* the court ignores the centrality of whether the product is "reasonably safe" in determining liability under the WPLA. *Second,* the court fails to acknowledge the difference between the WPLA definition of "reasonably safe" and the ordinary meaning of the phrase. *Third,* the court makes a category error by holding that proof of negligence, which relates to the manufacturer's *conduct,* eliminates the need to define "reasonably safe," which relates to the manufacturer's *product. Fourth,* the court does not reconcile its decision with the fact that the WPLA expressly provides that the consumer expectations test applies to

negligence claims for post-manufacture failure to warn. *See* RCW 7.72.030(1)(c) & (3). *Fifth,* the court does not recognize the natural affinity between the risk-utility test and the analysis of negligence. *See Ruiz-Guzman,* 141 Wn. 2d at 513 (Talmadge, J., concurring/dissenting, noting similarity with Judge Learned Hand's analysis of negligence in *United States v. Carroll Towing Co.,* 159 F.2d 169, 173 (2d Cir. 1947)). At a minimum, these problems with the Court of Appeals decision will engender confusion for the bench and bar.

This Court should grant review of the decision below to clarify the meaning of "reasonably safe" in the context of a design case subject to Comment *k*, and decide whether the phrase should be defined according to the statutory risk-utility and consumer expectations tests that apply to other design cases.

2. The decision below conflicts with this Court's precedent holding that jury instructions must properly inform the jury of the applicable law and allow parties to argue their theory of the case, warranting review under RAP 13.4(b)(1).

"Jury instructions are inadequate if they prevent a party from arguing its theory of the case, mislead the jury, or misstate the applicable law." *Barrett v. Lucky Seven Saloon, Inc.,* 152 Wn. 2d 259, 266, 96 P.3d 386 (2004). "As with a trial court's instruction

misstating the applicable law, a court's *omission* of a proposed statement of the governing law will be 'reversible error where it prejudices a party.'" *Barrett,* 152 Wn. 2d at 267 (quotation omitted). In particular, refusal to instruct the jury regarding statutory or other technical definitions of words or phrases constitutes reversible error. *See Barrett,* at 267-75 (involving "apparently intoxicated" statutory standard for over service of alcohol); *see also Hub Clothing Co. v. City of Seattle,* 117 Wn. 2d 251, 253-54, 201 Pac. 6 (1921) (involving standard for "reasonable inspection" of city water meters). The rationale for this rule is that courts cannot presume that jurors already know and understand the applicable law. That is precisely why such care and effort is expended in instructing the jury. Jurors must be informed of the law in all relevant particulars before they can make a meaningful decision regarding the merits of a case.

The decision below conflicts with *Barrett* and similar cases because the Court of Appeals affirmed the superior court's failure to instruct the jury regarding the statutory tests for determining whether a product is reasonably safe and failed to consider the resulting prejudice. The jury decided Anderson's claim against Medtronic without being instructed on the applicable law, and

prejudice should be presumed because the difference between the statutory risk-utility and consumer expectations tests and the ordinary meaning of the phrase "reasonably safe," i.e., "moderately" or "fairly" safe, renders the lack of instruction a clear misstatement of the law. *See Anfinson v. FedEx Ground Pkg. Sys., Inc.*, 174 Wn. 2d 851, 860, 281 P.3d 289 (2012); *see also Barrett,* at 267 (equating omission with misstatement). Prejudice is confirmed by the fact that counsel for Medtronic made the issue of reasonable safety the centerpiece of closing argument, unconstrained by the statutory definition of the phrase. *See Anfinson*, 174 Wn. 2d at 876-77 (stating "[n]o greater showing of prejudice from a misleading instruction is possible without impermissibly impeaching a jury's verdict").

The Court should grant review to remedy the conflict between the decision below and *Barrett*.

F. CONCLUSION

Ms. Payne asks the Court to grant her petition for review, reverse the judgment in favor of Medtronic, and remand this case for retrial of her product liability claim for negligent design of the Laser Shield II.

Respectfully submitted this 28th day of October, 2015.

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CERTIFICATE OF SERVICE

The undersigned does hereby declare the same under oath and penalty of perjury of the laws of the State of Washington:

On October 28, 2015, I served the document to which this is annexed by email and First Class Mail, postage prepaid, as follows:

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and upon Plaintiff's co-counsel, Joel Cunningham, Deborah Martin, Andy Hoyal, David Beninger and Steven R. Pruzan, via email pursuant to prior agreement for electronic service, as follows:

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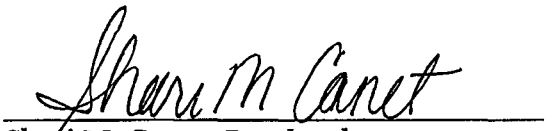
Signed on October 28, 2015 at Ephrata, Washington.



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APPENDIX

2015 WL 5682438
Only the Westlaw citation is currently available.
Court of Appeals of Washington,
Division 1.

Dorothy L. PAYNE, Individually and as the personal representative of the Estate of Becky S. Anderson, deceased, Appellant,
v.
Donald R. PAUGH; Wenatchee Valley Medical Center, P.S.; Linda K. Schatz; Wenatchee Anesthesia Associates; Laser Engineering, Inc., a foreign corporation; Medtronic, Inc.; Medtronic Xomed, Inc.; and Unknown John Does, Respondents,
Central Washington Health Services Association d/b/a Central Washington Hospital, a Washington Corporation; Nonparty Defendant.

No. 71411–2–I. | Sept. 28, 2015.

Synopsis
Background: Patient who was seriously injured during elective throat surgery brought product liability action against medical device manufacturer, alleging that design defect in single-cuff endotracheal tube used during laser surgery led to fire that caused serious burns to patient's trachea and lungs. The King County Superior Court, Michael J. Trickey, J., entered judgment, upon jury verdict, in favor of manufacturer. Patient appealed.

Holdings: The Court of Appeals, Schindler, J., held that:

[1] supplemental jury instruction on risk utility and consumer expectations tests to define whether medical device was reasonably safe was not warranted, and

[2] evidence was sufficient to support finding that depositions used by manufacturer were necessary to achieve successful result, such that manufacturer was entitled to award of cost of depositions.

Affirmed.

West Headnotes (13)

[1] **Appeal and Error**
⇐Conduct of Trial or Hearing in General

30Appeal and Error
30XVIReview
30XVI(H)Discretion of Lower Court
30k969Conduct of Trial or Hearing in General

Appellate court reviews the decision not to give a jury instruction for abuse of discretion.

Cases that cite this headnote

[2] **Trial**
⇐Language

388Trial
388VIIInstructions to Jury
388VII(C)Form, Requisites, and Sufficiency
388k228Form and Language
388k228(3)Language

The language of jury instructions are matters left to the trial court's discretion.

Cases that cite this headnote

[3] **Trial**
⇐Issues and Theories of Case in General
Trial
⇐Construction and Effect of Charge as a Whole

388Trial
388VIIInstructions to Jury
388VII(B)Necessity and Subject–Matter
388k203Issues and Theories of Case in General
388k203(1)In General
388Trial
388VIIInstructions to Jury
388VII(G)Construction and Operation
388k295Construction and Effect of Charge as a Whole
388k295(1)In General

Jury instructions are sufficient when they allow counsel to argue their theory of the case, are not misleading, and when read as a whole properly

inform the trier of fact of the applicable law.

Cases that cite this headnote

[4] **Trial**
⇐Duty to Give Requested Instruction; Erroneous Requests

388Trial
388VIIInstructions to Jury
388VII(E)Requests or Prayers
388k261Duty to Give Requested Instruction; Erroneous Requests

A trial court need never give a requested instruction that is erroneous in any respect.

Cases that cite this headnote

[5] **Appeal and Error**
⇐Cases Triable in Appellate Court

30Appeal and Error
30XVIReview
30XVI(F)Trial De Novo
30k892Trial De Novo
30k893Cases Triable in Appellate Court
30k893(1)In General

The appellate court reviews alleged errors of law in jury instructions de novo.

Cases that cite this headnote

[6] **Appeal and Error**
⇐Prejudicial Effect

30Appeal and Error
30XVIReview
30XVI(J)Harmless Error
30XVI(J)18Instructions
30k1064Prejudicial Effect
30k1064.1In General
30k1064.1(1)In General

An erroneous instruction is reversible error only if it is prejudicial to a party.

Cases that cite this headnote

[7] **Appeal and Error**
⇐Instructions

30Appeal and Error
30XVIReview
30XVI(J)Harmless Error
30XVI(J)1In General
30k1031Presumption as to Effect of Error
30k1031(6)Instructions

If a jury instruction contains a clear misstatement of law, prejudice is presumed and is grounds for reversal unless it can be shown that the error was harmless.

Cases that cite this headnote

[8] **Appeal and Error**
⇐Instructions

30Appeal and Error
30XVIReview
30XVI(J)Harmless Error
30XVI(J)1In General
30k1032Burden to Show Prejudice from Error
30k1032(3)Instructions

The party challenging a jury instruction bears the burden of establishing prejudice.

Cases that cite this headnote

[9] **Products Liability**
⇐Medical Devices and Appliances in General
Products Liability
⇐Design Defect

313AProducts Liability
313AIIIParticular Products
313Ak223Health Care and Medical Products
313Ak226Medical Devices and Appliances in General

313AProducts Liability
313AIVActions
313AIV(E)Instructions
313Ak426Design Defect

Supplemental jury instruction on risk utility and consumer expectations tests to define whether medical device was reasonably safe was not warranted in products liability action against medical device manufacturer that was premised on patient's assertion that design defect in single-cuff endotracheal tube used during patient's elective laser throat surgery led to fire that caused burns to patient's trachea and lungs, even though negligence instruction provided, describing duty of manufacturer of unavoidably unsafe product in designing reasonably safe medical devices, did not define "reasonably safe"; instruction that was provided explained reasonable care, and addressed factors jury was to consider in determining whether reasonable care was taken to design reasonably safe device.

Cases that cite this headnote

[10] **Appeal and Error**
⇐Costs and Allowances

30Appeal and Error
30XVIReview
30XVI(H)Discretion of Lower Court
30k984Costs and Allowances
30k984(1)In General

The appellate court reviews an award of costs for abuse of discretion. West's RCWA 4.84.010(7).

Cases that cite this headnote

[11] **Costs**
⇐Depositions and Affidavits

102Costs
102VIIAmount, Rate, and Items
102k154Depositions and Affidavits

A prevailing party is entitled to the costs of taking depositions if the depositions were taken and used at trial as substantive evidence or for impeachment purposes. West's RCWA 4.84.010(7).

Cases that cite this headnote

[12] **Costs**
⇐Depositions and Affidavits

102Costs
102VIIAmount, Rate, and Items
102k154Depositions and Affidavits

A party that prevails on a summary judgment motion may recover costs incurred in taking depositions specifically considered by the trial court. West's RCWA 4.84.010(7).

Cases that cite this headnote

[13] **Costs**
⇐Depositions and Affidavits

102Costs
102VIIAmount, Rate, and Items
102k154Depositions and Affidavits

Evidence was sufficient to support finding that depositions used by medical device manufacturer in patient's products liability action against it were necessary to achieve successful result, such that manufacturer was entitled to award of cost of depositions following jury verdict in its favor; two of depositions were played in their entirety at trial, remaining depositions were used during cross-examination and for impeachment purposes, and court considered depositions in granting manufacturer's motion for summary judgment on failure to warn claim. West's RCWA 4.84.010.

Cases that cite this headnote

Appeal from King County Superior Court; Honorable Michael J. Trickey, J.

Attorneys and Law Firms

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PUBLISHED OPINION

SCHINDLER, J.

*1 ¶ 1 Becky S. Anderson was seriously injured during elective throat surgery. Anderson filed a negligence lawsuit against otolaryngologist Dr. Donald Paugh and Wenatchee Valley Medical Center PS, anesthesiologist Dr. Linda Schatz and Wenatchee Anesthesia Associates, Central Washington Hospital, and medical device manufacturer Medtronic Inc. and Medtronic Xomed Inc. (Medtronic). Following a sevenweek trial, the jury found Dr. Paugh and Wenatchee Valley Medical Center, Dr. Schatz and Wenatchee Anesthesia Associates, and nonparty Central Washington Hospital negligent and that the negligence was a proximate cause of the injury to Anderson. The jury found medical device manufacturer Medtronic was not negligent. The jury awarded Anderson $18 million in damages. The jury attributed 42.5 percent of the negligence to Dr. Paugh and Wenatchee Valley Medical Center, 52.5 percent to Dr. Schatz and Wenatchee Anesthesia Associates, and 5 percent to the hospital. The court entered a judgment on the jury verdict against Dr. Paugh and Wenatchee Valley Medical Center, and Dr. Schatz and Wenatchee Anesthesia Associates. Anderson appeals the jury verdict in favor of Medtronic. Anderson concedes a negligence standard applies to the design defect claim against medical device manufacturer Medtronic under *Restatement (Second) of Torts* section 402A comment k (1965). Nonetheless, Anderson claims the court erred in refusing to give a proposed supplemental jury instruction that is used for a strict liability design defect claim to define the duty of a medical device manufacturer under *Restatement (Second) of Torts* section 402A comment k. We disagree, and affirm the jury verdict.

