No. 924163

SUPREME COURT OF THE STATE OF WASHINGTON

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

Petitioner,

v.

MEDTRONIC, INC., and MEDTRONIC XOMED, INC.,

Respondents.

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

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I. INTRODUCTION

Becky Anderson sustained injuries while undergoing throat surgery and sued – among other named defendants – Medtronic Xomed, Inc., the manufacturer of the endotracheal tube used during the surgical procedure, as well as Medtronic Xomed, Inc.'s corporate parent, Medtronic, Inc. (collectively, Medtronic), under a products liability theory of design defect. Although Anderson agreed that her design defect claim against Medtronic was governed by a *negligence* standard – because the medical device at issue fell into a narrow category of products the *Restatement (Second) of Torts*, Section 402A, comment k (1965) deems "unavoidably unsafe" – and even asked the superior court to instruct the jury on the applicable negligence standard at the beginning of trial, she nevertheless also asked the superior court to instruct the jury under a *strict liability* theory.[1] The superior court correctly denied Anderson's request for a strict liability instruction and instructed the jury in accordance with the negligent design defect pattern jury instruction. Applying that instruction, the jury assigned no fault to Medtronic.

Anderson challenged the superior court's ruling on appeal. The Court of Appeals rejected that challenge, however, because this Court's precedent – pursuant to which strict liability and negligent design defect

[1] On September 17, 2014, the Court of Appeals granted a motion to substitute Anderson, as appellant, with Dorothy L. Payne, the personal representative of Anderson's estate.

claims impose different standards of liability – allowed no other result.

In her Petition for Review, Anderson now asks this Court to "clarify" the law. But there is nothing to clarify. The superior court's ruling on Anderson's instruction argument was compelled by this Court's precedent, as was the Court of Appeals' affirmance. The Court need not address a question its precedent already clearly answers, and the superior court's application of the correct law does not create conflict necessitating resolution. There is thus no basis for review, and Anderson's Petition should be denied.

II. COUNTER-STATEMENT OF THE CASE

A. ANDERSON'S THROAT SURGERY.

After Dr. Donald Paugh diagnosed Anderson with a benign vocal polyp in January 2012, Anderson elected to have the polyp removed through tracheal laser surgery. CP 104.[2] During the February 3, 2012 surgery, Dr. Paugh and anesthesiologist Dr. Linda Schatz used Medtronic's single-cuff Laser–Shield II endotracheal tube, a medical device that had been cleared by the FDA for establishing and maintaining a patient's airway, as well as to facilitate the exchange of gases, during laser surgeries. CP 4, 3812. Although neither Dr. Paugh nor Dr. Schatz had previously used the Laser–Shield II, they nonetheless used the device

[2] The relevant portions of the record not submitted by Anderson with her Petition are included with the attached Appendix A.

and proceeded with the surgery without reviewing the device's Instructions for Use (IFU). CP 3846 (13:19-14:3); CP 3857 (60:1-6); CP 3870 (13:24-14:5); CP 3878 (47:18-14); CP 3888-89 (88:13-89:4).

Contrary to the IFU warnings, instructions, and recommendations, Dr. Schatz administered 100% oxygen (not the recommended 30%) to Anderson throughout the surgical procedure. CP 3812; CP 3850 (32:17-33:19). When the surgery was nearly complete, Dr. Paugh struck the Laser–Shield II's inflatable cuff with a laser beam, causing the 100% oxygen to enter the surgical site and ignite. CP 3812; CP 3880 (55:10-24); CP 4; CP 4424. The airway fire caused serious injury to Anderson. CP 3880 (55:10-24); CP 4.

B. ANDERSON'S DESIGN DEFECT CLAIM.

1. Anderson's Complaint.

Anderson subsequently brought an action alleging medical malpractice claims against Dr. Paugh, Dr. Schatz, their respective practices, and the hospital at which her surgery occurred, and product liability claims against Medtronic. CP 1-9; CP 2231-32. Anderson alleged in her Amended Complaint that Medtronic was "liable under the Washington Products Liability Act R.C.W. Chapter 7.72," which encompassed a design defect theory. CP 2232.

2. Medtronic's Motion for Summary Judgment on Anderson's Design Defect Claim.

Medtronic moved for summary judgment dismissal of Anderson's design defect claim on the basis that the Laser–Shield II is an "unavoidably unsafe" prescription medical device, such that a manufacturer's liability is governed by the negligence standard under *Restatement (Second) of Torts*, Section 402A, comment k (1965) ("comment k"), and there was no evidence of defective design. CP 3769-94. In response, Anderson did not dispute that the comment k negligence standard applied to her design defect claim. CP 4438. To the contrary, Anderson relied on WPI 110.02.01, which is titled "Manufacturer's Duty–Design–Unavoidably Unsafe Products–Negligence–Comment K", to argue that there were material issues of fact as to Medtronic's breach of its duty to use reasonable care to design a product that was reasonably safe, and as to proximate cause. CP 4437-41.

At the hearing on Medtronic's summary judgment motion, Anderson's counsel conceded that the comment k negligence standard applied to the design defect claim. RP 80:17-81:15 (09/20/13) ("on the record, I'm willing to accept a negligence standard in this case, because I don't want error").[3] The superior court denied Medtronic's motion to

[3] This statement confirmed Anderson's previously stated position. CP 4437 ("[T]he WPI instruction on design defects involving comment k products adopts a negligence

dismiss Anderson's negligent design defect claim, and that claim proceeded to trial. RP 80:17-81:15 (09/20/13); RP 100:10-13 (09/20/13).

3. The Trial on Anderson's Design Defect Claim.

a. The Pre-Instruction on negligent design.

Before opening statements, the superior court agreed to read several instructions on the governing law to the jury, including a Pre-Instruction submitted by Anderson on her negligent design defect claim, as well as instructions on Medtronic's duty and the standard of care that applies to the manufacturer of an unavoidably unsafe product under comment k. RP 7:12-23 (10/24/13 PM); RP 7:18-24 (10/25/13 AM).[4] Anderson's Pre-Instruction was based on WPI 110.02.01:

> 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.

RP 21:4-8 (10/25/13 AM).

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

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standard."); CP 4438 n.7 ("In order to avoid potential reversible error from an incorrect instruction, [Anderson] is presenting the design defect case under [WPI 110.02.01], and not under the consumer expectations test ....").

[4] Attached as Appendix B is a copy of Anderson's Proposed Jury Pre-Instructions (which Anderson had failed to file in the superior court). The Court of Appeals granted Medtronic's motion to supplement the record with Anderson's Pre-Instructions.

> reasonably safe. "Reasonable care" means the care that a reasonably prudent medical product manufacturer would exercise in the same or similar circumstances. A failure to use reasonable care is negligence.
>
> The question of whether a medical product manufacturer exercised reasonable care is to be determined by what the manufacturer knew or reasonably should have known at the time the product left the defendant's control.
>
> In determining what a medical product manufacturer reasonably should have known in regard to designing its product, you should consider the following:
>
> A medical product manufacturer has a duty to use reasonable care to test, analyze, and inspect the products it sells, and is presumed to know what such tests would have revealed.
>
> A medical product manufacturer has a duty to use reasonable care to keep abreast of scientific knowledge, discoveries, advances, and research in the field, and is presumed to know what is imparted thereby.

RP 25:21-26:16 (10/25/13 AM). Anderson neither objected to nor took written exception to her own requested Pre-Instruction. RP 28:8-19 (10/25/13 AM).

b. Anderson's proposed supplemental instruction.

The evidentiary portion of the trial concluded on November 27, 2013. RP 52:12-13 (11/27/13 PM). That afternoon, Anderson submitted Amended Proposed Instructions. CP 2463. Those instructions were identical to her Pre-Instructions, which the court had read to the jury at the commencement of trial. CP 2476-77; RP 25:8-26:16 (10/25/13 AM).

On December 2, 2013, however, Anderson submitted Supplemental Amended Proposed Instructions, which included an instruction setting forth the tests used to determine a manufacturer's duty in a strict liability design defect case under WPI 110.02, "Manufacturer's Duty–Design." CP 4463. WPI 110.02 defines whether a product is "not reasonably safe" for purposes of imposing strict liability by using the risk utility and consumer expectation tests.

The next day, Anderson filed a written objection to the superior court's jury instructions, arguing that because the "negligence instruction to be given by the [c]ourt refers to the duty of the manufacturer to use reasonable care 'to design medical devices that are *reasonably safe*,'" and because the instruction "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 strict liability instruction defining that term should be used. CP 4468-69.

c. The jury's verdict.

The court declined to give Anderson's proposed supplemental jury instruction based on WPI 110.02. CP 2567-68. Instead, the court used the Amended Proposed Instruction that Anderson previously had submitted on November 27 to instruct the jury on the negligent design defect claim in accordance with WPI 110.02.01. CP 2567-68. The jury found that

Medtronic complied with the applicable standard of care in its design of the Laser–Shield II and assigned no liability to Medtronic. CP 2544-45.[5]

C. THE COURT OF APPEALS' AFFIRMANCE.

On appeal, Anderson argued the superior court erred in refusing to give her supplemental proposed instruction under WPI 110.02 to define whether a medical device is "reasonably safe" for purposes of a strict liability design defect claim.[6] The Court of Appeals rejected Anderson's argument, holding that the superior court "did not err in refusing to give the supplemental jury instruction," because "[t]he 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." *Payne*, 2015 WL 5682438, at *17. In so holding, the Court of Appeals primarily relied upon this Court's decisions in *Falk v. Keene Corp.*, 113 Wn.2d 645, 649, 782 P.2d 974 (1989), and *Ruiz-Guzman v. Amvac Chemical Corp.*, 141 Wn.2d 493, 505-06, 7 P.3d 795 (2000), to draw a distinction between the standards for ordinary design

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[5] The jury also 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, which the superior court later reduced against the party defendants to $17.1 million. *Payne v. Paugh*, No. 71411-I, 2015 WL 5682438, at *10 (Wash. App. Sept. 28, 2015). The nonparty hospital settled before trial for $12 million. *Id.* at *3.

[6] Anderson also appealed the superior court's dismissal of her failure-to-warn claim and award of costs to Medtronic for entire depositions. However, she voluntary withdrew her assignment of error relating to the failure-to-warn claim on September 4, 2014, and does not seek review by this Court of the Court of Appeals' affirmance of the superior court's ruling on the cost issue.

defect claims and design defect claims governed by comment k.

The Court of Appeals reasoned that, on the one hand, ordinary design defect claims are "strict liability claim[s]" under the Washington Product Liability Act (WPLA), RCW 7.72.030, and focus "on the reasonable safety of the product." *Payne*, 2015 WL 5682438, at *13 (quoting *Falk*, 113 Wn.2d at 653). "[T]he 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.'" *Id.* at *14 (quoting RCW 7.72.030(1)(a), (3); *Falk*, 113 Wn.2d at 653). The language of the WPI for standard strict liability design defect claims, WPI 110.02, is "[c]onsistent with the WPLA and case law." *Id.*

Design defect claims governed by comment k, on the other hand, fall into "an exception to strict liability for 'unavoidably unsafe products' such as prescription drugs and medical devices," to which "a negligence standard" applies. *Payne*, 2015 WL 5682438, at *12 (citing *Ruiz-Guzman*, 141 Wn.2d at 507-08). The Court of Appeals explained that because "the standard is negligence" for a design defect claim under comment k, "the focus is on the conduct of the manufacturer to use reasonable care to design a medical product that is reasonably safe." *Id.* The WPI for

negligent design claims, WPI 110.02.01, in turn, "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." *Id.* at *16.

As Anderson acknowledges before this Court, "[t]he parties and the appellate court agreed that this case is governed by" comment k, "which provides that manufacturers of products deemed to be 'unavoidably unsafe' ... are not subject to strict liability." Petition at 9. Nevertheless, "Anderson assert[ed] the court erred in refusing to give her supplemental jury instruction," in which she "delete[d] 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 set[] forth verbatim the tests used in determining a strict liability design defect claim: the risk utility and consumer expectations tests." *Payne*, 2015 WL 5682438, at *16.

Ultimately, the Court of Appeals disagreed with Anderson's position that "the court must instruct the jury to use the risk utility and consumer expectation tests" because WPI 110.02.01 "does not define 'reasonably safe.'" *Id.* Instead, the Court of Appeals applied "the WPLA and case law" to conclude 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." *Id.* at *17. Because "[t]he instruction the court gave to the jury correctly describe[d] the duty of a manufacturer of unavoidably unsafe products in designing reasonably safe medical devices under comment k," the Court of Appeals held that the "court did not err in refusing to give the supplemental jury instruction." *Id.*

III. ARGUMENT WHY REVIEW SHOULD BE DENIED

Anderson now has conceded, at every level of the state's court system, that comment k liability is premised on negligence and that a negligence standard applies in this case. And she could not be heard to argue otherwise, because this Court unequivocally has adopted a negligence standard for design defect claims arising from comment k products. The pattern jury instruction on comment k liability that the superior court gave to the jury in this case, WPI 110.02.01, conforms to that standard, and as the Court of Appeals concluded, focuses on the correct inquiry: Medtronic's duty to use reasonable care to design a medical product that is reasonably safe.

Despite her acknowledgement that a negligence standard governs, as well as her concession before this Court that "the superior court instructed the jury ... in accordance with the applicable pattern jury instruction" (Petition at 1), Anderson nonetheless argues that this Court

should grant review of the Court of Appeals' decision – under the guise of presenting "a substantial issue of public interest" (Petition at 10) – to "clarify" whether principles that are reserved for determining liability in *strict liability design defect* claims must be superimposed on the *negligent* design defect pattern jury instruction with which the superior court correctly instructed the jury.

There is nothing to clarify. The superior court's ruling on Anderson's instruction argument was compelled by this Court's precedent, as was the Court of Appeals' affirmance of that ruling. Adopting Anderson's position would require this Court to abandon its well-settled case law to fashion a liability standard that this jurisdiction has never recognized. And, given that the superior court correctly instructed the jury on the applicable law, the Court of Appeals' affirmance could not conflict with any other decision on the grounds that the instruction misstated the law. As review is not warranted under either RAP 13.4(b)(1) or (4), this Court should accordingly deny review.

A. THE DECISION BELOW DOES NOT INVOLVE AN ISSUE OF SUBSTANTIAL PUBLIC INTEREST.

1. This Court's precedent on design defect claims.

This Court has long recognized a distinction between a manufacturer's liability for the design of ordinary defective products and

the design of "unavoidably unsafe products." *E.g.*, *Macias v. Saberhagen Holdings, Inc.*, 175 Wn.2d 402, 409, 282 P.3d 1069 (2012) ("[s]trict liability principles apply to ... defective design ... cases"); *Ruiz-Guzman v. Amvac Chem. Corp.*, 141 Wn.2d 493, 506, 7 P.3d 795 (2000) (liability for manufacturer of "unavoidably unsafe" product falls into an exception to strict liability); *see also Soproni v. Polygon Apartment Partners*, 137 Wn.2d 319, 326, 971 P.2d 500 (1999); *Young for Young v. Key Pharm., Inc.*, 130 Wn.2d 160, 170, 922 P.2d 59 (1996) (plurality); *Falk v. Keene Corp.*, 113 Wn.2d 645, 651, 782 P.2d 974 (1989); *Rogers v. Miles Labs., Inc.*, 116 Wn.2d 195, 207, 802 P.2d 1346 (1991); *Seattle-First Nat. Bank v. Tabert*, 86 Wn.2d 145, 149, 542 P.2d 774 (1975).

Since 1969, when this Court adopted Section 402A of the *Restatement (Second) of Torts* (1965) in *Ulmer v. Ford Motor Co.*, 75 Wn.2d 522, 531-32, 452 P.2d 729 (1969), strict liability has been the standard for product liability claims. Several years after adopting Section 402A, the Court made clear that such "strict liability extends to a design defect." *Tabert*, 86 Wn.2d at 149. In *Tabert*, the Court held that strict liability for defective design will attach "under section 402A if a product is not reasonably safe," measured "in terms of the reasonable expectations of the ordinary consumer," *i.e.*, "consumer expectations." *Id.* at 154.

After the Legislature enacted the WPLA, RCW Ch. 7.72, in 1981,

see laws of 1981, ch. 27, § 1, the Court was asked to decide whether the *Tabert* standard survived that enactment. Answering yes, the Court held in *Falk* that, despite the Legislature's use of the word "negligence" in RCW 7.72.030(1), strict liability would remain the standard for design defect product liability claims brought against manufacturers. *Falk*, 113 Wn.2d at 650-51, 653-54.[7]

The Court noted that before the WPLA's passage, "design defect claims were judged under the consumer expectations test of *Tabert*, with its balancing of risk and utility, and focus was on the product and its safety." *Falk*, 113 Wn.2d at 649. This would remain the law under the WPLA, because when defining the phrase "not reasonably safe" in the statute, "the Legislature set forth a risk-utility analysis and mandated that the trier of fact consider consumer expectations" – in other words, the strict liability "components of a design defect claim under *Tabert*." *Falk*, 113 Wn.2d at 651 (citing RCW 7.72.030(1)(a), (3)).

This Court's precedent followed a different trajectory, however, when imposing liability on a manufacturer for its design of products categorized as "unavoidably unsafe," such as the medical device at issue here. Most notably, in *Terhune v. A.H. Robins Co.*, 90 Wn.2d 9, 12-13,

[7] RCW 7.72.030(1) states 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."

577 P.2d 575 (1978), the Court adopted comment k to the *Restatement (Second) of Torts* Section 402A as an exception to strict liability for "unavoidably unsafe" products. The Court thereafter confirmed that the proper liability standard for comment k products is negligence, not strict liability. *Rogers*, 116 Wn.2d at 208; *accord Young*, 130 Wn.2d at 168-69 (plurality). And in *Ruiz-Guzman*, the Court recognized that comment k could apply in defective design cases where an "unavoidably unsafe" product was at issue. 141 Wn.2d at 505-11.

2. The pattern jury instructions conform to the law.

The separate pattern jury instructions used for strict liability and negligent design defect claims, WPI 110.02 and WPI 110.02.01, respectively, reflect this Court's different approaches to these theories of liability. The strict liability design defect instruction in WPI 110.02 tells the jury to "determin[e] whether a *product* is not reasonably safe as designed," WPI 110.02 (emphasis added), with the product's reasonable safety measured under alternative risk-utility and consumer-expectations tests. The negligent design defect instruction in WPI 110.02.01 tells the jury to decide whether a *manufacturer* has used "reasonable care to design ... medical products ... that are reasonably safe," with "reasonable care" measured by "what the manufacturer knew or should reasonably have known at the time of the plaintiff's injury." WPI 110.02.01.

The instructions ask the jury to answer different questions because, as this Court routinely has recognized, "[n]egligence and strict liability are not mutually exclusive." *Davis v. Globe Mach. Mfg. Co., Inc.*, 102 Wn.2d 68, 72, 684 P.2d 692 (1984); *accord Young*, 130 Wn.2d at 178 (plurality); *Lenhardt v. Ford Motor Co.*, 102 Wn.2d 208, 211-13, 683 P.2d 1097 (1984). When potential liability is based on strict liability, "the focus is on the product itself and the reasonable expectations of the user." *Simonetta v. Viad Corp.*, 165 Wn.2d 341, 356-57, 197 P.3d 127 (2008). By contrast, in a negligence action, the focus instead is placed "on the conduct of the defendant." *Id.*

3. The Court of Appeals correctly applied controlling precedent.

The Court of Appeals reviewed this Court's well-settled case law to reach the only conclusion that precedent allows: "[u]nder 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." *Payne*, 2015 WL 5682438, at *16. That conclusion, the Court of Appeals reasoned, was compelled by this Court's adoption of "a negligence standard for design defect claims involving comment k products," which standard focuses "on the conduct of the manufacturer to use reasonable care to design a medical

product that is reasonably safe." *Id.* at *15 (citing *Ruiz-Guzman*, 141 Wn.2d at 507-08). The WPI 110.02.01 instruction used at trial "correctly describe[d] the duty of a manufacturer of unavoidably unsafe products in designing reasonably safe medical devices under comment k." *Id.* at *17.