FACTS

The Surgery

¶ 2 In January 2012, Becky S. Anderson went to see otolaryngologist Dr. Donald Paugh about "[a] cough and some hoarseness." Dr. Paugh diagnosed a benign vocal cord polyp and recommended tracheal laser surgery. Anderson decided to proceed with the elective tracheal laser surgery. Dr. Paugh scheduled the surgery for February 3, 2012 at Central Washington Hospital.

¶ 3 Before the surgery began, the hospital operating room staff mistakenly told Dr. Paugh and anesthesiologist Dr. Linda Schatz that only the single-cuff "Laser–Shield II" endotracheal tube manufactured by Medtronic was available.

¶ 4 The Laser–Shield II is designed for endotracheal intubation during laser surgeries and has "a laser resistant overwrap on the main shaft." However, the "Instructions for Use" state the inflatable cuff that seals the airway and prevents oxygen and other flammable gas from reaching the surgical field is not laser resistant. The Instructions for Use warn users that contacting the cuff with a laser "may cause deflation of the cuff and result in combustion and fire." The instructions tell users to place wet cotton gauze around the cuff to protect from laser strike. To alert users to a rupture, the Laser–Shield II cuff-inflation valve is equipped with blue methylene dye that stains the cotton gauze if the cuff is punctured. The Instructions for Use warn of the risk of fire due to "elevated oxygen levels or other flammable gases" and recommend using a "30% oxygen / 70% helium, or 30% oxygen / 70% room air" combination.

*2 ¶ 5 Neither Dr. Paugh nor Dr. Schatz had ever used the Laser–Shield II. Dr. Paugh had used only a double-cuff endotracheal tube manufactured by Mallinckrodt Inc. The double-cuff tube has a lower cuff that seals the airway to prevent oxygen from leaking out and an upper cuff that shields the lower cuff from damage from the laser.

¶ 6 Nonetheless, Dr. Paugh and Dr. Schatz decided to proceed with the surgery and use the Laser–Shield II. Neither Dr. Paugh nor Dr. Schatz read the Laser–Shield II Instructions for Use. Contrary to the Instructions for Use, Dr. Schatz administered 100 percent oxygen, not the recommended 30 percent. During the surgery, Dr. Paugh perforated the inflatable cuff of the tube with the laser causing oxygen to leak into the surgical site and ignite. The airway fire caused serious burns to Anderson's trachea and lungs.

The Lawsuit

¶ 7 Anderson filed a complaint against Central Washington Hospital, Dr. Paugh and Wenatchee Valley Medical Center, and Dr. Schatz and Wenatchee Anesthesia Associates alleging medical negligence, and alleging product liability against medical device manufacturer Medtronic Inc. and Medtronic Xomed Inc. (Medtronic). Anderson alleged Dr. Paugh and Dr. Schatz breached the standard of care resulting in the injuries to Anderson. Anderson alleged Medtronic was "liable under the Washington Products Liability Act R .C.W. Chapter 7.72" for defect in production or construction. In the amended complaint, Anderson alleged Medtronic was liable under the Washington product liability act, chapter 7.72 RCW.

Summary Judgment

¶ 8 Anderson filed a motion for partial summary judgment arguing there was no dispute Dr. Schatz was negligent in administering 100 percent oxygen. Anderson also, argued Dr. Schatz acted as an agent of the hospital. The court granted the motion in part, ruling Dr. Schatz and Wenatchee Anesthesia Associates were negligent as a matter of law.

¶ 9 Following discovery, Medtronic filed a motion for summary judgment dismissal of claims alleging design defect, failure to warn, and manufacturing or production defect. Medtronic argued the Laser–Shield II is a prescription medical device governed by the negligence standard under *Restatement (Second) of Torts* section 402A comment k (1965), and there was no evidence of defective design. Medtronic argued that because the Laser–Shield II warnings "were adequate as a matter of law," it was entitled to dismissal of the failure to warn claim. Medtronic also argued Anderson could not show that "any allegedly deficient warnings or instructions proximately caused her injuries." Medtronic submitted the deposition testimony of Dr. Paugh and Dr. Schatz admitting they did not read the Laser–Shield II Instructions for Use before the surgery.

¶ 10 In response, Anderson did not dispute that the negligence standard under *Restatement (Second) of Torts* section 402A comment k applied to the design defect claim. Relying on the Washington Pattern Jury Instruction 110.02.01, "Manufacturer's Duty—Design—Unavoidably Unsafe Products—Negligence—Comment K," Anderson argued there were material issues of fact as to Medtronic's breach of the duty to use reasonable care to design a product that was reasonably safe and on proximate cause.[1] 6 WASHINGTON PRACTICE: WASHINGTON PATTERN JURY INSTRUCTIONS: CIVIL 110.02.01, at 635 (6th ed. 2012) (WPI). Anderson also argued that because the information on the Laser–Shield II box was inadequate and deceptive, there were material issues of fact on failure to warn.

*3 ¶ 11 At the summary judgment hearing, Anderson's attorney confirmed that the comment k negligence standard under *Restatement (Second) of Torts* section 402A applied to the design defect claim against Medtronic and withdrew any alleged claims for breach of warranty and construction or manufacturing defect.

¶ 12 The court granted in part and denied in part Medtronic's motion for summary judgment. The court granted Medtronic's motion to dismiss the failure to warn claim. The court denied the motion to dismiss the negligent design claim.

> The Court hereby ORDERS that Medtronic, Inc. and Medtronic, Xomed, Inc.'s Motion for Summary Judgment is hereby GRANTED IN PART and DENIED IN PART.
>
> The Medtronic Defendants' Motion is GRANTED as to Plaintiff's claims for failure to warn or inadequate warnings. All such claims are hereby dismissed with prejudice and without fees or costs to any party.
>
> Plaintiff has withdrawn her claims for breach of warranty and unsafe construction or manufacturing defect, to the extent such claims were stated in the Complaint.
>
> ....
>
> The Medtronic Defendants' motion is DENIED and Plaintiff may proceed against the Medtronic Defendants as to her claim for negligent design.

¶ 13 Before trial, Central Washington Hospital settled with Anderson for $12 million. The court entered an

agreed order dismissing the hospital but granted Anderson's motion to identify the hospital as a nonparty defendant at trial for purposes of allocating fault.

Trial

¶ 14 At the beginning of the seven-week jury trial and before opening statements, the court agreed to read a number of instructions on the law to the jury including the "Pre–Instruction" Anderson submitted on the negligent design claim, Medtronic's duty, and the standard of care that applies to the manufacturer of an unavoidably unsafe product under comment k, *Restatement (Second) of Torts* section 402A. The Pre–Instruction Anderson submitted is based on WPI 110.02.01, Manufacturer's Duty—Design—Unavoidably Unsafe Products—Negligence—Comment K.

¶ 15 The court told the jury the instructions "will apply throughout the trial."

> Now I'm going to instruct you on the law, which will guide your decision making in this case. We will reinstruct you at the end of the trial. There may be additional instructions, but these instructions will apply throughout the trial.
>
> The Pre–Instruction on the duty of medical device manufacturer Medtronic states:
>
> 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.
>
> *4 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.

¶ 16 During opening statement, Anderson argued Dr. Paugh breached the standard of care by failing to adequately protect the Laser–Shield II cuff, failing to make sure the oxygen was at a safe level, and failing to inform Anderson of the risk of fire. Anderson argued Dr. Schatz violated the standard of care by administering 100 percent oxygen during the laser procedure. Anderson also argued Dr. Paugh and Dr. Schatz violated the standard of care by proceeding with the surgery despite being unfamiliar with the Laser–Shield II, not reading the Instructions for Use, and failing to have a plan in place in the event of a fire.

¶ 17 Anderson argued Medtronic was negligent in using a single-cuff instead of a double-cuff design for the Laser–Shield II. Anderson also argued Medtronic was aware of problems with the Laser–Shield II, including a number of other airway fires, but did nothing to make the device safer. Anderson argued the negligence of each of the defendants was a proximate cause of injury.

¶ 18 More than 30 witnesses testified during the seven-week jury trial including a number of expert witnesses.

¶ 19 Anderson's experts testified that the fire occurred because Dr. Paugh perforated the cuff with the laser causing the extremely flammable 100 percent oxygen administered by Dr. Schatz to enter the surgical field and ignite. Anderson's experts testified that the fire would not have occurred if Dr. Schatz had administered a lower oxygen concentration or if Dr. Paugh had properly protected the cuff. Dr. James Reibel testified that Dr. Paugh violated the standard of care for a surgeon by failing to inform Anderson of the risk of fire before the laser surgery, proceeding with the surgery despite being unfamiliar with the Laser–Shield II endotracheal tube, not communicating with Dr. Schatz about the level of oxygen being administered, and not adequately protecting the cuff.

¶ 20 Dr. Barry Swerdlow and Dr. Vladimir Nekhedzy testified that Dr. Schatz violated the standard of care for an anesthesiologist by administering 100 percent oxygen to Anderson during the procedure and not telling Dr. Paugh about the high oxygen level.

¶ 21 Anderson's medical device expert Dr. George Samaras testified Medtronic failed to act as a "reasonably prudent medical product company" in not using a double-cuff design for the Laser–Shield II. Dr. Samaras testified that in his opinion, the single-cuff design is

"inherently less safe than the double cuff." Dr. Samaras stated a double-cuff design is safer because it provides a "redundant safety system." If the upper cuff is punctured, the lower cuff continues to seal the airway to prevent oxygen from leaking into the surgical field and coming into contact with the laser. Dr. Samaras testified that since 2000, there had been eight reported airway fires involving the Laser–Shield II. According to Dr. Samaras, during that same time, there had been only one reported airway fire involving the double-cuff endotracheal tube manufactured by Mallinckrodt.

*5 ¶ 22 Dr. Jonathan Benumof, an anesthesiologist and consultant for endotracheal tube manufacturers, testified that in his opinion, the fire would not have occurred if Dr. Schatz and Dr. Paugh had used a double-cuff endotracheal tube. However, on crossexamination, Dr. Benumof testified that the Laser–Shield II could be used safely. Dr. Benumof also said that surgeons and anesthesiologists in his hospital had used the Laser–Shield II for years without incident and continued to use the Laser–Shield II. In response to a juror question, Dr. Benumof stated he "personally and successfully" used the Laser–Shield II.

¶ 23 Dr. Paugh testified he decided to proceed with the laser surgery and use the Laser–Shield II because it "seemed like a very reasonable substitute" to the endotracheal tube he typically used and he had "no reason ... to question the safety of that device." Dr. Paugh admitted he did not read the Laser–Shield II Instructions for Use. Dr. Paugh testified he knew the cuff of an endotracheal tube is "susceptible to a laser strike" but believed he "adequately protected the cuff" during the surgery. Dr. Paugh denied perforating the cuff of the Laser–Shield II with the laser. Dr. Paugh testified he did not know what role the cuff played in the fire but he believed the fire would have been "[v]ery unlikely" to occur if he and Dr. Schatz had used the double-cuff tube he had previously used for laser surgeries.

¶ 24 Dr. Barry Wenig testified as an expert witness on behalf of Dr. Paugh. Dr. Wenig testified that in his opinion, Dr. Paugh "met the standard of care of a reasonably prudent otolaryngologist in his care and treatment of Ms. Anderson." In Dr. Wenig's opinion, the presence of oxygen "in the space between the cuff and the vocal cords" and the "likelihood" of oxygen passing from "the area below the cuff to the area above the cuff" caused the fire. On cross-examination, Dr. Wenig testified that since 2003, he has used the Laser–Shield II "almost exclusively" and did not have any safety concerns with the device.

¶ 25 Dr. Schatz testified that she did not read the Laser–Shield II Instructions for Use because she had "used lots of different endotracheal tubes" and the Laser–Shield II "was not different in form or function than any other endotracheal tube." Dr. Schatz testified she knew that the cuff was not laser resistant and that a 30 percent oxygen concentration was recommended in laser procedures. Dr. Schatz admitted she made a "mistake" by leaving "the oxygen on 100 percent" but testified she was more than "99 percent" sure she "got a proper, adequate seal of the cuff" to prevent oxygen from leaking into the surgical field. Dr. Schatz testified the first indication that there was a problem during surgery was when she "heard a pop" and "heard Dr. Paugh ask for saline." Dr. Schatz testified she did not know what caused the fire.