"Anderson assert[ed] 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," but the Court of Appeals rejected this argument, noting this Court's precedent demonstrated that such principles were reserved for "determin[ing] whether a manufacturer is strictly liable." *Id.* at *16. Anderson could not request the court to give a supplemental instruction that merely "delete[d] the clearly inapplicable language of the Strict Liability Instruction [WPI 110.02] that states, 'A manufacturer has a duty to design products that are reasonably safe as designed,' but otherwise set[] forth verbatim the tests used in determining a strict liability design defect claim: the risk utility and consumer expectations tests." *Id.* Therefore, "[t]he court did not err in refusing to give the supplemental jury instruction." *Id.* at *17.

4. Precedent unequivocally provides the answer to the issues that Anderson seeks to present to this Court.

Anderson argues that review should be granted principally because "this Court has never addressed whether the plaintiff must also show that

the [unavoidably unsafe] product is not 'reasonably safe' or what that showing might entail," under either the strict liability risk-utility or consumer expectations tests. Petition at 13. But the Court does not need to address a question that its precedent already unequivocally answers.

Anderson agrees that "[c]omment k liability is premised on negligence." Petition at 13 (citing *Rogers*, 116 Wn.2d at 207). In a negligence action, the manufacturer's conduct is the precise focus of the jury's attention, because negligence arises from a failure to use ordinary care. *E.g.*, *Simonetta*, 165 Wn.2d at 356-57; *Young*, 130 Wn.2d at 178 (plurality); *Davis*, 102 Wn.2d at 72; *Lenhardt*, 102 Wn.2d at 211-14. The pattern jury instruction given here conforms to that standard – WPI 110.02.01 (manufacturer "has a duty to use reasonable care to design ... medical products ... that are reasonably safe," and "[a] failure to use reasonable care is negligence") – as the Court of Appeals correctly held.

In her Petition, Anderson claims that "problems with the Court of Appeals' decision will engender confusion for the bench and bar" (Petition at 15), yet at the same time, she implores this Court to overrule long-established precedent to engraft inapplicable strict liability tests onto a negligence cause of action. The Court of Appeals rightly recognized the law is clear, and applied that law in affirming the trial court. This Court accordingly should deny review.

B. THE DECISION BELOW DOES NOT CONFLICT WITH THIS COURT'S CASE LAW.

Attempting to build upon her faulty premise that the superior court was required to instruct the jury on a comment k negligence claim using strict liability standards, Anderson argues that further review is necessary because the Court of Appeals' decision conflicts with this Court's precedent holding that instructions must properly inform the jury of the applicable law and allow parties to argue their theory of the case. Petition at 15-17. This argument presupposes that the Court of Appeals reached the wrong conclusion. But it did not. Argument, Point A., *supra*. Indeed, approving Anderson's proposed instructions would have misstated, not clarified, the applicable standard of liability.

The cases to which Anderson refers for purported conflict do not state otherwise, nor do they decide – let alone reference – the legal standard of liability applicable to the design defect claim at issue in this case. *E.g.*, *Anfinson v. FedEx Ground Pkg. Sys., Inc.*, 174 Wn. 2d 851, 860-74, 281 P.3d 289 (2012) (addressing whether jury instructions correctly stated the law for determining whether a worker is an employee under the Minimum Wage Act, and that evidence must be common to the class members in a class action); *Barrett v. Lucky Seven Saloon, Inc.*, 152 Wn.2d 259, 266-74, 96 P.3d 386 (2004) (addressing whether jury

instruction on alcohol prohibition statute stated the correct law on civil liability); *Hub Closing Co. v. City of Seattle*, 117 Wn. 251, 253-54, 201 P. 6 (1921) (addressing whether jury should have been instructed on term "reasonable inspection" in negligence action against city). Because these cases fail to establish conflict on any legal question decided below, this Court has no basis to accept review.

IV. CONCLUSION

For the reasons set forth above, this Court should deny Anderson's Petition for Review.

RESPECTFULLY SUBMITTED THIS 30th day of November, 2015.

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CERTIFICATE OF SERVICE

The undersigned certifies under penalty of perjury under the laws of the State of Washington that on this date I caused to be served in the manner indicated a copy of the within and foregoing document upon the following persons:

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Cc: Denton, Stephania <DentonS@LanePowell.com>; Van Buren, Helen <VanBurenH@LanePowell.com>; Nichol, Sharlee <NicholS@LanePowell.com>; Gabu, Ann <GabuA@LanePowell.com>; 'Ralph@luveralawfirm.com' <Ralph@luveralawfirm.com>; 'paul@luveralawfirm.com' <paul@luveralawfirm.com>; 'joel@luveralawfirm.com' <joel@luveralawfirm.com>; 'david@luveralawfirm.com' <david@luveralawfirm.com>; deborah@luveralawfirm.com; 'spruzan@miraclelaw.com' <spruzan@miraclelaw.com>; 'gahrend@ahrendlaw.com' <gahrend@ahrendlaw.com>; 'cohenl@gtlaw.com' <cohenl@gtlaw.com>; 'scherkere@gtlaw.com' <scherkere@gtlaw.com>; 'cechsamoleb@gtlaw.com' <cechsamoleb@gtlaw.com>; 'yagodaj@gtlaw.com' <yagodaj@gtlaw.com>
Subject: RE: Dorothy Payne and Becky Anderson v. Medtronic, Inc. and Medtronic Xomed, Inc. Supreme Court Case No. 924163

Dear Clerk: Attached for filing are the following documents:

Case No.: 924163
Case Name: Dorothy Payne and Becky Anderson v. Medtronic, Inc. and Medtronic Xomed, Inc.
Filing Attorney: Stephania Denton, WSBA No. 21920
Documents: Answer Brief of Respondent, appendices to follow via regular mail due to size.

Sincerely,

Ann Gabu | Lane Powell PC
Legal Assistant
1420 Fifth Avenue, Suite 4200
P.O. Box 91302 | Seattle, WA 98111-9402
Direct: 206.223.7122
GabuA@LanePowell.com | www.lanepowell.com

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924163

APPENDIX A

SUPERIOR COURT OF THE STATE OF WASHINGTON
COUNTY OF KING

BECKY S. ANDERSON, a single person, Plaintiff, vs. 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.	CAUSE NO. COMPLAINT FOR MEDICAL NEGLIGENCE AND PRODUCT LIABILITY

COMES NOW the plaintiff, and for claim for relief against defendants alleges as follows:

1. IDENTIFICATION OF PLAINTIFF

1.1 Becky S. Anderson was born on April 22, 1958, and was at all times mentioned herein a patient receiving medical care and treatment from the defendant doctors and health

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care providers above-named.

2. IDENTIFICATION OF DEFENDANTS

2.1 Upon information and belief, plaintiff alleges defendant Central Washington Health Services Association, d/b/a Central Washington Hospital (hereinafter referred to as "Hospital") is believed to be a Washington corporation, doing business in Chelan County. At all times material hereto, defendant Hospital was a medical care provider supplying medical care and treatment to its patients in the State of Washington, comprised of physicians and other health care individuals, nurses, employees and agents for purposes of providing medical care and treatment. The acts and omissions of these physicians, nurses, health care providers, employees and/or agents were their individual acts and the acts and omissions of defendant Hospital.

2.2 Upon information and belief, defendant Donald Paugh is a licensed physician who provided medical care and treatment to plaintiff.

2.3 Upon information and belief, Wenatchee Valley Medical Center is believed to be a Washington corporation or partnership that employed defendant Donald Paugh at all times pertinent to this action.

2.4 Upon information and belief, defendant Linda K. Schatz is a licensed physician who provided medical care and treatment to plaintiff.

2.5 Upon information and belief, Wenatchee Anesthesia Associates is believed to be a Washington corporation and/or partnership that employed defendant Linda K. Schatz at all times pertinent to this action.

2.6 Upon information and belief, Laser Engineering, Inc. is a foreign corporation which made, manufactured and supplied the Ultra MD 40 Laser System that was used during

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Ms. Anderson's surgical procedure on or about February 3, 2012. It's corporate headquarters are believed to be in Tennessee.

2.7 Upon information and belief, Medtronic, Inc. and/or Medtronic Xomed, Inc., is a corporation which made, manufactured and supplied the Laser-Shield II Endotracheal Tube which was utilized during Ms. Anderson's surgical procedure on or about February 3, 2012.

2.8 Upon information and belief, plaintiff further alleges that there may be other health care providers whose negligence contributed to plaintiff's injuries as hereinafter alleged, but whose correct identity is not now known and are referred to herein as John Does. Plaintiff requests that these pleadings be amended to reflect the true identities of these defendants when their identification becomes known.

3. DATE OF OCCURRENCE

3.1 Plaintiff Becky S. Anderson presented to defendant Hospital on or about February 3, 2012, for laser surgery. Within three years of the date of the commencement of this action, the plaintiff suffered injuries and damages as hereinafter alleged in the State of Washington, due to the negligence of defendants in providing medical care, defective products and treatment as hereinafter alleged.

4. COMPLIANCE WITH LAWS PECULIAR TO HEALTH CARE LAWSUITS

3.1 Attached as Exhibit A is the Declaration of Plaintiff Regarding Voluntary Arbitration, electing to:

[X] Opt out of voluntary arbitration and seek a jury trial

[ ] Opt into the Voluntary Arbitration Act recognizing there is a $1 million limit on any recovery.

5. OCCURRENCE

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5.1 On or around February 3, 2012, plaintiff Becky S. Anderson was admitted to defendant Hospital for elective surgery. As part of the surgical procedure, she was given general anesthesia by the anesthesiologist, defendant Linda Schatz. Defendant Schatz utilized an endotracheal tube, the Medtronic Laser-Shield II, to provide air and oxygen to the plaintiff during the procedure. The endotracheal tube was made, manufactured and provided by defendant Medtronic. The level of oxygen administered was controlled by Dr. Schatz.

5.2 Defendant Dr. Donald Paugh attempted to perform a surgical procedure on the plaintiff's throat utilizing a laser. The laser was a model Ultra MD 40 which was made, manufactured and provided by defendant Laser Engineering, Inc.

5.3 During the procedure, a fire occurred at the surgical site severely injuring the plaintiff. Plaintiff was airlifted to Harborview in King County, Washington where she has received extensive care and undergone multiple surgeries. Plaintiff remains a patient at Harborview, in King County at the time this action was commenced.

6. GENERAL NEGLIGENCE OF HOSPITAL

6.1 Plaintiff Becky Anderson sustained injuries and damages as hereinafter alleged due to the negligence of defendant Hospital and its failure to exercise reasonable prudence under the circumstances.

6.2 Defendant Hospital, through its agents, or apparent agents, including the defendant physicians, representatives and employees, failed to possess and exercise the

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degree of care, skill and learning of a reasonably prudent health care facility within the State of Washington acting in the same or similar circumstances.

6.3 Defendant Hospital's failure to exercise such skill, care and learning and failure to exercise reasonable prudence was a direct and proximate cause of the negligent treatment rendered plaintiff.

6.4 Defendant Linda K. Schatz, the anesthesiologist involved in the case, was the actual or apparent agent of the defendant Hospital.

7. NEGLIGENCE OF PHYSICIANS INVOLVED

7.1 Plaintiff Becky Anderson sustained injuries and damages as hereinafter alleged due to the negligence of defendant physicians in failing to exercise reasonable prudence under the circumstances.

7.2 Defendant physicians further failed to possess and exercise the degree of care, skill and learning of a reasonably prudent health care provider within the State of Washington acting in the same or similar circumstances.

7.3 Defendant physicians' failure to exercise such skill, care and learning and failure to exercise reasonable prudence was a direct and proximate cause of the negligent treatment to plaintiff Becky Anderson.

8. NEGLIGENCE OF WENATCHEE VALLEY MEDICAL CENTER, P.S.

8.1 Defendant Wenatchee Valley Medical Center, through its employee or agent, Donald R. Paugh, failed to exercise such skill, care and learning and failure to exercise

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reasonable prudence was a direct and proximate cause of the negligent treatment rendered plaintiff.

9. NEGLIGENCE OF WENATCHEE ANESTHESIA ASSOCIATES

9.1 Defendant Wenatchee Anesthesia Associates, through its employee or agent, Linda K. Schatz, failed to exercise such skill, care and learning and failure to exercise reasonable prudence was a direct and proximate cause of the negligent treatment rendered plaintiff.

10. ALLEGATIONS OF FAULT AGAINST LASER ENGINEERING, INC., METRONIC, INC. AND MEDTRONIC XOMED, INC.

In the alternative, plaintiffs allege as follows:

10.1 Defendant Laser Engineering, Inc. is liable under the Washington Products Liability Act R.C.W. Chapter 7.72. See WPI Chapter 110.

10.2 Specifically, defendant Laser Engineering, Inc. is liable under R.C.W. 7.72.030(2) (Defect in production or construction, WPI 110.01).

10.3 Defendants Medtronic, Inc. and/or Medtronic Xomed, Inc. are liable under the Washington Products Liability Act R.C.W. Chapter 7.72. See WPI Chapter 110.

10.4 Specifically, defendants Medtronic, Inc. and/or Medtronic Xomed, Inc. are liable under R.C.W. 7.72.030(2) (Defect in production or construction, WPI 110.01).

11. INFORMED CONSENT

11.1 Defendants failed to inform plaintiff of material facts relating to treatment regarding plaintiff Becky Anderson.

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11.2 The plaintiff was not fully informed or made aware of material facts relating to medical treatment and care resulting in injuries and damages as hereinafter alleged.

11.3 The injuries and damages would not have occurred had plaintiff been fully informed and made aware of material facts relating to the treatment.

12. INFERENCE OF NEGLIGENCE (RES IPSA)

12.1 The manner of injury to plaintiff Becky Anderson and the attending circumstances are of such a character which would warrant an inference that the injuries would not have occurred if ordinary care had been exercised by defendants.

12.2 The agency, instrumentality or thing which produced the injuries were at all times under the control of the defendants when the injury occurred.

12.3 The injury which occurred would not have ordinarily occurred and resulted had defendants exercised ordinary care and/or utilized products that were not defective.

13. INJURIES RECEIVED

13.1 As a direct and proximate cause of the facts as alleged herein, plaintiff has sustained severe and permanent injuries, the exact extent of which are unknown, but which include injuries to the mind and body and other injuries, all of which are permanent and disabling.

13.2 As a further direct and proximate result of the facts as alleged herein, the plaintiff has suffered and will in the future continue to suffer, pain, mental anguish, mental injury and suffering.

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13.3 That as a direct and proximate result of the facts as alleged herein, the plaintiff is entitled to damages in an amount now unknown but which will be proven at the time of trial.

14. EXPENSES INCURRED

14.1 The plaintiff has incurred out-of-pocket expenses and will continue to incur the same associated with these injuries, the exact extent of which are unknown but which will be proven at the time of trial.

14.2 Plaintiff is further entitled to interest on medical costs, wage loss, or other out-of-pocket liquidated known sums from the time the expenses were incurred to the time of trial at the appropriate and proper interest rate in an amount now unknown but which will be proven at the time of trial.

WHEREFORE, plaintiff prays for judgment against the above-named defendants, as follows:

1. For an award of general damages in an amount to be proven at trial;

2. For an award of special damages in an amount to be proven at trial;

3. For plaintiff's costs, disbursements and prejudgment interest as allowed by law;

4. For the right to amend this Complaint to conform to evidence as discovery takes place;

5. For the right to amend the Complaint to join additional and further

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defendants who come to light during discovery; and

6. For such other and further relief as the Court deems just.

DATED this 12th day of May, 2012.

LUVERA, BARNETT,
BRINDLEY, BENINGER & CUNNINGHAM

RALPH J. BRINDLEY, WSBA 8391
PAUL N. LUVERA, WSBA 849
Attorneys for Plaintiff

MIRACLE, PRUZAN & PRUZAN

STEVEN R. PRUZAN, WSBA 6061
Attorney for Plaintiffs

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Becky S Anderson
1/17/2012 2:30 PM Initial consult
MRN: 180738478

Description: Female DOB: 4/22/1958
Provider: KEITH ULNICK, DO
Department: MI Ent

Follow-up and Disposition

Return if symptoms worsen or fail to improve.

Routing History Recorded

Diagnoses

Vocal cord polypoid degeneration [478.5BP] - Primary

Reason for Visit

Laryngitis

Vitals - Last Recorded

BP	Pulse	Resp	Ht	Wt	BMI
98/70	76	16	5' 7" (1.702 m)	206 lb (93.441 kg)	32.26 kg/m2

Progress Notes

KEITH ULNICK, DO 1/17/12 03:11 PM Signed

Chief Complaint

Patient presents with

- Laryngitis

MRN: 444205 ANDERSON, BECKY S
FIN: 2127986 DOB: 04/22/1958

Consultation Requested By: Dr. Marcus Kubosumi, M.D.

History of present illness:

Becky is a 53 y.o. female who I was asked to see in consultation for evaluation of voice changes. The patient reports a two-month history of hoarseness. Her hoarseness progresses as the day goes on to the point where she has difficulty vocalizing. She has a history Graves' orbitopathy reconstructive surgery performed in August of 2011 requiring 5 hours of intubation. Her hoarseness started approximately 2 months following the surgery. She does have her previous history vocal cord nodule/mass resection over 20 years ago. She does not remember the pathology. She is a nonsmoker. She consumes approximately 2 beers a month. She does not complain about any fevers, chills, night sweats, odynaphagia or dysphagia she does have intermittent gastric reflux but is well controlled on her current medication. She has no unintentional weight loss. She has been given several courses oral steroids along with intravenous steroids without significant improvement in her voice quality. She currently is not in any pain. No complaints of postnasal drainage or chronic throat clearing. She recently underwent a pulmonary function test which was normal. She does use multiple inhaled steroids due to a questionable asthma which has not improved her voice quality.

Patient Active Problem List

Diagnoses	Date Noted
• Vocal cord polypoid degeneration [478.5BP]	01/17/2012
• Grave's disease [242.00AD]	07/22/2011
• Diplopia [368.2]	02/24/2011
• Paralysis, unspecified [344.9]	02/24/2011
• Esophageal reflux [530.81]	12/04/2010
• Helicobacter pylori (H. pylori) [041.86]	12/04/2010
• Personal history of other infectious and parasitic disease [V12.09]	12/04/2010
• Thyrotoxicosis NOS w/o crisis [242.90]	09/19/2010
• Hemorrhage of rectum and anus [569.3]	04/29/2010
• Tobacco use disorder [305.1]	04/29/2010
• Paroxysmal ventricular tachycardia [427.1]	04/29/2010
• Paroxysmal supraventricular tachycardia [427.0]	04/29/2010
• Blood in stool [578.1]	04/29/2010
• Atrial flutter [427.32]	04/28/2010
• Chest pain, unspecified [786.50]	04/28/2010
• Sciatica [724.3]	12/01/2009
• Diarrhea [787.91]	07/20/2009

limit on any recovery.

5. OCCURRENCE

5.1 On or around February 3, 2012, plaintiff Becky S. Anderson was admitted to Central Washington Hospital for elective surgery. As part of the surgical procedure, she was given general anesthesia by the anesthesiologist, defendant Linda Schatz. Defendant Schatz utilized an endotracheal tube, the Medtronic Laser-Shield II, to provide air and oxygen to the plaintiff during the procedure. The endotracheal tube was made, manufactured and provided by defendant Medtronic. The level of oxygen administered was controlled by Dr. Schatz.

5.2 Defendant Dr. Donald Paugh attempted to perform a surgical procedure on the plaintiff's throat utilizing a laser. .

5.3 During the procedure, a fire occurred at the surgical site severely injuring the plaintiff. Plaintiff was airlifted to Harborview in King County, Washington where she has received extensive care and undergone multiple surgeries. Plaintiff remains a patient at Harborview, in King County at the time this action was commenced.

6. NEGLIGENCE OF PHYSICIANS INVOLVED

6.1 Plaintiff Becky Anderson sustained injuries and damages as hereinafter alleged due to the negligence of defendant physicians Donald Paugh and/or Linda Schatz in failing to exercise reasonable prudence under the circumstances.

6.2 Defendant physicians further failed to possess and exercise the degree of care, skill and learning of a reasonably prudent health care provider within the State of Washington acting in the same or similar circumstances.