¶ 26 Medtronic called a number of witnesses to testify at trial including James Hissong, the mechanical engineer responsible for the design and testing of the LaserShield II; medical device design expert Dr. Samsun Lampotang; and otolaryngologist Dr. Paul Flint. Medtronic also presented evidence regarding compliance with United States Food and Drug Administration (FDA) regulations, medical device reporting, and corrective and preventive actions related to the Laser–Shield II.

*6 ¶ 27 Hissong testified that in 1989, Medtronic initially considered using a double-cuff design but ultimately decided to use a single-cuff design for the Laser–Shield II. Hissong testified a double-cuff design can give users a "false sense of security" in continuing the procedure even though the lower cuff and tube are vulnerable to puncture. Hissong also testified the double cuff can prevent the user from realizing that the upper cuff is damaged.

¶ 28 Hissong testified that Medtronic modified the Laser–Shield II in 1999 to prevent "inadvertent cuff rupture" by "extend[ing] the wrapping" underneath the cuff and adding a section "that would be more laser resistant," making "the Laser–Shield II the most laser-resistant tube on the market." Hissong testified Medtronic investigated each of the reports of airway fires and concluded that in seven of the eight reports, the surgeon or anesthesiologist was responsible for the airway fire.

¶ 29 Mechanical engineer and medical device design expert Dr. Samsun Lampotang is a professor of anesthesiology, affiliate professor of mechanical engineering and aerospace engineering, and affiliate professor of biomedical engineering at the University of Florida. Dr. Lampotang testified that in his opinion, Medtronic exercised the care that a reasonably prudent medical device manufacturer would exercise in designing

and testing the Laser–Shield II and the device was reasonably safe. Dr. Lampotang disagreed with Dr. Samaras that the double-cuff design is a "redundant safety system." Dr. Lampotang testified the two cuffs perform different functions: the upper cuff acts as a barrier, protecting the cuff below from laser strike, while the lower cuff seals the trachea and prevents oxygen from leaking out. Dr. Lampotang testified that in his opinion, the single "lay flat" cuff on the Laser–Shield II "provides a better seal" than the "preshaped" cuff used in the double-cuff design. Dr. Lampotang also testified that it was more difficult to detect quickly a leak in a double-cuff endotracheal tube.

¶ 30 Dr. Paul Flint, the chair of otolaryngology, head, and neck surgery at Oregon Health and Science University, testified about the double-cuff and single-cuff endotracheal tubes manufactured by Mallinckrodt and Medtronic. Dr. Flint testified that he had used the Mallinckrodt double-cuff endotracheal tube in approximately 50 surgeries and the Medtronic Laser–Shield II in approximately 200 surgeries. Dr. Flint testified the Laser–Shield II provided "better laser resistance" and additional protection. Dr. Flint also testified about a 1994 study published by Dr. Mitchell Sosis. Dr. Flint testified that it was the only study that compared the Mallinckrodt double-cuff endotracheal tube and the single-cuff Laser–Shield II endotracheal tube. Dr. Flint said the study showed that "under extreme conditions," the Mallinckrodt dual-cuff tube combusted but the Laser–Shield II did not. Dr. Flint also testified about Medtronic's investigation of each of the eight "adverse events" involving the Laser–Shield II and agreed with the conclusion that "user error" on the part of the surgeon or anesthesiologist was involved in seven of the eight events.

*7 ¶ 31 Timothy Ulatowski is the vice president of a consulting company for medical device manufacturers. Ulatowski testified about the design of the Laser–Shield II and the FDA regulations, procedures, and policies. Ulatowski testified that as designed, the Laser–Shield II "is reasonably safe and effective." Ulatowski testified that the FDA also determined that the Laser–Shield II was reasonably safe as designed.

¶ 32 The evidentiary portion of the trial concluded the day before Thanksgiving on Wednesday, November 27. Anderson had submitted "Amended Proposed Instructions" that included the same jury instruction the court read to the jury at the start of the case defining the duty of care that applies to the manufacturer of an unavoidably unsafe medical device based on WPI 110.02.01.

¶ 33 The court scheduled closing arguments for Tuesday, December 3. Before adjourning for the Thanksgiving recess, the court provided the parties with a packet of proposed jury instructions. The court stated it compared the instructions the parties proposed "to the preinstructions to try to be consistent." The court stated the jury instruction on the duty of care of Medtronic as a medical device manufacturer was consistent with the "agreed" Pre–Instruction.

¶ 34 On Monday, December 2, Anderson filed "Supplemental Amended Proposed Instructions." The supplemental instructions included a jury instruction on adherence to governmental standards, an instruction informing the jury that Medtronic did not claim a patent prevented "incorporating a double-cuff into their product," and a jury instruction that sets forth the tests that are used to determine the duty of a manufacturer in a strict liability design defect case.

¶ 35 On December 3, Anderson filed written "Objections and Exceptions to Jury Instructions." Anderson argued that because the "negligence instruction to be given by the Court refers to the duty of the manufacturer to use reasonable care 'to design medical devices that are *reasonably safe* " ' and the instruction "taken from WPI 110.02.01 ... defines 'reasonable care' but it does not define 'reasonably safe' or instruct the jury as to the factors to be considered in determining whether or not a product is reasonably safe," the "instructions for the jury in determining whether a product is not reasonably safe are found in WPI 110.02."[2] Anderson claimed the "proposed instructions are based upon WPI 110 .02, and should be given in addition to those in WPI 11[0].02.01, which define the reasonable care."

¶ 36 The court refused to give the proposed supplemental jury instruction based on WPI 110.02. The court decided to use the Amended Proposed Instruction Anderson previously submitted on November 27 to instruct the jury on the negligent design defect claim against Medtronic based on WPI 110.02.01, Manufacturer's Duty—Design—Unavoidably Unsafe Products—Negligence—Comment K, to instruct the jury on the duty of a medical device manufacturer of an unavoidably unsafe product under comment k of *Restatement (Second) of Torts* section 402A.

*8 ¶ 37 In closing argument, Anderson argued the hospital was negligent in giving the doctors the "wrong tube." Anderson argued Dr. Paugh violated the standard of care by "hitting the cuff and deflating the cuff with the laser" causing the airway fire. Anderson also argued Dr.

Paugh did not obtain Anderson's informed consent to use the LaserShield II. Anderson asserted Dr. Schatz violated the standard of care and caused the airway fire by administering "100 percent oxygen." Anderson argued Medtronic did not design the "safest device possible for all reasonably foreseeable circumstances" and did not "test and analyze [the] product to make it safer." Anderson argued Medtronic knew of problems with the Laser–Shield II and failed to act to make its product safer by incorporating a double-cuff design.

> I would like you to think about this question as you listen to counsel for Medtronic talk. Since September of 2000, when the Laser–Shield II enhanced was launched, what did you do to test and analyze your product to try to make it safer? What did they do? Just listen to the evidence. What did they do?
>
> One thing we know is that including [Anderson's] case, that there were ten adverse events. Four of those events were life-threatening. Four of those events were life-threatening before [Anderson]. What we do know is that the company has told you that they didn't do anything since September of 2000. They have no plans to do anything in the future. No testing. No study. No analysis. They're just going to blame the doctors and the hospitals and the users for what's gone on out there with this product.
>
> ....
>
> I wanted to say that first because I think that's the single most important thing in terms of Medtronic's case that you're here to decide. Well, what did they do? Did they take actions to try and make their product safer or did they close their eyes?
>
> ....
>
> In terms of reasonable care, if you could turn to exhibit number 20, the next exhibit. This defines what reasonable care is. And reasonable care, pardon me if I don't read it all, is basically to design the medical devices that are reasonably safe, and their obligation and duty is to act as a reasonably prudent medical device company.
>
> ....
>
> So when you answer this question, since September of 2000, what did you do to test and analyze your product to make it safer, this is the standard that would apply. Were they 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 when [Anderson] got burned?

¶ 38 If you'd go back to ... the burden of proof instruction, it gives you a guide. If you go back to instruction number 19, we're claiming that they did not—they did not meet their burden to make the safest and best device possible because they didn't test and analyze their product. They didn't incorporate into their product a known safety feature, which is the double cuff.

*9 ¶ 39 Dr. Paugh argued the fire occurred because oxygen leaked out around the cuff of the Laser–Shield II "without the laser striking the cuff at all." Dr. Paugh also argued he did not have a duty to warn Anderson of the risk of airway fire during a laser procedure because it was an "incredibly rare event."

¶ 40 Dr. Schatz argued the high oxygen level was not a proximate cause of the fire. According to Dr. Schatz, "there was no leak with that cuff" and there were a number of other ways the fire could have occurred, including laser strike and perforation of the cuff.

¶ 41 Medtronic argued the only witness Anderson called to testify about the design of the Laser–Shield II was not qualified and the overwhelming evidence presented by the other witnesses established it was not negligent. Medtronic described the testimony of the design engineers and medical experts to show the Laser–Shield II was reasonably safe as designed and Medtronic met the standard of care.

> [W]hat about all these standard, regulations, guidances, information, all the parties brought before you.
>
> ....
>
> ... [I]f you are going to use these endotracheal tubes, which can be lit on fire, can be caught on fire unfortunately, you know, then use one with a cuff. Use one that's laser resistant. Which ours meets both those qualifications. It doesn't say use a dual cuff or a triple cuff or a quadruple cuff. It says cuffed. Cuffed. That's what this standard says.
>
> ... And so what is the literature? Well, you know, you heard Dr. Flint, and I used this also with Dr. Benumof, the Sosis article. You hear Sosis' name. He's written quite a bit on airway fires. And he did a study and you heard, remember Dr. Flint said, this is the only study that compares the two, in terms of peer-reviewed literature, Dr. Flint says, and I believe based on this and everything else, my use, my clinical use, the single cuff laser is safer. But if you look at this with the application of a liability there was immediate combustion in all four Mallinckrodt LaserFlex tubes,

and it ultimately said this is the Xomed Laser Shield II endotracheal tubes provides good protection. Reasonably safe design. Standards say so. Regulations say so. Vast majority of witnesses say so.

¶ 42 Medtronic also pointed to the evidence that showed it met the standard of care to test, analyze, and inspect and to keep abreast of scientific knowledge and research.

[T]he manufacturer has a duty to use reasonable care to test and analyze and inspect. As had been described by Mr. Hissong, and Mr. Ulatowski with submissions, and Dr. Lampotang, Dr. Flint. And then also the manufacturer has a duty to use reasonable care to keep abreast of scientific knowledge, discoveries, advances, and researches in the field.

Well, you will remember that, on this point, what was the evidence on this? On testing, analyzing and inspecting? Well, you received testimony from Mr. Hissong, Mr. Ulatowski, Dr. Lampotang. They all reviewed the extensive testings, including on the cuff and the area below. ... The FDA reviewed testing and they didn't request anymore. They asked questions.... You will see all that.

*10 The testing that's listed right on the [Instructions for Use], which is Exhibit 503, that you will have in evidence. Years of clinical results. Thousands and thousands of patients. Feedback from the physicians, the leaders at the conferences. And remember that testimony that was every single cuff is tested one last time. And in addition he said, worst case scenario testing is conducted.... So all that testing was described to you.

And what about keeping abreast of the scientific, knowledge, discoveries, advances, and research of the field? Well, remember the slide in his testimony? I had Mr. Hissong on the stand. And I went through all this because I thought this would be important one day. This is all the information, and you will remember this, you will have your notes. He attends conferences. His team is looking at all the data. Keeping abreast. They get monthly reports of all the literature. They have a clinical affairs department. Their marketing department is monitoring. The quality assurance and customer loyalty is looking at adverse events, and doing testing on each returned device, and all the—they have a one eight hundred number to take information. They are attending regulatory conferences.

¶ 43 There is so much information coming in and they are monitoring this. It's not like they put this on the market and that's it. No. Look at all the different departments that are set up out of Jacksonville, out of Xomed keeping abreast of scientific, knowledge, discoveries, advantages of the research of the field. And that's how it's done. That's how they meet this. And [Anderson] didn't present a shred of evidence to counter this.

¶ 44 By special verdict form, the jury found Dr. Schatz and Wenatchee Anesthesia Associates, Dr. Paugh and Wenatchee Valley Medical Center, and nonparty Central Washington Hospital were negligent and proximately caused Anderson's damages in the amount of $18 million. The jury found Dr. Paugh did not fail to obtain the informed consent of Anderson. The jury found Medtronic was not negligent. The jury attributed 52.5 percent of the fault to Dr. Schatz and Wenatchee Anesthesia Associates, 42.5 percent to Dr. Paugh and Wenatchee Valley Medical Center, and 5 percent to the hospital. The court reduced the judgment by $900,000 to account for the fault attributed to the nonparty hospital. The court entered a judgment of $17.1 million against Dr. Schatz and Wenatchee Anesthesia Associates, and Dr. Paugh and Wenatchee Valley Medical Center.

Appeal

¶ 45 Dr. Paugh and Wenatchee Valley Medical Center, and Dr. Schatz and Wenatchee Anesthesia Associates appealed entry of the judgment on the jury verdict. Anderson appealed the order granting Medtronic's motion for summary judgment on failure to warn, the judgment on the verdict in favor of Medtronic, and the award of costs.[3] In July 2014, Dr. Schatz and Wenatchee Anesthesia Associates, and Dr. Paugh and Wenatchee Valley Medical Center filed a motion to withdraw their appeals and dismiss the appeals with prejudice. We granted the motion.

*11 ¶ 46 In September 2014, Anderson withdrew her assignment of error as to the summary judgment dismissal of the failure to warn claim against Medtronic. On September 17, we granted the motion to substitute Dorothy L. Payne as the personal representative of the Estate of Becky S. Anderson, deceased, and amend the caption.

ANALYSIS

Refusal to Give Proposed Jury Instruction

¶ 47 Anderson contends the court erred in refusing to give the supplemental proposed instruction based on the WPI

used for a strict liability design defect claim, WPI 110.02, "Manufacturer's Duty—Design," to define "reasonably safe" as used in the WPI for a negligent design comment k claim against Medtronic, WPI 110.02.01, Manufacturer's Duty—Design—Unavoidably Unsafe Products—Negligence—Comment K.

Standard of Review

[1] [2] [3] [4] ¶ 48 We review the decision not to give a jury instruction for abuse of discretion. *Fergen v. Sestero,* 182 Wash.2d 794, 802, 346 P.3d 708 (2015). The language of jury instructions are matters left to the trial court's discretion. *Young v. Key Pharmaceuticals, Inc.,* 130 Wash.2d 160, 176, 922 P.2d 59 (1996). " 'Jury instructions are sufficient when they allow counsel to argue their theory of the case, are not misleading, and when read as a whole properly inform the trier of fact of the applicable law." ' *Keller v. City of Spokane,* 146 Wash.2d 237, 249, 44 P.3d 845 (2002) (quoting *Bodin v. City of Stanwood,* 130 Wash.2d 726, 732, 927 P.2d 240 (1996)). "[A] 'trial court need never give a requested instruction that is erroneous in any respect.' " *Crossen v. Skagit County,* 100 Wash.2d 355, 360–61, 669 P.2d 1244 (1983) (quoting *Vogel v. Alaska S.S. Co.,* 69 Wash.2d 497, 503, 419 P.2d 141 (1966)).[4]

[5] [6] [7] [8] ¶ 49 We review alleged errors of law in jury instructions de novo. *Anfinson v. FedEx Ground Package Sys., Inc.,* 174 Wash.2d 851, 860, 281 P.3d 289 (2012). "An erroneous instruction is reversible error only if it is prejudicial to a party." *Fergen,* 182 Wash.2d at 803, 346 P.3d 708; *Barrett v. Lucky Seven Saloon, Inc.,* 152 Wash.2d 259, 267, 96 P.3d 386 (2004). If the instruction contains a clear misstatement of law, prejudice is presumed and is grounds for reversal unless it can be shown that the error was harmless. *Fergen,* 182 Wash.2d at 803, 346 P.3d 708. The party challenging an instruction bears the burden of establishing prejudice. *Griffin v. W. RS, Inc.,* 143 Wash.2d 81, 91, 18 P.3d 558 (2001).

Strict Liability Design Defect Claim Restatement (Second) of Torts Section 402A

¶ 50 The *Restatement (Second) of Torts* section 402A addresses design defect claims. *Restatement (Second) of Torts* section 402A states, in pertinent part, "One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user." § 402A(1).

¶ 51 In 1969, the Washington Supreme Court adopted *Restatement (Second) of Torts* section 402A and strict liability for design defect claims against manufacturers. *Ulmer v. Ford Motor Co.,* 75 Wash.2d 522, 532, 452 P.2d 729 (1969). In *Seattle–First National Bank v. Tabert,* 86 Wash.2d 145, 154, 542 P.2d 774 (1975), the court held that "[i]f a product is unreasonably dangerous, it is necessarily defective. The plaintiff may, but should not be required to prove defectiveness as a separate matter." For purposes of defining "unreasonably dangerous," the Washington Supreme Court used the consumer expectations standard of "reasonably safe" adopted in *Tabert. Falk v. Keene Corp.,* 113 Wash.2d 645, 649, 782 P.2d 974 (1989) (citing *Tabert,* 86 Wash.2d at 154, 542 P.2d 774); *see also Lenhardt v. Ford Motor Co.,* 102 Wash.2d 208, 212, 683 P.2d 1097 (1984) ("our rule of strict liability focuses attention upon the product and not upon the actions of the seller or manufacturer").

***12** ¶ 52 After examining a number of possible formulations for "consumer expectations," we held that liability is imposed if the product is

> "unsafe to an extent beyond that which would be reasonably contemplated by the ordinary consumer....
>
> In determining the reasonable expectations of the ordinary consumer, a number of factors must be considered. The relative cost of the product, the gravity of the potential harm from the claimed defect and the cost and feasibility of eliminating or minimizing the risk may be relevant in a particular case. In other instances the nature of the product or the nature of the claimed defect may make other factors relevant to the issue."

Falk, 113 Wash.2d at 649, 782 P.2d 974[5] (quoting *Tabert,* 86 Wash.2d at 154, 542 P.2d 774).

Restatement (Second) of Torts Section 402A Comment K

¶ 53 The *Restatement (Second) of Torts* section 402A comment k establishes an exception to strict liability for "unavoidably unsafe products" such as prescription drugs and medical devices. *Ruiz–Guzman v. Amvac Chem. Corp.,* 141 Wash.2d 493, 505–06, 7 P.3d 795 (2000) (citing *Terhune v. A.H. Robins Co.,* 90 Wash.2d 9, 12, 577 P.2d 975 (1978)). The comment k exception applies to medical devices that have a high risk of possible harmful effects but are "necessary regardless of the risks involved to the user." *Rogers v. Miles Labs., Inc.,* 116 Wash.2d 195, 204, 802 P.2d 1346 (1991).

¶ 54 *Restatement (Second) of Torts* section 402A comment k states:

> *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk. [6]

*13 ¶ 55 The rationale underlying the comment k exception is that the social utility of having certain products available outweighs the risk posed by their use.

> Comment k justifies an exception from strict liability by focusing on the product and its relative value to society, rather than on the manufacturer's position in the stream of commerce. Some products are necessary regardless of the risk involved to the user. The alternative would be that a product, essential to sustain the life of some individuals, would not be available—thus resulting in a greater harm to the individual than that risked through use of the product.

Rogers, 116 Wash.2d at 204, 802 P.2d 1346.[7]

Washington Product Liability Act

¶ 56 In 1981, the legislature adopted the Washington product liability act (WPLA), chapter 7.72 RCW. Laws of 1981, ch. 27, § 1. Under RCW 7.72.030(1), "[a] product manufacturer is subject to liability to a claimant if the claimant's harm was proximately caused by the negligence of the manufacturer in that the product was not reasonably safe as designed or not reasonably safe because adequate warnings or instructions were not provided." RCW 7.72.030(1)(a) states a product "is not reasonably safe" if

> at the time of manufacture, the likelihood that the product would cause the claimant's harm or similar harms, and the seriousness of those harms, outweighed the burden on the manufacturer to design a product that would have prevented those harms and the adverse effect that an alternative design that was practical and feasible would have on the usefulness of the product.

The statute states that "[i]n determining whether a product was not reasonably safe under this section, the trier of fact shall consider whether the product was unsafe to an extent beyond that which would be contemplated by the ordinary consumer." RCW 7.72.030(3).

¶ 57 In *Falk,* the Washington Supreme Court held that although RCW 7.72.030(1) uses the word "negligence," "ordinary negligence is not the standard for design defect claims" under the WLPA. *Falk,* 113 Wash.2d at 653, 782 P.2d 974. The court held that "because consumer expectations are still to be considered by the trier of fact, the Legislature has retained aspects of the buyer-oriented approach which existed before the tort reform act of 1981." *Falk,* 113 Wash.2d at 653, 782 P.2d 974.

> Section (2) [of RCW 7.72.030] provides that a manufacturer is "strictly liable" for harm caused by products not reasonably safe in construction or in nonconformance with warranties. Significantly, there is no risk-utility balancing test required for this type of product liability claim. Because the Legislature thought that type of balancing to be "akin" to negligence, but did not intend that it be undertaken for claims under section (2), it is also not surprising that the term "strict liability" is used in the section. Put simply, the Legislature evidently doubted that what we termed

"strict liability" in *Tabert* is, or should be called, "strict liability."

***14** This semantic distinction does not alter the fact that the statute sets forth the same type of design defect analysis which we adopted in *Tabert.* Therefore, a design defect product liability claim is still a strict liability claim, as the term is used in *Tabert.* Further, the focus is still on the reasonable safety of the product. Moreover, because consumer expectations are still to be considered by the trier of fact, the Legislature has retained aspects of the buyer-oriented approach which existed before the tort reform act of 1981. This is entirely consistent with the stated purpose of the act "that the right of the consumer to recover for injuries sustained as a result of an unsafe product not be unduly impaired." Laws of 1981, ch. 27, § 1.

Falk, 113 Wash.2d at 653, 782 P.2d 974.

¶ 58 The court held the WPLA allows the plaintiff to show the product is "not reasonably safe as designed" under a risk utility test or, in the alternative, under the consumer expectations test that requires the plaintiff to show the product was "unsafe to an extent beyond that which would be contemplated by the ordinary consumer." RCW 7.72.030(1)(a), (3); *Falk,* 113 Wash.2d at 653, 782 P.2d 974.

¶ 59 Consistent with the WPLA and case law, the WPI for a strict liability design defect claim against a manufacturer, WPI 110 .02, Manufacturer's Duty–Design (Strict Liability Instruction), states the risk utility and consumer expectations tests are used to determine whether a product is not reasonable safety as designed. The comment to the Strict Liability Instruction states that "because the risk-utility test involves strict liability principles," the instructions do not include the term "negligence."[8] WPI 110.02, at 632. The Strict Liability Instruction states:

> A manufacturer has a duty to design products that are reasonably safe as designed.
>
> There are two tests for determining whether a product is not reasonably safe as designed. The plaintiff may prove that the product was not reasonably safe at the time it left the manufacturer's control using either of these two tests.
>
> The first test is a balancing test. Under that test, you should determine whether, at the time the product was manufactured:
>
> the likelihood that the product would cause injury or damage similar to that claimed by the plaintiff, and the seriousness of such injury or damage
>
> outweighed
>
> the burden on the manufacturer to design a product that would have prevented the injury or damage, and the adverse effect that a practical and feasible alternative design would have on the usefulness of the product.
>
> The second test is whether the product is unsafe to an extent beyond that which would be contemplated by the ordinary user. In determining what an ordinary user would reasonably expect, you should consider the following:
>
> a. The relative cost of the product;
>
> b. The seriousness of the potential harm from the claimed defect;
>
> c. The cost and feasibility of eliminating or minimizing the risk; and
>
> *15 d. Such [other] factors as the nature of the product and the claimed defect indicate are appropriate.
>
> [A product can be "not reasonably safe" even though the risk that it would cause the plaintiff's harm or similar harms was not foreseeable by the manufacturer at the time the product left the manufacturer's control.]
>
> If you find that the product was not reasonably safe as designed at the time it left the manufacturer's control and this was a proximate cause of the plaintiff's [injury] [and][or] [damage], then the manufacturer is [subject to liability] [at fault].

¶ 60 The comment k exception for unavoidably unsafe products continues to apply to a negligent design defect claim against a manufacturer even though not expressly provided for in the WPLA. The Washington Supreme Court in *Ruiz–Guzman* holds "[t]here is no debate" the comment k exception to the *Restatement (Second) of Torts* section 402A "has been expressly adopted by this court." *Ruiz–Guzman,* 141 Wash.2d at 506, 7 P.3d 795 (citing *Terhune,* 90 Wash.2d at 9, 577 P.2d 975). The court states that although "the comment k exception to strict liability was not expressly provided for by the Legislature in adopting the WPLA, ... it is implicit that products that are 'unavoidably unsafe' are not products that ever *could* be 'reasonably safe as designed.' " *Ruiz–Guzman,* 141 Wash.2d at 506, 7 P.3d 795[9] (quoting RCW 7.72.030(1)). The exception "recognize[s] the

unique protection provided to the consumers of such products by the prescribing physician (and/or pharmacist) intermediary." *Ruiz–Guzman,* 141 Wash.2d at 508, 7 P.3d 795. Because an unavoidably unsafe product such as a medical device is incapable of being made completely safe, the court adopted a negligence standard for design defect claims involving comment k products. *Ruiz–Guzman,* 141 Wash.2d at 507–08, 7 P.3d 795.