6.3 Defendant physicians' failure to exercise such skill, care and learning and failure to exercise reasonable prudence was a direct and proximate cause of the negligent

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treatment to plaintiff Becky Anderson.

7. NEGLIGENCE OF WENATCHEE VALLEY MEDICAL CENTER, P.S.

7.1 Defendant Wenatchee Valley Medical Center, through its employee or agent, Donald R. Paugh, failed to exercise such skill, care and learning and failure to exercise reasonable prudence was a direct and proximate cause of the negligent treatment rendered plaintiff.

8. NEGLIGENCE OF WENATCHEE ANESTHESIA ASSOCIATES

8.1 Defendant Wenatchee Anesthesia Associates, through its employee or agent, Linda K. Schatz, failed to exercise such skill, care and learning and failure to exercise reasonable prudence was a direct and proximate cause of the negligent treatment rendered plaintiff.

9. ALLEGATIONS OF FAULT AGAINST., MEDTRONIC, INC. AND MEDTRONIC XOMED, INC.

9.1 Defendants Medtronic, Inc. and/or Medtronic Xomed, Inc. are liable under the Washington Products Liability Act R.C.W. Chapter 7.72. See WPI Chapter 110.

10. INFORMED CONSENT

10.1 Defendants failed to inform plaintiff of material facts relating to treatment regarding plaintiff Becky Anderson.

10.2 The plaintiff was not fully informed or made aware of material facts relating to medical treatment and care resulting in injuries and damages as hereinafter alleged.

10.3 The injuries and damages would not have occurred had plaintiff been fully informed and made aware of material facts relating to the treatment.

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HON. MICHAEL TRICKEY

ORIGINAL

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 AMENDED PROPOSED INSTRUCTIONS [CITED]

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

DATED this 27th day of November, 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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NO. _____

As to the plaintiff's claims against the Medtronic Defendants, a medical device 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 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 product left its control.

In determining what a medical device manufacturer reasonably should have known in regard to designing its product, 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.

WPI 110.02.01 (modified)
PLAINTIFF'S AMENDED PROPOSED INSTRUCTION NO. 11

NO. _____

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

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

Second, that plaintiff was injured; and

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

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

WPI 110.21 (modified)
PLAINTIFF'S AMENDED PROPOSED INSTRUCTION NO. 12

(If you answered "yes" to Question 3, proceed to Question 4. If you answered "no" to Question 3, proceed to Question 5)

Question No. 4: Was Dr. Donald Paugh's failure to obtain the informed consent of Becky Anderson to the treatment undertaken a proximate cause of injury to Becky Anderson?

ANSWER: Yes_____ No_____

(If you answered "yes" or "no" to Question 4, proceed to Question 5.

Question No. 5: Was Dr. Linda Schatz negligent?

ANSWER: Yes_✓_ No_____

(If you answered "yes" to Question 5, proceed to Question 6. If you answered "no" to Question 5, proceed to Question 7.)

Question No. 6: Was Dr. Schatz's negligence a proximate cause of injury to Becky Anderson?

ANSWER: Yes_✓_ No_____

(If you answered "yes" or "no" to Question 6, proceed to Question 7.)

Question No. 7: Was Medtronic, Inc./Medtronic Xomed, Inc. negligent?

ANSWER: Yes_____ No_✓_

(If you answered "yes" to Question 7, proceed to Question 8. If you answered "no" to Question 7, proceed to question 9.)

Question No. 8: Was Medtronic, Inc./Medtronic Xomed, Inc.'s negligence a proximate cause of injury to Becky Anderson?

ANSWER: Yes_____ No_____

(If you answered "yes" or "no" to Question 8, proceed to Question 9.)

Question No. 9: Was Non-Party Central Washington Hospital negligent?

ANSWER: Yes_✓_ No_____

(If you answered "yes" to Question 9, proceed to Question 10. If you answered "no" to Question 9, proceed to the DIRECTION to Question 11.)

Question No. 10: Was Non-Party Central Washington Hospital's negligence a proximate cause of injury to Becky Anderson?

ANSWER: Yes_✓_ No_____

(If you answered "yes" or "no" to Question 10, proceed to the DIRECTION to Question 11.)

(DIRECTION to Question 11: If you have indicated by your responses to Questions 1 through 8 above that plaintiff has established both negligence and proximate cause as to one or more defendants, proceed to Question 11. If not, then stop, sign this Special Verdict Form and notify the bailiff.)

Question No. 11: What do you find to be the plaintiffs amount of damages?

ANSWER:

Past economic damages	$ 2.6 million
Future economic damages	$ 7.4 million
Past non-economic damages	$ 2 million
Future non-economic damages	$ 6 million

(DIRECTION: If you answered Question 11 with any amount of money, answer Question 12. If you found no damages in Question 11, sign this Special Verdict Form and notify the bailiff.)

Question No. 12: Assume that 100% represents the total combined negligence that proximately caused the plaintiff's injury and damage. What percentage of this 100% is attributable to each defendant and non-party whose negligence, or failure to obtain informed consent, was found by you to have been a proximate cause of the injury and damage to the plaintiff? Your total must equal 100%.

ANSWER:

To Defendants Dr. Donald Paugh/Wenatchee Valley Medical Center	42.5 %
To Defendants Dr. Linda Schatz/Washington Anesthesia Associates	52.5 %
To Defendants Medtronic Inc./Medtronic Xomed, Inc.	Ø %
To Non-Party Central Washington Hospital	5 %
TOTAL: (Must equal 100%)	100%

(If you answered Question 12, along with all previous questions required to be answered, in accordance with the Court's Instructions and the directions included in this Special Verdict Form, have the Presiding Juror sign the Special Verdict Form and notify the bailiff so that your verdict can be announced in open Court.)

DATED this 5th day of ~~June~~ December, 2013.

Presiding Juror

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.

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

DEFENDANT MEDTRONIC, INC. AND MEDTRONIC XOMED, INC.'S MOTION FOR SUMMARY JUDGMENT

LAW OFFICES OF
MILLS MEYERS SWARTLING P.S.
1000 SECOND AVENUE, 30TH FLOOR
SEATTLE, WASHINGTON 98104-1064
TELEPHONE (206) 382-1000
FACSIMILE (206) 386-7343

I. RELIEF REQUESTED

Despite having well over a year of accelerated discovery and over forty depositions taken to date in this case, Plaintiff has failed to establish a prima facie case under any theory of liability against Medtronic, Inc. and Medtronic Xomed, Inc. for the injuries sustained by Ms. Anderson. Discovery has now closed, and insufficient competent evidence has been produced to support any claim against these Defendants related to the Laser-Shield II device at issue in this case. Rather, the evidence amassed to date establishes the Laser-Shield II is a safe and effective device cleared by the FDA with adequate warnings and instructions, and that Ms. Anderson's airway fire would not have occurred if the device had been used in accordance with its Instructions for Use and all warnings therein. Thus, Defendants Medtronic, Inc. ("Medtronic") and Medtronic Xomed, Inc. ("Xomed") respectfully move for judgment as a matter of law in their favor and ask this Court to dismiss all of Plaintiff Becky Anderson's claims against them pursuant to CR 56.

Specifically, Medtronic and Xomed (together, the "Medtronic Defendants") request judgment as a matter of law (1) on Plaintiff's design defect, failure to warn, unsafe construction and warranty claims under Washington's Product Liability Act for failure to prove both liability and causation; (2) as to any theory based on res ipsa loquitur; (3) that the causal chain was broken by an intervening cause; and (4) as to any alleged failure to follow federal regulations because such claims are preempted. Plaintiff has failed to produce any competent evidence, expert or otherwise, to support her product liability claim that the Xomed Laser-Shield II was defectively designed or constructed pursuant to Washington law. Further, Plaintiff has failed to produce any competent evidence or expert support for her claim that any alleged defect in the Laser-Shield II was the proximate cause of her injuries. Therefore, Plaintiff's claims against the Medtronic Defendants fail as a matter of law.

II. STATEMENT OF PERTINENT FACTS

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A. Ms. Anderson's February 3, 2013 Surgery at Central Washington Hospital

This medical malpractice and product liability lawsuit arises from an airway fire that occurred during a February 3, 2012 surgery to remove polyps from Plaintiff Becky Anderson's vocal chords at Central Washington Hospital ("CWH"). Complaint at ¶5.1. Defendant Donald Paugh, M.D., a board certified otolaryngologist, performed the procedure using a carbon dioxide laser to remove the polyps. Complaint at ¶5.2. Defendant Linda Schatz, M.D., a board certified anesthesiologist, administered anesthesia to Ms. Anderson during the procedure, which included the delivery of 100% oxygen. Declaration of Victoria Lockard dated September 3, 2013 ("*Lockard Decl.*"), Ex. 1 (Defendants Linda Schatz, M.D. and Wenatchee Anesthesia Associates' Responses to Plaintiff's First Requests to Admit). Dr. Paugh and Dr. Schatz utilized a Xomed Laser-Shield II ("Laser-Shield II"), a laser-resistant endotracheal tube manufactured by Xomed,[1] to facilitate the administration of the oxygen to Plaintiff. Complaint at ¶5.1. Contrary to the warnings, instructions and recommendations contained in the Instructions for Use (package insert), which accompanied the Laser-Shield II, Dr. Schatz administered oxygen to Plaintiff at a concentration of 100% during the procedure.[2] *Lockard Decl.*, Ex. 1 and Ex. 2 (Laser-Shield II Instructions for Use). Plaintiff alleges that during the procedure, Dr. Paugh contacted the Laser-Shield II with a laser beam, which Xomed also warned against in the Instructions for Use, thereby perforating the cuff and causing the 100% oxygen to reach the surgical field and ignite. Complaint at ¶5.1; *Lockard Decl.*, Ex. 2.

B. THE XOMED LASER-SHIELD II ENDOTRACHAEL TUBE IS A SAFE,

[1] The Laser-Shield II was designed, made and manufactured by Xomed. Medtronic, Inc. did not design, manufacture, distribute or sell the Laser-Shield II. Medtronic is filing a separate motion for summary judgment on these grounds.

[2] This Court granted Plaintiff's Motion for Summary Judgment on the issue of whether Dr. Schatz's administration of 100% oxygen was negligent as a matter of law. Dkt. 145. Plaintiff recently filed a separate Motion for Summary Judgment seeking an order that the negligent administration of 100% oxygen was a proximate cause of Plaintiff's injuries. This motion is currently pending before the Court.