¶ 61 Accordingly, the WPI for a design defect claim against a medical device manufacturer of an unavoidably unsafe product under comment k, WPI 110.02.01 (Comment K Negligence Instruction), makes clear that the standard is negligence and the focus is on the conduct of the manufacturer to use reasonable care to design a medical product that is reasonably safe. "Reasonable care is to be determined by what the manufacturer knew or reasonably should have known at the time of the plaintiff's injury." WPI 110.02.01, at 635. The Comment K Negligence Instruction states:

> A [pharmaceutical] [medical product] manufacturer has a duty to use reasonable care to design [drugs] [medical products] that are reasonably safe. "Reasonable care" means the care that a reasonably prudent [pharmaceutical] [medical product] manufacturer would exercise in the same or similar circumstances. A failure to use reasonable care is negligence.
>
> The question of whether a manufacturer exercised reasonable care is to be determined by what the manufacturer knew or reasonably should have known at the time of the plaintiff's injury.
>
> In determining what a manufacturer reasonably should have known in regard to designing its product, you should consider the following:
>
> ***16** A [pharmaceutical] [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 [pharmaceutical] [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.

¶ 62 Here, the court used Anderson's proposed Comment K Negligence Instruction to instruct the jury. Jury instruction 20 states:

> As to the plaintiff's claim against the Medtronic Defendants, a medical device manufacturer has a duty to use reasonable care to design medical devices that are reasonably safe. "Reasonable care" means the care that a reasonably prudent medical device manufacturer would exercise in the same or similar circumstances. A failure to use reasonable care is negligence.
>
> The question of whether a medical device manufacturer exercised reasonable care is to be determined by what the manufacturer knew or reasonably should have known at the time the device left its control.
>
> In determining what a medical device manufacturer reasonably should have known in regard to designing its device, you should consider the following:
>
> A medical device 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 device 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.

[9] ¶ 63 But Anderson asserts the court erred in refusing to give her supplemental jury instruction on the risk utility and consumer expectations tests to define whether a medical device is reasonably safe. The proposed supplemental instruction deletes the clearly inapplicable language of the Strict Liability Instruction that states, "A manufacturer has a duty to design products that are reasonably safe as designed," but otherwise sets forth verbatim the tests used in determining a strict liability design defect claim: the risk utility and consumer expectations tests.[10]

¶ 64 To prove a strict liability claim against a manufacturer, the WPLA and case law make clear the plaintiff can show the product is not reasonably safe two different ways: the risk utility and consumer expectations tests. Anderson claims that because the Comment K Negligence Instruction does not define "reasonably safe," the court must instruct the jury to use the risk utility and consumer expectations tests. We disagree.

¶ 65 Under the WPLA and case law, the risk utility and consumer expectations tests are used to determine whether a manufacturer is strictly liable and do not apply to a negligence design defect claim under comment k. And contrary to the assertion of Anderson, the Comment K Negligence Instruction addresses the factors the jury should consider in determining whether a medical device manufacturer used reasonable care to design a medical

device that is reasonably safe. Specifically, "[i]n determining what a medical device manufacturer reasonably should have known in regard to designing its device," the jury must consider:

> *17 A medical device 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 device 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.

¶ 66 The court did not err in refusing to give the supplemental jury instruction. The instruction the court gave to the jury correctly describes the duty of a manufacturer of unavoidably unsafe products in designing reasonably safe medical devices under comment k of the *Restatement (Second) of Torts* section 402A.

Costs Award under RCW 4.84.010

¶ 67 Anderson also contends the court erred by awarding Medtronic the cost of eight depositions. Anderson asserts Medtronic did not show that the depositions used at trial were "necessary to achieve the successful result." RCW 4.84.010(7). Anderson also argues Medtronic did not establish the pro rata cost for depositions used at trial under RCW 4.84.010(7). Anderson argued the costs of the depositions should be "disallowed in total."

[10] [11] ¶ 68 We review an award of costs for abuse of discretion. *In re Discipline of VanDerbeek,* 153 Wash.2d 64, 99, 101 P.3d 88 (2004). Under RCW 4.84.010(7), a prevailing party is entitled to the costs of taking depositions if the depositions were taken and used at trial as substantive evidence or for impeachment purposes. *Kiewit–Grice v. State,* 77 Wash.App. 867, 874, 895 P.2d 6 (1995); *Andrews v. Burke,* 55 Wash.App. 622, 630–31, 779 P.2d 740 (1989). RCW 4.84.010 states, in pertinent part:

> The measure and mode of compensation of attorneys and counselors, shall be left to the agreement, expressed or implied, of the parties, but there shall be allowed to the prevailing party upon the judgment certain sums for the prevailing party's expenses in the action, which allowances are termed costs, including, in addition to costs otherwise authorized by law, the following expenses:
>
> ....
>
> (7) To the extent that the court or arbitrator finds that it was necessary to achieve the successful result, the reasonable expense of the transcription of depositions used at trial or at the mandatory arbitration hearing: PROVIDED, That the expenses of depositions shall be allowed on a pro rata basis for those portions of the depositions introduced into evidence or used for purposes of impeachment.

[12] ¶ 69 In addition, "[a] party that prevails on a summary judgment motion may recover costs 'incurred in taking depositions specifically considered by the trial court.' " *Estep v. Hamilton,* 148 Wash.App. 246, 260, 201 P.3d 331 (2008) (quoting *Herried v. Pierce County Pub. Transp. Benefit Auth. Corp.,* 90 Wash.App. 468, 476, 957 P.2d 767 (1998)). If only a portion of the deposition transcript was used, the prevailing party can recover for that portion on a pro rata basis. RCW 4.84.010(7).

*18 [13] ¶ 70 The record supports the award of costs for the eight depositions. Two of the videotaped depositions, the deposition of Dr. Paugh and Scott Van Doren, were played in their entirety at trial. The record shows the other depositions were used at trial during cross-examination and for impeachment purposes. Further, in its order granting Medtronic's motion for summary judgment on the failure to warn claim, the court states it considered the depositions of Dr. Paugh, Dr. James Reibel, Dr. Barry Wenig, and Scott Van Doren and both depositions of Dr. Samaras. The court did not abuse its discretion by awarding Medtronic the costs for the eight depositions.

¶ 71 We affirm the jury verdict.

WE CONCUR: VERELLEN and COX, JJ.

1 The brief in opposition to summary judgment states, in pertinent part:

> For comment k products, this standard is modified to the extent that negligence is included within the legal standard. WPI 110.02.01 has modified the jury instruction as follows:
>
> 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 manufacturer exercised reasonable care is to be determined by what the manufacturer knew or reasonably should have known at the time of the plaintiffs injury.
>
> In determining what a 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.

2 Emphasis in original.

3 This court consolidated the defendants' appeals and linked Anderson's appeal.

4 Here, unlike in *Hub Clothing Co. v. City of Seattle,* 117 Wash. 251, 253–54, 201 P. 6 (1921), and *Barrett v. Lucky Seven Saloon, Inc.,* 152 Wash.2d 259, 274–75, 96 P.3d 386 (2004), the instructions correctly informed the jury of the applicable law, were not misleading, and permitted Anderson to argue her theory of the case. Anderson's theory of the case was that Medtronic violated its duty of care to design medical devices that are reasonably safe.

5 Alteration in original.

6 Emphasis in original.

7 Italics omitted.

8 Further, neither of the burden of proof instructions, the Strict Liability Instruction nor WPI 110.21, include the term "negligence." *See Soproni v. Polygon Apartment Partners,* 137 Wash.2d 319, 326–30, 971 P.2d 500 (1999); *Falk,* 113 Wash.2d at 657, 782 P.2d 974.

9 Italics omitted, emphasis in original.

10 Anderson's proposed supplemental jury instruction states:

> There are two tests for determining whether a medical product is not reasonably safe as designed. The plaintiff may prove that the medical product was not reasonably safe using either of these two tests.
> The first test is a balancing test. Under that test, you should determine whether, at the time the product was manufactured:
> the likelihood that the product would cause injury or damage similar to that claimed by the plaintiff, and the seriousness of such injury or damage outweighed
> the burden on the manufacturer to design a product that would have prevented the injury or damage, and the adverse effect that a practical and feasible alternative design would have on the usefulness of the product.
> The second test is whether the product is unsafe to an extent beyond that which would be contemplated by the ordinary health care provider user. In determining what an ordinary health care provider user would reasonably expect, you should consider the following:
> a. The relative cost of the product;
> b. The seriousness of the potential harm from the claimed defect;
> c. The cost and feasibility of eliminating or minimizing the risk; and
> d. Such [other] factors as the nature of the product and the claimed defect indicate are appropriate.

All Citations

--- P.3d ----, 2015 WL 5682438

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KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

West's Revised Code of Washington Annotated
Title 7. Special Proceedings and Actions (Refs & Annos)
Chapter 7.72. Product Liability Actions (Refs & Annos)

West's RCWA 7.72.030

7.72.030. Liability of manufacturer

Currentness

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

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

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

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

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

(a) A product is not reasonably safe in construction if, when the product left the control of the manufacturer, the product

deviated in some material way from the design specifications or performance standards of the manufacturer, or deviated in some material way from otherwise identical units of the same product line.

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

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

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

Credits

[1988 c 94 § 1; 1981 c 27 § 4.]

Notes of Decisions (194)

West's RCWA 7.72.030, WA ST 7.72.030
Current with all laws from the 2015 Regular Session and 2015 1st, 2nd, and 3rd Special Sessions

End of Document

6 Wash. Prac., Wash. Pattern Jury Instr. Civ. WPI 110.02 (6th ed.)

Washington Practice Series TM
Washington Pattern Jury Instructions--Civil
Database updated June 2013
Washington State Supreme Court Committee on Jury Instructions
Part IX. Particularized Standards of Conduct
Chapter 110. Product Liability

WPI 110.02 Manufacturer's Duty—Design

A manufacturer has a duty to design products that are reasonably safe as designed.
There are two tests for determining whether a product is not reasonably safe as designed. The plaintiff may prove that the product was not reasonably safe at the time it left the manufacturer's control using either of these two tests.
The first test is a balancing test. Under that test, you should determine whether, at the time the product was manufactured:

the likelihood that the product would cause injury or damage similar to that claimed by the plaintiff, and the seriousness of such injury or damage

outweighed

the burden on the manufacturer to design a product that would have prevented the injury or damage, and the adverse effect that a practical and feasible alternative design would have on the usefulness of the product.

The second test is whether the product is unsafe to an extent beyond that which would be contemplated by the ordinary user. In determining what an ordinary user would reasonably expect, you should consider the following:
a. the relative cost of the product;
b. the seriousness of the potential harm from the claimed defect;
c. the cost and feasibility of eliminating or minimizing the risk; and
d. such [other] factors as the nature of the product and the claimed defect indicate are appropriate.
[A product can be "not reasonably safe" even though the risk that it would cause the plaintiff's harm or similar harms was not foreseeable by the manufacturer at the time the product left the manufacturer's control.]
If you find that the product was not reasonably safe as designed at the time it left the manufacturer's control and this was a proximate cause of the plaintiff's [injury] [and] [or] [damage], then the manufacturer is [subject to liability] [at fault].

NOTE ON USE

Use this instruction if there is a claim against a manufacturer that the product was not reasonably safe as designed. If only one of the two tests is being used by the court, modify the instruction accordingly.
Use bracketed material as applicable. Use the bracketed paragraph concerning foreseeability when there are claims of negligence as well as strict liability or when foreseeability concepts have otherwise been injected into the trial. The bracketed "at fault" language is intended to be used in conjunction with WPI 110.31.01.02 (defining "fault") and with WPI 110.31.01.01 (the corresponding special verdict form) for cases involving mixed standards of care (e.g., negligence and strict liability); see the Notes on Use and Comments for WPI 110.31.01.01 and WPI 110.31.01.02.
A special instruction may be needed if the product defect did not cause the accident, but it is claimed that the defect was a proximate cause of enhanced injury. See the discussion in the Comment below; see also WPI 110.02.02, Crashworthiness—Manufacturing and/or Design Defect.
Use WPI 110.04, Seller—Manufacturer—Defined, with this instruction.

COMMENT

RCW 7.72.030(1).

The instruction was rewritten in 2012 to improve the use of plain language. The changes are intended for ease of juror understanding; no substantive change is intended. The committee has used an unusual format in setting forth the balancing test in the first part of the instruction. The committee isolated the word "outweighed" in order to emphasize which factors are being balanced against which.

The statute states in part that a "product manufacturer is subject to liability to a claimant if the claimant's harm was proximately caused by the negligence of the manufacturer in that the product was not reasonably safe as designed." RCW 7.72.030(1).

The Washington Product Liability Act (WPLA) provides two different ways for plaintiffs to show that a product was defectively designed. First, the plaintiff may use the risk-utility approach from RCW 7.72.030(1)(a), which provides that:

> A product is not reasonably safe as designed, if, at the time of manufacture, the likelihood that the product would cause the claimant's harm or similar harms, and the seriousness of those harms, outweighed the burden on the manufacturer to design a product that would have prevented those harms and the adverse effect that an alternative design that was practical and feasible would have on the usefulness of the product.

Second, the plaintiff may show under RCW 7.72.030(3) that the product "was unsafe to an extent beyond that which would be contemplated by the ordinary consumer."

The risk-utility approach of RCW 7.72.030(1)(a) and the consumer-expectations approach of RCW 7.72.030(3) are alternative, independent means of proving defective design. A plaintiff needs to prove only one, not both, of these alternatives. Ruiz-Guzman v. Amvac Chem. Corp., 141 Wn.2d 493, 502–03, 7 P.3d 795 (2000); Falk v. Keene Corp., 113 Wn.2d 645, 782 P.2d 974 (1989).

Risk-utility test—Strict liability. The term "negligence" has not been included in this instruction because the risk-utility test involves strict liability principles that are set forth in Seattle-First National Bank v. Tabert, 86 Wn.2d 145, 542 P.2d 774 (1975), notwithstanding the reference in RCW 7.72.030(1) to negligence. Soproni v. Polygon Apartment Partners, 137 Wn.2d 319, 971 P.2d 500 (1999); Falk v. Keene Corp., supra; Couch v. Mine Safety Appliances Co., 107 Wn.2d 232, 239 n. 5, 728 P.2d 585 (1986). In Falk, the court held that that the "negligence" referred to in RCW 7.72.030(1) is the "negligence of the manufacturer *in that* the product was not reasonably safe." 113 Wn.2d at 657 (italics supplied by court). The court in Falk specifically approved WPI 110.02 in its pre-2012 form. 113 Wn.2d at 657.

Risk-utility test—Balancing of factors. RCW 7.72.030(1)(a)'s risk-utility test requires a balancing of factors. In Ayers v. Johnson & Johnson Baby Products Co., 117 Wn.2d 747, 818 P.2d 1337 (1991), a case alleging that the manufacturer failed to provide adequate warnings with a product (baby oil), the court stated:

> On one side of the balance in subsection (a) are the likelihood that the product would cause the claimant's harm or similar harms and the seriousness of those harms. On the other side of subsection (a)'s balance are the burden on the manufacturer to design a product that would have prevented those harms, and the adverse effect that a feasible alternative design would have on the usefulness of the product.

117 Wn.2d at 763.

The statutory balancing test has a separate proviso for firearms and ammunition. RCW 7.72.030(1)(a).

Risk-utility test—Alternative design—Other products. Consideration of reasonably safe alternative designs is not limited to analysis of the product at issue in the case. Rather, a plaintiff may "establish an alternative safer design through 'other products already available on the market [that] may serve the same or very similar function at lower risk and at comparable cost. Such products may serve as *reasonable alternatives to the product in question.*' " Ruiz-Guzman v. Amvac Chem. Corp., 141 Wn.2d at 504 (italics supplied by court) (quoting Restatement (Third) of Torts § 2, comment f, at 24 (1998)). The court rejected the manufacturer's argument that the plaintiff had to show the existence of an alternative design that could have been incorporated into the defendant's product at the time it was manufactured. 141 Wn.2d at 499, 504. Accordingly, the "other products" may include products produced by the defendant manufacturer's competitors. See 141 Wn.2d at 503–04.

Because the statute requires that an alternative design be "practical and feasible," RCW 7.72.030(1)(a), consideration of other products is limited to alternative designs or products that are "technologically achievable and economically viable." 141 Wn.2d at 505 n.8.

Enhanced injury. In Couch v. Mine Safety Appliances Co., 107 Wn.2d at 241–43, the court discussed enhanced injury

instructions in a design defect action brought under RCW 7.72.030. See also Baumgardner v. Am. Motors Corp., 83 Wn.2d 751, 522 P.2d 829 (1974). See WPI 110.02.02, Crashworthiness—Manufacturing and/or Design Defect.

Industry custom. Under RCW 7.72.050(1), evidence of custom in the product seller's industry or of technological feasibility, whether relating to design, construction, or performance of the product, may be considered by the trier of fact. See also Crittenden v. Fibreboard Corp., 58 Wn.App. 649, 794 P.2d 554 (1990) (trial judge committed reversible error by rejecting an instruction that prohibited jurors from considering industry customs and state of the art evidence). Evidence of compliance with codes or standards is relevant, but not determinative, in analyzing either the consumer-expectations approach or the risk-utility approach. Soproni v. Polygon Apartment Partners, 137 Wn.2d at 328; Falk v. Keene Corp., 113 Wn.2d at 655.

This statute modified previous case law. See, e.g, Lenhardt v. Ford Motor Co., 102 Wn.2d 208, 683 P.2d 1097 (1984) (a pre-WPLA case holding that a defendant may not introduce evidence of compliance with industry customs and standards unless the plaintiff first raises this issue).

Consumer expectations. See the Comment to WPI 110.01, Manufacturer's Duty—Defect in Construction.

Unavoidably unsafe products. See the Comment to WPI 110.02.01, Manufacturer's Duty—Design—Unavoidably Unsafe Products—Negligence—Comment K.

[Current as of January 2012.]

End of Document

6 Wash. Prac., Wash. Pattern Jury Instr. Civ. WPI 110.02.01 (6th ed.)

Washington Practice Series TM
Washington Pattern Jury Instructions--Civil
Database updated June 2013
Washington State Supreme Court Committee on Jury Instructions
Part IX. Particularized Standards of Conduct
Chapter 110. Product Liability

WPI 110.02.01 Manufacturer's Duty—Design—Unavoidably Unsafe Products—Negligence—Comment K

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

The question of whether a manufacturer exercised reasonable care is to be determined by what the manufacturer knew or reasonably should have known at the time of the plaintiff's injury.

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

A [pharmaceutical] [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 [pharmaceutical] [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.

NOTE ON USE

Use this instruction in cases involving prescription drugs and medical devices. In cases of other products that may be considered unavoidably unsafe, such as pesticides, the language should be adapted accordingly.

COMMENT

The instruction was added in 2012.

This instruction is based on Rogers v. Miles Laboratories, Inc., 116 Wn.2d 195, 802 P.2d 1346 (1991); see also Transue v. Aesthetech Corp., 341 F.3d 911 (9th Cir. 2003) (applying Washington law while holding that comment k applies as a blanket rule to prescription drugs and medical products).

Unavoidably unsafe products. Prior to the adoption of the WPLA, Washington courts had adopted comment k to Restatement (Second) of Torts § 402A (1965). E.g., Terhune v. A.H. Robins Co., 90 Wn.2d 9, 12, 577 P.2d 975 (1978). For design cases involving comment k products, the legal standard is negligence. See Young v. Key Pharms., Inc., 130 Wn.2d 160, 175–76, 922 P.3d 857 (1996); Wash. State Physicians Ins. Exch. v. Fisons Corp., 122 Wn.2d 299, 858 P.2d 1054 (1993); Rogers v. Miles Labs., Inc., supra.

Comment k to Restatement (Second) of Torts § 402A identifies a category of products for which a manufacturer cannot avoid a high risk of possible harmful effects. Vaccines with side effects are examples, along with other drugs where the prescription drug can possibly save a patient's life, but the risks of physical harm from the drug itself are substantial, even when the drug is properly manufactured. Comment k explains: "The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." Under comment k, these unavoidably unsafe products are excluded from the general rule of strict liability, as long as the products are properly prepared and marketed and proper warnings are given.

Comment k's exception for unavoidably unsafe products continues to apply to cases under the WPLA, even though the exception is not expressly provided for in the act. Ruiz-Guzman v. Amvac Chem. Corp., 141 Wn.2d 493, 505–06, 7 P.3d 795 (2000); Estate of LaMontagne v. Bristol-Myers Squibb,127 Wn.App. 335, 111 P.3d 857 (2005). The court in Ruiz-Guzman, noting the act's omission of this exception, cautioned that "we must be sparing in [comment k's] application lest we defeat the letter or policy of the WPLA." 141 Wn.2d at 506.

In Ruiz-Guzman, the court concluded that "a pesticide *can* be an 'unavoidably unsafe product' as described in [comment k], but only if its utility greatly outweighs the risk posed by its use." 141 Wn.2d at 511 (italics in original). The court did

not explain in greater detail how this balancing test is to be carried out. Nor did the Ruiz-Guzman court specify the other types of products that qualify as unavoidably unsafe products. The court did note that the exception has previously been applied to medical products available only through a physician, including prescription drugs. 141 Wn.2d at 504–07.

When it cannot be determined as a matter of law whether a product is unavoidably unsafe, this threshold issue must be submitted to the jury. Ruiz-Guzman v. Amvac Chem. Corp., 141 Wn.2d at 511. In such a case, special instructions will need to be drafted guiding the jurors in determining this issue (see generally 141 Wn.2d at 505–11) and informing jurors of the different standards of liability to apply depending on their resolution of the threshold issue.

For a related discussion in the context of a warnings case, see the Comment to WPI 110.03, Manufacturer's Duty to Provide Warnings or Instructions with Product (discussing comment k of Restatement (Second) of Torts § 402A).

[Current as of January 2012.]

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

BECKY 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

COURT'S INSTRUCTIONS TO THE JURY

DATED this 3rd day of December, 2013

Judge Michael J. Trickey

NO. 19

As to the plaintiff's claim against the Medtronic Defendants, the plaintiff has the burden of proving each of the following propositions:

First, that the Medtronic defendants failed to exercise reasonable care in the design of the Laser-Shield II at the time the product left their control;

Second, that the plaintiff was injured; and

Third, that the unsafe condition of the product was a proximate cause of the 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 Medtronic defendants.

NO. 20

As to the plaintiff's claim against the Medtronic Defendants, a medical device manufacturer has a duty to use reasonable care to design medical devices that are reasonably safe. "Reasonable care" means the care that a reasonably prudent medical device manufacturer would exercise in the same or similar circumstances. A failure to use reasonable care is negligence.

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

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

A medical device 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 device 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.

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 THIRD SUPPLEMENTAL PROPOSED JURY INSTRUCTIONS DEALING WITH DESIGN CLAIMS AGAINST MEDTRONIC DEFENDANTS [CITED]

COMES NOW Plaintiff Becky Anderson, by and through her attorneys of record, and respectfully submits these third supplemental jury instructions for presentation to the jury.

DATED this 19th day of October, 2013.

LUVERA, BARNETT,
BRINDLEY, BENINGER & CUNNINGHAM

/s/ Joel D. Cunningham
PAUL N. LUVERA, WSBA #849
JOEL D. CUNNINGHAM, WSBA #5586
RALPH J. BRINDLEY, WSBA #8391
Attorneys for Plaintiffs

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INSTRUCTION NO. _____

There are two tests for determining whether a medical product is not reasonably safe as designed. The plaintiff may prove that the medical product was not reasonably safe using either of these two tests.

The first test is a balancing test. Under that test, you should determine whether, at the time the product was manufactured:

> the likelihood that the product would cause injury or damage similar to that claimed by the plaintiff, and the seriousness of such injury or damage
>
> outweighed
>
> the burden on the manufacturer to design a product that would have prevented the injury or damage, and the adverse effect that a practical and feasible alternative design would have on the usefulness of the product.

The second test is whether the product is unsafe to an extent beyond that which would be contemplated by the ordinary health care provider user. In determining what an ordinary health care provider user would reasonably expect, you should consider the following:

a. The relative cost of the product;

b. The seriousness of the potential harm from the claimed defect;

c. The cost and feasibility of eliminating or minimizing the risk; and

d. Such [other] factors as the nature of the product and the claimed defect indicate are appropriate.

WPI 110.02 (modified for prescription medical products to define "not reasonably safe"); RCW7.72.030(1)
PLAINTIFF'S THIRD SUPPLEMENTAL PROPOSED INSTRUCTIONS DEALING WITH DESIGN CLAIM NO. 2

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 SUPPLEMENTAL AMENDED PROPOSED INSTRUCTIONS [CITED]

COMES NOW Plaintiff Becky Anderson, by and through her attorneys of record, and respectfully submits these Supplemental Amended Proposed Jury Instructions for presentation to the jury.

DATED this 2nd day of December, 2013.

LUVERA, BARNETT,
BRINDLEY, BENINGER & CUNNINGHAM

/s/ Joel D. Cunningham
PAUL N. LUVERA, WSBA #849
JOEL D. CUNNINGHAM, WSBA #5586
RALPH J. BRINDLEY, WSBA #8391
Attorneys for Plaintiffs

INSTRUCTION NO. _____

There are two tests for determining whether a medical product is not reasonably safe as designed. The plaintiff may prove that the medical product was not reasonably safe using either of these two tests.