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EFFECTIVE DEVICE THAT WAS CLEARED BY THE FDA WITH A SINGLE CUFF DESIGN

In August of 1990, the Laser-Shield II was cleared to market by the Food and Drug Administration ("FDA") as a Class II device through the 510(k) process. *Lockard Decl.*, Ex. 3 (Medtronic Xomed, Inc. Answers, Objections, and Responses to Plaintiff's First Interrogatories, at No. 11). In January of 2000, following a supplemental 510(k) application to reflect a design change involving an enhancement to the Laser-Shield II's laser resistant wrapping, the FDA again reviewed the Laser-Shield II and it's labeling and cleared the modified Laser-Shield II to market. *Id.*, Ex. 4 (FDA Clearance Letter for K993582 dated January 20, 2000).

The Laser-Shield II, like any standard endotracheal tube, is a catheter that is inserted into the trachea for the primary purpose of establishing and maintaining a patient's airway and to facilitate the adequate exchange of gases. Unlike standard endotracheal tubes, however, the Laser-Shield II is designed to be used in laser surgeries. Its main shaft is covered in a laser resistant overwrap made of aluminum and Teflon over the silicone shaft of the tube. The Laser-Shield II has a dye-filled inflatable cuff near the distal (i.e., bottom) end of the tube, which pursuant to its Instructions for Use, should be inflated with saline during use to help seal the airway and serve as a heat sink. *See Lockard Decl.*, Ex. 2.

The Laser-Shield II's Instructions for Use also warns that the cuff is not laser resistant and instructs users to protect the cuff area by placing wet cotton gauze around the cuff. *See id.* As an additional safety feature, the cuff contains a powder blue methylene dye, which is designed to mix with the saline in the cuff. *See id.* In the event that the cuff is perforated by a laser strike, the blue-dyed saline is designed, assuming it is placed properly, to stain the wet cotton gauze and thus help the surgeon detect a cuff rupture. *See id.*

C. THE LASER-SHIELD II'S INSTRUCTIONS FOR USE WERE CLEAR, UNAMBIGUOUS, AND CLEARED BY THE FDA

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As required by the FDA, every Laser-Shield II comes with a package insert titled "Instructions for Use" which includes instructions and warnings for the safe and proper use of the Laser-Shield II. The Instructions for Use were reviewed and cleared by the FDA. The Instructions for Use for the Laser-Shield II utilized in Ms. Anderson's procedure were in the operating room and were available to Dr. Paugh, Dr. Schatz and the operative team on the morning of February 3, 2012. *Lockard Decl.*, Ex. 5 (Deposition of Linda K. Schatz, M.D. dated January 19, 2012 (Schatz Dep.") at 75:3-9).

The Instructions for Use contained clear, unambiguous and redundant warnings of the risk of fire and serious injury due to elevated oxygen levels. The Instructions for Use stated in the "WARNINGS" section: "Do not use surgical lasers or thermal cautery power sources in the presence of elevated oxygen levels or other flammable gases, or damage to the tube may result in ignition and serious patient injury." In addition, the Instructions for Use explicitly directed: "Dilute oxygen or other flammable gases with Helium, Nitrogen or room air as needed. Dilute oxygen to the minimal inspired concentration compatible with satisfactory oxygen concentration." It further provided, "RECOMMENDATION: Use 30% oxygen / 70% helium, or 30% oxygen / 70% room air." *Id.* at Ex. 2. It also stated, "EXTREME CARE MUST BE TAKEN IN MAINTAINING . . . THE OXYGEN GAS MIXTURE CONCENTRATIONS FOR LASER APPLICATIONS. Failure to comply . . . will cause unnecessary risk to the health and safety of the patient" *Id.* Finally, it stated that "equipment used must be capable of providing diluted gas mixture concentrations for the safe use of this endotracheal tube in laser surgery.'

The Instructions for Use were also very clear as to the risk of striking the device, and particularly the cuff, with a laser beam. It warned users in the WARNINGS section, "Do not impact the LASER-SHIELD II with a laser beam" and "Do not contact the cuff or distal end of the shaft with a laser beam or electrosurgical instrument. Contact may cause deflation of

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the cuff and result in combustion and fire." *Id.* It also specified in the very first paragraph that "[t]he proximal and distal end of the silicone elastomer shaft and cuff are not covered and therefore, are not laser resistant."

D. PLAINTIFF'S MEDICAL PROVIDERS DID NOT READ THE LASER-SHIELD II'S INSTRUCTIONS FOR USE, YET THEY WERE INDEPENDENTLY AWARE OF THE RISKS OF USING ELEVATED OXYGEN LEVELS, CUFF PERFORMATION AND FIRE

Though they were experienced clinicians, neither Dr. Paugh nor Dr. Schatz had performed a laser surgery using the Laser-Shield II prior to Ms. Anderson's procedure. *Id.* at Ex. 5 (Schatz Dep. at 13:19-14:3), Ex. 6 (Deposition of Donald Paugh, M.D. dated December 17, 2012 ("Paugh Dep.") at 13:24-14:5). Nevertheless, Dr. Paugh and Dr. Schatz, as well as the attending laser safety nurse, Scott Vandoren, did not review any of the product literature accompanying the Laser-Shield II, including the Instructions for Use. *Id.* at Ex. 5 (Schatz Dep. at 60:1-6), Ex. 6 (Paugh Dep. at 88:13–89:4), Ex.7 (Deposition of Scott VanDoren dated December 18, 2012 ("Van Doren Dep.") at 42:22–43:2). Despite not reviewing the Instructions for Use, however, Dr. Schatz, Dr. Paugh, and Nurse Vandoren were all independently aware of the risk of fire and that administering oxygen above 30% increased the risk of an airway fire and was to be avoided except in cases where medically necessary. *Id.* at Ex. 5 (Schatz Dep. at 21:21-21:24, 61:13-61:19, 62:362:23), Ex. 6 (Paugh Dep. at 40:2-40:8, 93:20 – 94:12, 97:8-97:16), Ex. 7 (VanDoren Dep. at 9:17-10:20). In addition, even without reading the Instructions for Use, Dr. Paugh and Dr. Schatz were also independently aware that the proximal and distal ends of the shaft and the cuff are not protected and thus not laser-resistant. *Id.* at Ex. 6 (Paugh Dep. At 99:3-99:21); Ex. 5 (Schatz Dep. at 61:4-61:12, 61:20-62:2).

E. THE TESTIMONY OF PLAINTIFF'S SOLE LIABILITY EXPERT AND CAUSATION EXPERTS CANNOT HELP PLAINTIFF MEET HER BURDEN OF PROOF

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The Laser-Shield II was cleared by the FDA with a single, inflatable cuff design. Plaintiff has named just one liability expert against the Medtronic Defendants, George Samaras, Ph.D., a hybrid engineer/regulatory/"human factors" expert with no experience with laser-resistant endotracheal tubes. Dr. Samaras opined that the Laser-Shield II's design was unsafe because it used a single cuff instead of a double, "redundant" cuff. Dr. Samaras points to a competitor device on the market, the Mallinckrodt "Laser-Flex" endotracheal tube, as a supposedly safer, double-cuff design. Dr. Samaras, however, is unqualified to render such opinions, his conclusions are not relevant and not the product of reliable methodology, and thus his liability opinions are subject to exclusion.

Moreover, Dr. Samaras could not offer a causation opinion to connect these alleged design flaws to Ms. Anderson's injuries. Instead, three other of Plaintiff's experts, Richard Hughes, Ph.D., David Eimerl, Ph.D., and James Reibel, M.D., two physicists and a otolaryngologist, have testified that they thought a double cuff design could have prevented the fire and Ms. Anderson's injuries. The opinions of these three experts are likewise subject to exclusion, for lack of qualifications, reliability and relevance. The unqualified and speculative opinions of these four experts are insufficient to create a triable issue for the jury. The Medtronic Defendants are filing contemporaneously herewith motions to exclude the opinions of each of these experts as to the Medtronic Defendants, and the Medtronic Defendants incorporate the facts, arguments, and authority cited in their motions to exclude as if fully incorporated herein.

III. STATEMENT OF ISSUES

1. Whether the Medtronic Defendants are entitled to judgment as a matter of law on Plaintiff's design defect claim because (a) the Restatement (Second) of Torts, § 402A, comment k, provides a "blanket exception" from strict liability for design defect for prescription medical devices; (b) Plaintiff cannot offer any reliable expert testimony that the

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Laser-Shield II is defectively designed; and (c) Plaintiff cannot offer any reliable expert testimony that the design of the Laser-Shield II proximately caused her injuries.

2. Whether the Medtronic Defendants are entitled to judgment as a matter of law on Plaintiff's failure to warn claim because (a) under comment k, the warnings accompanying the Laser-Shield II were adequate as a matter of law; and (b) Plaintiff cannot show that any allegedly deficient warnings or instructions proximately caused her injuries, because Plaintiff's medical providers did not review the Laser-Shield II's Instructions for Use, and they were independently aware of the risks.

3. Whether the Medtronic Defendants are entitled to judgment as a matter of law on Plaintiff's claims for unsafe construction and breach of warranty because Plaintiff has not and cannot produce any evidence to support these claims.

4. Whether the Medtronic Defendants are entitled to judgment as a matter of law on Plaintiff's negligence/res ipsa loquitur claim because the claim is preempted by the Washington Product Liability Act, RCW Ch. 7.72 ("WPLA") and, in any event, Plaintiff is unable to satisfy the prerequisites.

5. Whether the Medtronic Defendants are entitled to judgment as a matter of law on all claims because the administration of 100% oxygen during Plaintiff's surgery was an unforeseeable, intervening cause of Plaintiff's injuries.

6. Whether the Medtronic Defendants are entitled to judgment as a matter of law on any purported claims relating to the Medtronic Defendants' alleged failure to follow FDA regulations, because such claims are impliedly preempted by the U.S. Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001).