The first test is a balancing test. Under that test, you should determine whether, at the time the product was manufactured:

> the likelihood that the product would cause injury or damage similar to that claimed by the plaintiff, and the seriousness of such injury or damage
>
> outweighed
>
> the burden on the manufacturer to design a product that would have prevented the injury or damage, and the adverse effect that a practical and feasible alternative design would have on the usefulness of the product.

The second test is whether the product is unsafe to an extent beyond that which would be contemplated by the ordinary health care provider user. In determining what an ordinary health care provider user would reasonably expect, you should consider the following:

a. The relative cost of the product;

b. The seriousness of the potential harm from the claimed defect;

c. The cost and feasibility of eliminating or minimizing the risk; and

d. Such [other] factors as the nature of the product and the claimed defect indicate are appropriate.

WPI 110.02 (modified for prescription medical products to define "not reasonably safe"); RCW7.72.030(1)
PLAINTIFF'S AMENDED PROPOSED INSTRUCTIONS NO. 30
(Previously submitted as PLAINTIFF'S THIRD SUPPLEMENTAL PROPOSED INSTRUCTIONS DEALING WITH DESIGN CLAIM NO. 2)

FILE COPY

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.; MEDTRONIC XOMED, INC. *Defendants.*	NO. 12-2-17928-0 SEA PLAINTIFF'S OBJECTIONS AND EXCEPTIONS TO JURY INSTRUCTIONS

In making these objections and exceptions in writing, Plaintiff does not waive the right to make other objections and exceptions, either orally or in writing. The numbers refer to the number in Medtronic's Supplemental and Amended Requested Jury Instructions.

A. <u>Preponderance of the Evidence, Plaintiff's Amended Proposed Instruction No. 2</u>

Plaintiff excepts to the failure of the Court to give Plaintiff's Amended Proposed Instruction No. 3 regarding preponderance of the evidence. The Court's instruction on preponderance of the evidence omits language from *Anderson v. Akzo Nobel Coatings, Inc.*, 172 Wn.2d 593, 619 (2011), explaining that the preponderance of the evidence means proof by more than 50%. The instruction given is misleading and does not fully set out the law, and allows the jury to require a higher percentage of minimum proof to establish preponderance. Plaintiff excepts to the failure of the

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7.72.050(1). FDA regulations, however, only establish minimum standards, and are determinative on the issue of negligence. *Washington State Physicians Ins. Exchange v. Fisons Corp*, 122 Wn.2d 299, 328 (1993). It is essential that for the jury to fairly consider the regulatory compliance evidence, it must be instructed as to the effect of compliance or non-compliance with regulations. The language for the instruction is from *Fisons*, and is taken verbatim from the first paragraph of the jury instruction given by Judge Downing in another products liability case against a device manufacturer, *Rufer v. Abbott Laboratories,* King County Superior Court No. 99-2-27090.

H. Patent Defense, Plaintiff's Amended Proposed Instruction 29

Plaintiff excepts to the failure of the Court to give Plaintiff's Amended Proposed Instruction No. 29 regarding Medtronic's patent defense. The jury heard evidence regarding patents on the double cuff design. Plaintiff was prepared to offer evidence in the case that patent laws did not prevent Medtronic from adopting a double cuff design. Medtronic represented outside the hearing of the jury that it would not be presenting a defense that patent law prevented a design change. The Court therefore excluded the evidence. In fairness, the jury should be instructed that Medtronic is not making a patent law defense. The jury has heard that there is a patent, but has not been told that the patent would not prevent a design change. In fairness, the jury should be told that there is no patent defense, so that it does not otherwise assume that a patent prevented the design change.

I. Definition of Not Reasonably Safe Product, Plaintiff's Amended Proposed Instruction 30

Plaintiff excepts to the failure of the Court to give Plaintiff's Amended Proposed Instruction No. 30 regarding the definition of a product not reasonably safe as designed. The negligence instruction to be given by the Court refers to the duty of the manufacturer to use reasonable care "to design medical devices that are *reasonably safe*." This instruction, taken from WPI 110.02.01,

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defines "reasonable care" but it does not define "reasonably safe" or instruct the jury as to the factors to be considered in determining whether or not a product is not reasonably safe. The instructions for the jury in determining whether a product is not reasonably safe are found in WPI 110.02. The proposed instructions are based upon WPI 110.02, and should be given in addition to those in WPI 11.02.01, which define the reasonable care.

J. **No Guarantee/Poor Result**

Plaintiff objects to the Court's Instruction No.__, regarding poor medical results and no guarantee. The standard for negligence is covered by other instructions relating to standard of care. This is no issue which even raises the issue of a guarantee of a result. On the other, this instruction unduly highlights and emphasizes a particular part of the evidence related to the standard of care. This instruction is argumentative and over emphasizes the particular issue.

K. **Medical Expenses**

Plaintiff objects to the special verdict form in that it fails to include and fill in for the jury the undisputed past medical expenses. Those undisputed expenses are $2,655, 461.19

DATED this 2nd day of December, 2013.

LUVERA, BARNETT,
BRINDLEY, BENINGER, & CUNNINGHAM

/s David Beninger
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Honorable Jeffrey M. Ramsdell

IN THE SUPERIOR COURT OF WASHINGTON
FOR KING COUNTY

BECKY S. ANDERSON, a single person,

Plaintiff,

v.

CENTRAL WASHINGTON HEALTH SERVICES ASSOCIATION d/b/a CENTRAL WASHINGTON HOSPITAL, a Washington Corporation; DONALD R. PAUGH; WENATCHEE VALLEY MEDICAL CENTER, P.S.; LINDA K. SCHATZ; WENATCHEE ANESTHESIA ASSOCIATES; LASER ENGINEERING, INC., a foreign corporation; MEDTRONIC, INC.; MEDTRONIC XOMED, INC.; and UNKNOWN JOHN DOES,

Defendants.

NO.: 12-2-17928-0SEA

DEFENDANTS MEDTRONIC XOMED, INC.'S AND MEDTRONIC, INC.'S REQUESTED JURY INSTRUCTIONS

DEFENDANTS' PROPOSED JURY INSTRUCTION NO. 30

DESIGN DEFECT

To establish that the Laser-Shield II had a design defect, the plaintiff must prove, by a preponderance of the evidence, that the product was not reasonably safe as designed. To meet this burden, the plaintiff must show that, at the time the product was manufactured, the likelihood that the product would cause injury similar to that claimed by the plaintiff, and the seriousness of such damage outweighed the manufacturer's burden to design a product that would have prevented those harms and any adverse effect a practical, feasible alternative would have had on the product's usefulness. In order to prove that a medical device such as the one at issue in this case is defective, plaintiff must present expert testimony establishing how the product was defective and that the defect caused plaintiff's injuries as described in Instruction No. ____.[30]

[30] Washington Pattern Jury Instructions—Civil No. WPI 110.02 (modified); *Soprini v. Polygon Apartment Partners*, 137 Wn.2d 319, 326, 971 P.2d 500 (1999), *review denied*, 139 Wn.2d 1025, 994 P.2d 845 (2000)

WASHINGTON STATE COURRT OF APPEALS

DIVISION I

DOROTHY L. PAYNE, individually and as the personal representative of the Estate of BECKY S. ANDERSON, Plaintiff/Appellant,	)	NO. 71411-2-I
vs.	)	
DONALD R. PAUGH; WENATCHEE VALLEY MEDICAL CENTER, P.S.; LINDA K. SCHATZ; WENATCHEE ANESTHESIA ASSOCIATES; MEDTRONIC, INC.; MEDTRONIC XOMED, INC., Defendants/Respondents.	)	

VERBATIM REPORT OF ORAL ARGUMENT

DATE: March 3, 2015

LOCATION: Seattle, Washington

Shari M. Canet, Transcriptionist
Post Office Box 1633
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APPEARANCES

FOR APPELLANT: GEORGE M. AHREND, Attorney at Law
Attorney for Appellant

FOR APPELLEE: LORI COHEN, Attorney at Law
Attorney for Respondent Medtronic

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MR. AHREND: Good morning, your Honor, and may it please the Court. I'm George Ahrend for the personal representative of the Estate of Becky Anderson. I'd like to reserve three of my ten minutes for rebuttal if I may.

THE COURT: Okay.

MR. AHREND: With me at counsel table is Andy Hoyal, plaintiff's lawyer as well.

THE COURT: Before you begin, can you confirm what you have said in your reply brief, which is that you are, or the estate is, withdrawing the assignment of error to the decision on summary judgment related the failure to warn?

MR. AHREND: Yes, we are doing that. The only relief we are seeking is a re-trial of the negligent design claim against Medtronic defendants, respondents here, and included in that re-trial is the apportionment of fault that would be involved in determining liability.

THE COURT: And if I understand correctly, your—your argument related to why you are entitled to a new trial is that the court erred in refusing to give the proposed instruction under 110.02 as modified?

MR. AHREND: Yes. The law and the instructions impose the burden on the plaintiff to prove that the product—the Medtronic's Laser Shield II in this case, was not reasonably safe. The phrase reasonably safe is a legal

term of art defined under the Washington Product Liability Act in terms of both—in terms of two alternative tests—one based on risk utility, and the other based on consumer expectations. In the absence of that definition, the jury was not instructed on the governing law, the plaintiff was not allowed to argue in accordance with the technical term of these meanings, and the defense was free to argue unconstrained by the technical term of the risk utility test and—or reasonable safety defined in terms of the risk utility and consumer expectations test.

THE COURT: Now, there's—there's—let me just verify, there's no dispute that the claim was for a design defect?

MR. AHREND: Correct.

THE COURT: And comment *k* would apply?

MR. AHREND: Correct. Meaning that a negligence—

THE COURT: Standard—

MR. AHREND: Standard was superimposed onto the normal design defect case, but otherwise leaving a normal design defect case unchanged and, of course, the argument has been made here that the requirement to prove negligence is somehow incompatible with the risk utility and consumer expectation test, which define reasonable safety.

THE COURT: And, as a general rule, those tests are as set

forth in the WPIC—or WPI are related to strict liability claims.

MR. AHREND: Not true. They're related to reasonable safety.

THE COURT: Well, when you're talking about the consumer—the consumer test and the other test that's laid out, are your—is it your position those relate to negligence and are not exclusively related to strict liability?

MR. AHREND: Yes. We know that both from the text of the WPLA and from the—the fact that it's really a category—a type of category difference looking at the state of culpable conduct on the part of the defendant that's required to impose liability. In a comment *k* case, it's negligence. In a strict liability case, you focus solely on the product. That's one category. The second category focuses on the product, and the product has to be unreasonably safe or not reasonably safe in both a negligence case and a strict liability case. We know this from the text of RCW 7.72.030, which provides, at least with respect to the consumer expectations test, that it applies to a negligent claim for post manufacture failure to warn. That's in the text of the WPLA. We have no authority that would preclude—no case law authority or for that matter in the text of the WPLA—that would preclude defining reasonable safety in terms of risk utility and consumer expectations either.

THE COURT: So your argument is that—that the two instructions are compatible—that's—that's how you describe it, I think, in your reply brief?

MR. AHREND: Yes. And—I mean—and—and not only is it compatible, it's required because, in a product liability case, even when negligence is required—whether it's a negligent post manufacture failure to warn or a negligence case based on the Restatement 402A's comment *k*. The reasonable safety of the product is at issue, and reasonable safety both when we're talking about risk utility and consumer expectations is a risk centric analysis not a product centric analysis, and what I mean by that is the plaintiff is obligated to prove that this product could reasonably be made safer in order to prevail and establish liability, not that the product should be banned, but if we don't—and—and the—if you look at 7.72.030, if you look at the pattern jury instruction, risk utility is defined in terms of the risk that injured the plaintiff, or the injury causing aspect of the product, and consumer expectations is similarly defined in terms of the injury causing aspect of the product, but if you don't have those definitions that focus on the risk that injured the plaintiff, then you allow the defense to defend the case by arguing that this product, if you would count up all the risks and you

count up all the benefits, as long as the total risks outweigh the benefits and the product shouldn't necessarily be banned, they get to prevail on this case—and, of course, that's exactly what the defense spent almost the entirety—over ninety percent of the closing argument in this case was focused on a product century—centric reasonable safety kind of analysis.

THE COURT: What—what evidence was there at trial as to risk utility and consumer expectations?

MR. AHREND: Well, the plaintiff's liability experts uniformly testified that this product could have been and should have been made safer by installing a double cuff. That is the risk utility evidence that's in the case, and there's a significance amount of it because that was the focus of their testimony. The consumer expectations testimony came from Dr. Paugh, who thought that this—based on when he went into surgery with this cuff, which he had used—was using for the first time, he did not expect that it would be as dangerous as it ended up being. So that's the evidence of—of both of those tests. But I want to emphasize too that there's—the—the instruction—

THE COURT: There's—there's no question—I don't—he did not read the warnings, did he?