IV. AUTHORITY

A. LEGAL STANDARD FOR SUMMARY JUDGMENT

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Under Civil Rule 56, summary judgment should be granted when "the pleadings . . . together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." CR 56(c). Summary judgment in favor of defendant is proper if the plaintiff fails to make a prima facie case concerning an essential element of his or her claim. *Young v. Key Pharmaceuticals, Inc. ("Young I")*, 112 Wn.2d 216, 225, 770 P.2d 182 (1989); *see also Wagner Development, Inc. v. Fidelity & Deposit Co. of Maryland*, 95 Wn. App. 896, 900, 977 P.2d 639 (1999) ("Summary judgment is appropriate if reasonable persons could reach but one conclusion.").

Summary judgment under CR 56 is subject to a burden-shifting scheme where the party moving for summary judgment bears the initial burden of showing the absence of a genuine issue of material fact. *Young I*, 112 Wn.2d at 225. If the moving party is a defendant and meets this initial showing, then the burden shifts to the plaintiff. *Id.* "If, at this point, the plaintiff 'fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial,' then the trial court should grant the motion." *Id.* (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)).

In responding to a motion for summary judgment, a nonmoving party cannot merely rely on the allegations made in her pleadings. *Id.*; *see also* CR 56. If the non-moving party does not respond with appropriate evidence setting forth specific facts indicating that a material issue of fact remains, summary judgment should be entered. CR 56(e).

B. THE MEDTRONIC DEFENDANTS CANNOT BE HELD LIABLE FOR MS. ANDERSON'S INJURIES UNDER ANY THEORY

Plaintiff has sued the Medtronic Defendants alleging liability under various provisions of the WPLA, including design defect, failure to warn and manufacturing defect/unsafe construction (Complaint at ¶¶ 10.3-10.4). Plaintiff has also alleged liability under the doctrine of res ipsa

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loquitur (Complaint at ¶¶ 12.1-12.3). In addition, Plaintiff's purported expert witness George Samaras, Ph.D. has opined that the Medtronic Defendants failed to follow FDA regulations in their design and development of the Laser-Shield II. All of these claims are subject to dismissal on summary judgment because they fail as a matter of law.

1. Plaintiff Cannot Establish a Claim for Design Defect

a. Plaintiff's design defect claim fails under comment k.

Plaintiff asserts a design defect claim under the Washington Product Liability Act. *See* Complaint at ¶¶ 10.3-10.4. However, such a claim is not recognized in Washington for prescription medical devices. Rather, in this state, plaintiffs who allege to have been injured by a product that is available only by prescription or through the services of a physician are limited to asserting a "failure to warn" negligence claim pursuant to the standards set forth in "comment k" of the Restatement (Second) of Torts, § 402A (1965). *Young v. Key Pharmaceuticals, Inc.*, 130 Wn.2d 160, 922 P.2d 59 (1996) (citing *Terhune v. A.H. Robins Co.*, 90 Wn.2d 9, 577 P.2d 975 (1978)). Prescription drugs and medical products are unique because a consumer can have access to them only with the approval of a "learned intermediary" – a licensed health care professional – upon whom he or she can rely for the necessary specialized risk/benefit assessment. Under the Restatement, such products are said to be "unavoidably unsafe" to a certain extent, but nonetheless socially beneficial when used with appreciation for their benefits and risks. *See Restatement (Second) of Torts*, § 402A comment k.

Under comment k, a product manufacturer may be liable only if it "becomes aware or should have become aware of dangerous aspects" of a product and fails "to act with regard to issuing warnings or instructions concerning any such danger in the manner that a reasonably prudent [product] manufacturer would act in the same or similar circumstances." *Id.* at 175. This duty to warn runs only to the physician who uses the product, not the patient. *Adams v.*

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Synthes Spine Co., LP, 298 F.3d 1114, 1117 (9th Cir. (Wash.) 2001).

As recognized by the Court in *Adams*, "Washington law rules out strict liability for prescription medical products . . . provided that proper warning is given to the physician." *Id.* at 1118; *see also Ruiz-Guzman v. Amvac Chem. Corp.*, 141 Wn.2d 493, 508-11, 7 P.3d 795 (2000) (noting that medical products have a "blanket exemption" from strict liability for design defect, even after enactment of the WPLA). Consequently, the only issues in this case relating to Plaintiff's claim against the Medtronic Defendants are whether the Medtronic Defendants were negligent in failing to give proper warnings to Dr. Paugh and to Dr. Schatz and, if so, whether that negligence proximately caused Plaintiff's injuries.

b. Plaintiff's design defect claim also fails due to her inability to produce competent expert testimony of a defective design

Even if comment k's "blanket exception" for prescription medical devices from strict liability design defect claims did not apply, Plaintiff's design defect claim would also fail due to her lack of expert support. In order to establish a claim for design defect, a plaintiff must prove that her harm was "proximately caused [because] the product was not reasonably safe as designed... ." RCW 7.72.030(1). A plaintiff may establish that a product is not reasonably safe as designed using either a risk-utility analysis or a consumer expectation test. *Soproni v. Polygon Apartment Partners*, 137 Wn.2d, 319, 326-27, 971 P.2d 500 (1999). Both standards require the trier of fact to determine whether a product is not reasonably safe based upon objective criteria. Under the risk-utility analysis, the plaintiff must show that the likelihood and seriousness of the harm caused by the product outweighed the burden on the manufacturer to design a feasible alternative product *that would have prevented the harm*, and the adverse effect the alternative design would have on the product's usefulness. *See* RCW 7.72.030(1)(a). Under the consumer expectation standard, a plaintiff must show that the

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product was unsafe to an extent beyond that which the ordinary user of that product would reasonably contemplate. *See* RCW 7.72.030(3); *Wagner v. Flightcraft, Inc.*, 31 Wn. App. 558, 564, 643 P.2d 906 (1982).

"[R]eliable and specific expert testimony" is generally required to "establish the nature of the alleged dangerous condition in a products liability case." *See Bruns v. PACCAR, Inc.*, 77 Wn. App. 201, 210, 890 P.2d 469 (1995), citing *Wagner*, 31 Wn. App. 558. Thus, in this case, Plaintiff must produce reliable expert testimony to allow the jury to understand the complex interaction of the Laser-Shield II endotracheal tube with a laser, oxygen, blue-dyed saline, and placement of the device and protective cottonoids during an airway laser surgery. Without such expert testimony, the jury will be unable to properly evaluate Plaintiff's allegation of a defect in the Laser-Shield II's single cuff design.

Here, Plaintiff disclosed just one expert witness against the Medtronic Defendants to testify that the design of the Laser-Shield II was not reasonably safe: George Samaras, Ph.D. As detailed in the Medtronic Defendants' Motion to Exclude, Samaras does not have expertise in the design or manufacture of medical devices, and has no expertise or experience with laser-resistant endotracheal tubes or laser surgeries. Nevertheless, Dr. Samaras offers the conclusory opinion that the Laser-Shield II used in Plaintiff's procedure "was inherently less safe for oropharyngeal surgery than an endotracheal tube ... with two independent cuffs." *Lockard Decl.*, Ex. 8 (Exhibit 1 to Declaration of George Samaras dated July 23, 2013 ("Samaras Decl."), at 2). In forming his opinion that the Laser-Shield II's single cuff design was not reasonably safe and was "inherently less safe" than a double cuff design, Samaras did not review the incidence rates of serious injury from airway fire for either design. *Lockard Decl.*, Ex. 9 (Deposition of George Samaras, Ph.D. dated August 5, 2013 ("Samaras Dep. I") at 132:15-18). He did not conduct a design failure mode effects analysis ("FMEA") on either design. *Id.* (Samaras Dep. I at 94:21 – 95:9). Nor did he review any adverse event reports

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("AERs") for the Mallinckrodt Laser-Flex tube. *Id.* (Samaras Dep. I at 32:24 – 33:3). Dr. Samaras admitted that he is "not that familiar with the Mallinckrodt device and that his examination of the Laser-Flex was limited to a visual verification that it actually incorporates a double cuff design. *Id.* (Samaras Dep. I at 73:12-18 and 21:5-18).

Dr. Samaras' testimony as to the single cuff design is nothing more than his speculative, personal opinion that two cuffs must be better than one and as such it cannot carry Plaintiff's burden. Because Plaintiff has failed to establish an alleged defect through competent, reliable and relevant expert testimony, her design defect claim fails.

c. Plaintiff's design defect claim fails due to her inability to show proximate causation

Notwithstanding comment k's "blanket exception" for design defect claims related to prescription medical products, and even if this Court does not strike Samaras' design defect opinion, Plaintiff's design defect claim still fails due to her inability to present any reliable expert testimony that the design of the Laser-Shield II proximately caused Ms. Anderson's injuries. To establish a prima facie case of design defect product liability, Plaintiff must show that the alleged defect or unsafe condition proximately caused her injuries. *See* RCW 7.72.030(1); *Bruns*, 77 Wn. App. at 214. This required expert testimony must provide proof that the defect "more probably than not" caused a plaintiff's injuries. *Id.* at 215. "Less certain evidence, such as may, might, could or possibly, does not provide enough guidance to the jury to remove the decision-making process from speculation and conjecture." *Id.* The testimony must be based on a reasonable degree of medical certainty. *McLaughling v. Cooke*, 112 Wn.2d 829, 836, 774 P.2d 1171 (1989).

In this case, the cause of the fire in Plaintiff's airway during her laser surgery procedure and her resulting injuries are highly complex questions which involve "obscure" medical and scientific factors. Multiple expert witnesses from various parties have testified

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that the exact mechanism that started the fire is unknown. Experts have offered a number of theories regarding what provided the fuel for the fire and how 100% oxygen entered the surgical site. Clearly, the question of whether the Laser-Shield II's single cuff design caused the fire "lies beyond ordinary lay knowledge and requires expert medical testimony to demonstrate a causal link." *See Bruns*, 77 Wn. App. at 215. Moreover, with uncertainty over just how this event occurred and how the oxygen reached the surgical site, it would be entirely speculative for any of Plaintiff's experts to opine that a double cuff design would have made any difference.