MR. AHREND: He did not—no, he did not read the IFU. He did see the box, but—and he did read the name of the

product is a Laser Shield II implying that it's going to shield from—

THE COURT: Right.

MR. AHREND: The laser, but—

THE COURT: I—I thought the evidence was clear that the doctor did not read the warnings or the IF—

MR. AHREND: If you narrowly define the warnings solely in terms of the IFU, yes, he did not read that. He did read the box.

THE COURT: Before you run out of time completely, I've got one question and it just seems to me that if you take a step back and you say, comment *k* is intended to differentiate significantly from pure strict design defect liability, but if the ultimate test for strict liability is risk utility—consumer expectation, focusing on the products, how is that any different in any significant way from the comment *k* approach, if it culminates in the same exact two tests?

MR. AHREND: Briefly, strict liability requires proof of one thing—product's not reasonably safe. Comment *k* case requires proof of two things—defendant was negligent, and the product was not reasonably safe. Reasonably safe—safe nature of the product is still at the heart of a comment *k* case, and was still at the heart of—of plaintiff's liability case here. Does that answer your

question?

THE COURT: I think so.

MR. AHREND: I'll reserve the rest of my time for rebuttal, please.

MS. COHEN: Thank you. May it please the Court, your Honors. Lori Cohen on behalf of the appellees/defendants Medtronic, Inc., and Medtronic Xomed. And as your Honors pointed out already, this case was tried over the course of two months and—and also prior to that, there were pretrial proceedings, and the focus of this case as to my clients has always been on negligent design for a prescription medical device that falls squarely within the Washington law unavoidably unsafe comment *k* specific design issues, and that's how the case was started, that's how the case was alleged against my clients, that's how the case at summary judgment time was argued by—by both parties, and that's how the case was tried from start to finish. I think that's a very important aspect, that if you go back and look as we noted in our briefing, at the chronology and evolution of the case starting with September, 2013, when we argued summary judgment, all the way from then until the jury decided the case, the focus was on negligent design and Judge Trickey in his ultimate instructions—jury instructions, he—he—he gave the appropriate instructions looking at a comment *k*

prescription medical device case.

THE COURT: Well, there—I—I don't think the estate disputes that—that negligence was the standard from the oral argument today and the record is clear. Their argument is though that the court erred in not defining reasonably safe by giving the proposed—the instruction they proposed and modified under 110.02, so what is your response to that?

MS. COHEN: Yes, your Honor, and—and I did hear that today, but I think in their briefing they do argue that this was—that this falls into the other definition, that is a non-comment *k* type definition, and if—if the court had in fact followed their late in the game, December 2nd, at the very end of—of evidence kind of last minute proposal of a supplemented amended jury instruction, if the court had done that, it would have been inconsistent with the instruction that the court did give under the comment *k* provision.

THE COURT: Well, the argument is that it's not inconsistent because it's focusing on the reasonable safety of the product, which is the crux of a comment *k* case, and that the only—the only WPI that defines reasonably safe is the proposed instruction that they gave based on 110.02.

MS. COHEN: No, and—and I heard that, your Honor. I do understand that, but—

THE COURT: So what—what is your—your response to that argument?

MS. COHEN: The response is it would have been inconsistent—reasonably safe as used in the WPIC 110.02.01, which was the comment *k* one given by Judge Trickey, it's not a term of art that has to be defined or further flushed out for the jury.

THE COURT: What are you relying on for that proposition?

MS. COHEN: Well, I think that the note on use in the WPI, which specifically says use this instruction in cases involving prescription drugs and medical devices, and there's nothing in this or any of the case law that we've cited, and there's a whole slew of cases where they do not go further and give the—sort of the additional definition of reasonably safe. As we—as we look at the language of this WPI, where it says a—a pharmaceutical or medical product manufacturer has a duty to use reasonable care to design drugs or medical products that are reasonably safe, there's no case law, there's no statutory provision that says that has to be further defined. I know that the plaintiffs/appellants here came in again at the very end after two months of trial where they had never proposed a definition under either the consumer expectation or the—the—the risk balancing test, and they came in at the end and they proposed that to

Judge Trickey, but there was no need for that, there—there was no presentation of evidence as your Honor had asked about those tests, and again, the—the term reasonably safe is not one that needs to be further defined for the jury. If we—

THE COURT: Well, the—the argument was that—that the—the expert did testify about the risk utility test, and Dr. Paugh testified as to the consumer—the consumer expectation—

MS. COHEN: We—we would disagree with that, your Honor, respectfully because, again, from the start of the case, even going back to summary judgment time, and then the start of the case with the pre-instructions that the plaintiffs presented, which mirrored what the judge ultimately gave, that is the—the unavoidably unsafe products—the comment *k*—that was given—everybody agreed that that was the governing pre-instruction, the governing instruction, at summary judgment arguing that's what was presented, and when they presented—whether it was Dr. Paugh or their expert witness, Samaris, or cross examining our expert witnesses, they never got into the two tests of reasonably safe. The focus always was on the comment *k* definition of the negligent and the activities and conduct of my clients. That was the focus from the start, and ultimately, if we look at the

special jury instructions where the jury found in favor of my clients, they checked off no negligence. They did not anywhere on that form check off anything about the product being unreasonably safe or reasonably safe. That wasn't even part of the evaluation.

THE COURT: Well, but—well, that's not true. I mean, as instructed, they had to reach some sort of determination as to reasonably safe in order to consider the negligence claim.

MS. COHEN: That—that was subsumed within the negligence analysis—

THE COURT: And so the argument is why wouldn't you then define reasonably safe, and the only thing you could look at would be this WPI.

MS. COHEN: Right. And—and, your Honor, on that you look at the WPI 110.02 the manufacturer's duty design, which plaintiffs again, late in the game, for the very first time on December 2nd raised this, when you look at that and you look at the note on use, it doesn't apply to the comment *k* definition. It's a strict liability standard, as we've said in our brief, and the other one applies to the negligence, which governed the case from start to finish. You're looking more at the conduct at my clients as opposed to the strict liability design defect approach on the product, so you're looking more at the activities, the

conduct, and when we talk about expert witnesses, whether it be Dr. Paugh or any of the many witnesses that testified over the course of two months, the focus as to my clients was, did they meet their duty of care? Were they negligent? Again, using the specific—

THE COURT: Well, there was—there was a lot of testimony about the double cuff.

MS. COHEN: There was a lot of—of testimony, and it was all grounded in terms of—

THE COURT: So that was all focused on the product?

MS. COHEN: But it was focused on whether my clients—whether the manufacturers, again, because of it being the special comment *k* unavoidably unsafe prescription medical device, whether they take—took the right actions in focusing on the conduct, actions and inactions of my clients, and that's why it falls within the very specific comment *k* instruction, and Judge Trickey got it absolutely right, and, by the way, he followed not just our instructions, but all of the plaintiff's instructions—their pre-instructions, their comments at summary judgment, the way they presented their case, they—when we look at the actual trial testimony and the questions they posed to their expert witness in terms of establishing negligence, it was all grounded in terms of—of conduct, it wasn't determined in looking at the focus

on the product. Again, yes, that—that is woven into and—and interwoven in the definition of whether the manufacturer met their duty to use reasonable care in the design to ultimately have a product that was reasonably safe, but there was no reason to go beyond that and use an inconsistent, different definition to help define reasonably safe. That is a term that the jury understood based on all of the testimony. It wasn't something that required—

THE COURT: Comment *k* is only available if it's an unavoidably unsafe product, right?

MS. COHEN: Yes, your Honor, and—and specifically defined in the use part as prescription medical devices, which apply here.

THE COURT: So, if it has to be unavoidably unsafe to even get to the comment *k* analysis, why does the pattern instruction lead off with anything about the product—a duty to make it reasonably safe?

MS. COHEN: Because—

THE COURT: Doesn't comment *k* acknowledge you can't make it safe? No one can make it safe?

MS. COHEN: No one—

THE COURT: Apparently unsafe—

MS. COHEN: No one can make it 100% safe and that's why you get into the issue of comment *k* treating these cases

distinctly, and when you look at the case law that we cited, again, there is no cases cited by the appellants or that were utilized at trial or at summary judgment time that applies—what they're proposing again late in the game the—the WPI 110.02—

THE COURT: Then, I guess—

MS. COHEN: In a prescription drug or device case.

THE COURT: I'm not sure I'm—I'm, of course, it may not be that clear, but I'm just saying, why even have an instruction that brings up reasonably safe, if the whole premise of this analysis is you can't make it safe?

MS. COHEN: You—

THE COURT: I mean doesn't that mislead the jury? Does that leave the jury hanging on what—what's reasonably safe and what that means?

MS. COHEN: No, your Honor. See you cannot make it 100% safe. You cannot eliminate risks—

THE COURT: —reasonably safe—

MS. COHEN: Well, you can make it reasonably safe, but you can't make it entirely safe, and that's why, again, they comment *k* applies to these types of prescription medical devices or medical products because we know as a matter of fact that they can't be 100% safe because of the inherent nature of these devices. They have risks. That's why—you know—they have risks and that's why the case

law is such that there's no cases at all that do what plaintiffs are asking to be done here, which is apply that provision—the 110.02—in the context of a prescription medical device.

THE COURT: Thank you.

MS. COHEN: Thank you, your Honor.

MR. AHREND: The Court's questions raise what I think is a excellent point and I wouldn't want to see any decision in this case foreclose the possibility that the issue of reasonable safety should be omitted from future comment *k* type cases and the sole focus should be negligence, but in this case, we have a pattern instruction that was adopted by the—advocated by both parties and adopted by the court that—it's Instruction No. 20—that requires proof of negligence and that the product was not reasonably safe, and so while not foreclosing the possibility that in future cases we may need to modify that instruction, in this case, the question is having placed the burden on the plaintiff to prove reasonable safety, must we define that in—in accordance with the statutory definitions of the term—

THE COURT: Does it impose that burden or does it just say there's a duty, now let's talk about reasonable care?

MR. AHREND: There is—it—let me say, it imposes an obligation—I mean the Instruction No. 20 and actually

No. 19 both require proof that it's not reasonably safe, or in 19, that there was an unsafe condition. So, I think the instructions do place the issue of reasonable safety in front of the jury, and so then the question is, undefined is that misleading? Well, the dictionary definition of reasonably safe is just moderately safe, whereas, the statutory definition requires both with respect to consumer expectations and risk utility, consideration of a—a number of factors, and focus on the particular risk that injured the plaintiff. Again, the plaintiff's burden is to prove can and should this product be made safer, not can or should this product be banned, and yet what it—without that definition, it allowed arguments to be made that this product on balance serves enough good purposes that it shouldn't essentially be banned. And I want to address the point that there was evidence to support the application of the risk utility and the consumer expectations test. That's important and I think that evidence is there, but it's equally important, you know, we know the standard for evaluating jury instructions is—they've got to permit a party to argue its theory of the case. Not having these definitions, not only didn't allow the counsel for the plaintiff to make use of that evidence, but they also didn't allow them to argue in closing argument how that evidence should be evaluated and how

it fit into the instructions, and that's just as important as the evidence that was present to support the instruction.

THE COURT: Well, the—the estate was not precluded from—from—in—during oral—during closing argument pointing to the testimony of their expert and Dr. Paugh.

MR. AHREND: They were precluded from objecting to closing argument saying this product essentially shouldn't be banned because the benefits outweigh the risks because they didn't have an instruction to hold defense counsel accountable.

THE COURT: So, it's a very specific argument that you're making about what they were precluded from arguing, which is the risk utility test and consumer expectations?

MR. AHREND: And having the jury properly instructed on the law.

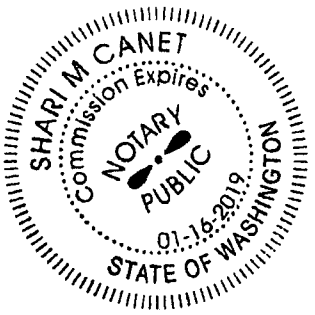
THE COURT: Thank you.

STATE OF WASHINGTON)
)
COUNTY OF GRANT)

CERTIFICATE

I, SHARI M. CANET, Notary Public, in and for the County of Grant, State of Washington, do hereby certify that:

I am a paralegal employed by Ahrend Law Firm PLLC. Pages 1 through 19 contained in the foregoing VERBATIM TRANSCRIPT OF ORAL ARGUMENT MARCH 3, 2015, is a true, correct and complete transcript of the recording taken at the time and place hereinbefore stated, available on the courts website, and was transcribed personally by myself to the best of my ability and completed on the 21st day of October, 2015.



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