Three of Plaintiff's eighteen experts, however, testified that a double-cuff design might have prevented the fire during Ms. Anderson's airway surgery: Richard Hughes, Ph.D., David Eimerl, Ph.D., and James Reibel, M.D.[3] Upon the exclusion of these speculative causation opinions, Plaintiff will be left with no expert testimony to support her causation case against the Medtronic Defendants. In any event, such causation opinions are insufficient to support Plaintiff's theory that the single cuff design of the Laser-Shield II was the proximate cause of the fire and Plaintiff's injuries. *Bruns*, 77 Wn. App. at 215. The jury would be left to speculate as to whether the fire would have occurred even if a double cuff tube had been used. As the jury would "have to resort to speculation in order to find proximate cause" with regard to the device's design, Plaintiff's design defect claim would fail on this basis alone. *Bruns* at 217; *Fabrique*, 144 Wash. App. at 688 (2008) (dismissing claims due to plaintiff's failure to produce expert testimony establishing proximate cause).

2. Plaintiff Cannot Establish a Claim for Failure to Warn

a. Plaintiff's failure to warn claim fails under comment k and the learned intermediary doctrine.

[3] The Medtronic Defendants are filing motions to strike each of these opinions, as they lack reliability and relevance, are not based on anything more than speculation, and none of the experts are qualified to offer such opinions.

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Courts have had a limited opportunity to consider comment k together with the WPLA in the context of failure to warn cases. In *Estate of La Montagne*, the court analyzed a claim that a prescription drug manufacturer failed to provide adequate warnings *only under comment k* with no reference whatsoever to the WPLA. 127 Wn. App. at 343-52. However, in *Adams v. Synthes Spine Co.*, the court noted the inapplicability of strict liability but applied the provisions of the WPLA to a medical device product liability claim in light of comment k. 298 F.3d 1114, 1117 (9th Cir. 2002); *see also Laisure-Radke v. Par Pharmaceutical, Inc.*, 426 F. Supp. 2d 1163, 1171-72 (W.D. Wash. 2006) (same). Under any of these analyses, Plaintiff cannot establish a claim because the Laser-Shield II's warnings were adequate as a matter of law.

Even if Dr. Samaras' opinions regarding the Laser-Shield II are not excluded[4], however, Plaintiff's failure to warn claims still fail because the Laser-Shield II's warnings were adequate as a matter of law. The question of whether a prescription product manufacturer satisfies its duty to warn physicians of known dangers associated with use of the product "raises an issue of negligence, not strict liability." *See Young II*, 130 Wn.2d at 169; *see also Estate of LaMontagne*, 127 Wn. App. at 343 ("Whether a prescription drug manufacturer provides adequate warnings to physicians is governed by the negligence standard [of comment k]."). Although the adequacy of a warning is generally a question of fact, it can be determined as a matter of law when "reasonable minds can reach only one conclusion from the admissible evidence." *See id.* A warning for a prescription product may be adequate as a matter of law if it provides "specific and detailed information" about the risks of using the product. *See id.* (citing comment k). To determine whether a warning is

[4] As described above, the Medtronic Defendants are filing a motion to strike all of Dr. Samaras' opinions, including his criticisms of the Laser-Shield II's labeling. If this Court excludes Dr. Samaras' opinions, Plaintiff will have no evidence to support a claim that the labeling and/or warnings of the Laser-Shield II were somehow defective, and any failure to warn claims would fail on that basis alone.

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adequate requires an analysis of the warnings as a whole and the language used. *Id.* "The court must examine the meaning and context of the language and the manner of expression to determine if the warning is accurate, clear and consistent and whether the warning portrays the risks involved in [using the product]." *See id.*

In addressing whether a medical device manufacturer has met its duty to give adequate warnings, Washington courts apply the "learned intermediary" doctrine to hold that a medical device manufacturer satisfies its duty to warn of dangers involved in using a product "if it gives adequate warning to the physician who prescribes it." *Terhune*, 90 Wn.2d at 13; *see also Adams*, 298 F.3d at 1117 ("Under Washington law, the 'consumer' of a prescription-only medical device . . . is the physician, not the patient."). Specifically, when a product that is available only through prescription "is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient." *Terhune*, 90 Wn.2d at 14; *see also Estate of LaMontagne*, 127 Wn. App. at 346-52 (where the "contraindication" section of the package insert for a prescription drug used to treat diabetes "unequivocally warned" of the risks of using the drug with patients who also have kidney dysfunction, the warnings were adequate as a matter of law); *Adams*, 298 F.3d at 1116 (manufacturer warnings to physicians to remove metal plates from the spine following spinal fusion surgery were adequate as a matter of law because they "plainly said" that the plate could break and the manufacturer recommended removal).

The Laser-Shield II came with explicit warnings and instructions regarding the serious risks of an airway fire, the risks of using elevated levels of oxygen, and of the need to protect the cuff of the tube and prevent impact from a laser strike. *See Lockard Decl.*, Ex. 2. These warnings and instructions were clear, detailed, redundant, well-understood and completely

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adequate under the law governing warnings by manufacturers of prescription medical products.

This is especially true here because Ms. Anderson's medical providers were *actually and independently aware* of the risks of airway fire, the risks of using elevated levels of oxygen, and of the risks from striking the tube and cuff with a laser. As a matter of law, the Laser-Shield II's warnings were adequate, and Plaintiff's failure to warn claims fail. *See Estate of LaMontagne*, 127 Wn. App. at 343.

b. Plaintiff's failure to warn claim fails due to her inability to show proximate causation

Plaintiff's failure to warn claim also fails because she cannot present any reliable expert testimony that the design of the Laser-Shield II proximately caused Ms. Anderson's injuries. "In a product liability action, the plaintiff must prove that his or her injuries were proximately caused by a product not reasonably safe as designed or not reasonably safe because adequate warnings or instructions were not provided." *Soproni*, 137 Wn.2d at 325. Proximate causation includes both cause in fact and legal causation. *Hiner v. Bridgestone/Firestone, Inc.*, 138 Wn.2d 248, 256, 978 P.2d 505. Cause in fact refers to the "but for" consequences of an act – the physical connection between an act and an injury. *Id.* Although cause in fact is usually a jury question, "it may become a question of law 'when the facts are undisputed and the inferences therefrom are plain and inescapable of reasonable doubt or difference of opinion . . . .'" *Anderson v. Weslo, Inc.*, 79 Wn. App. 829, 840, 906 P.2d 336 (1995) (finding no proximate cause as a matter of law where plaintiff, who was injured while doing a double-flip on a trampoline, read the safety instructions and was aware of the risks of injury but chose to disregard the risks) (quoting *Baughn v. Honda Motor Co.*, 107 Wn.2d 127, 142, 727 P.2d 655 (1986)).

Where a plaintiff's evidence does not establish that the user of the product would have

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acted any differently even if different warnings were provided, there is no proximate cause as a matter of law. *See Davis v. Globe Mach. Mfg. Co., Inc.,* 102 Wn.2d 68, 74, 684 P.2d 692 (1984) ("If an event would have occurred regardless of defendant's conduct, that conduct is not the proximate cause of the plaintiff's injury"). Specifically, if a product user does not attempt to read the warnings that are provided, summary judgment is appropriate on the grounds that no proximate cause can be shown. *See Hiner*, 138 Wn.2d at 257-258 (finding no proximate cause as a matter of law because plaintiff failed to either read the provisions in the owner's manual about snow tires or examine the snow tires themselves for warnings).

Here a different warning would not have made any difference in the outcome because none of Ms. Anderson's medical providers actually read the Instructions for Use that accompanied the Laser-Shield II. *Lockard Decl.,* Ex. 5 (Schatz Dep. at 60:1-6), Ex. 6 (Paugh Dep. at 88:13–89:4), Ex. 7 (VanDoren Dep. at 42:22–43:2). As such, any alleged inadequacies in the warnings had no effect on Ms. Anderson's outcome because different warnings would not have prompted a different result anyway. Plaintiff's failure to warn claims therefore fail for lack of causation. *See e.g. Ayers By and Through Smith v. Johnson & Johnson Baby Products Co.*, 59 Wn.App. 287, 291, 797 P2d 527 (1990) (a plaintiff must prove that if adequately warned of the risk "they would have treated the product differently and avoided the harm"); *Motus v. Pfiser, Inc.*, 196 F.Supp.2d 984, 999 (C.D. Cal. 2001) (granting summary judgment for defendant drug manufacturer on failure to warn claims for lack of causation because there was no evidence that the prescribing physician read or relied on the package insert before prescribing the drug in question).

Moreover, such failure to warn claims fail because Ms. Anderson's medical providers uniformly admit they were all independently aware of the dangers associated with the product. An inadequate warning cannot constitute proximate cause of an injury as a matter of law if the user of the product is actually aware of the danger through other sources. *See*

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Soproni, 137 Wn.2d at 326 (affirming summary judgment in favor of window manufacturer on failure to warn claim where mother was aware that her child had easily opened the window just prior to his fall and that she was aware that this presented a danger). Here, Dr. Paugh, Dr. Schatz, and Scott Vandoren were all aware of the risks of elevated oxygen levels, striking the unprotected areas of the tube and cuff with the laser, and that serious injury could result due to combustion and fire. *Lockard Decl.*, Ex. 5 (Schatz Dep. at 21:21-21:24, 62:3-62:12), Ex. 6 (Paugh Dep. at 40:2-40:8), Ex. 7 (VanDoren Dep. at 9:17-10:20). Thus, different or stronger warnings would not have made a difference in the medical providers' actions, and therefore proximate cause fails.

3. Plaintiff cannot prove any claim under RCW 7.72.030(2) for unsafe construction or breach of warranty.

Although the "comment k" authority discussed above made clear that manufacturers of prescription medical products are not subject to strict liability, it has not addressed the question of whether the manufacturer of a medical device may be held liable pursuant to RCW 7.72.030(2). Assuming for the sake of argument and for purposes of this motion only, and without conceding the point, that claims under RCW 7.72.030(2) may be asserted against a medical device manufacturer, they are unsupported under the facts of this case.

a. Plaintiff does not have an "unsafe construction" or manufacturing defect claim under RCW 7.72.030(2)(a).

Under RCW 7.72.030(2)(a), a manufacturer may be liable if its product is "not reasonably safe in construction." A product is not reasonably safe in construction "if, when [it] left the control of the manufacturer, [it] 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." Plaintiff cannot and has not presented any evidence, expert or otherwise, that the Laser-Shield II was not manufactured in conformity

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with Xomed's design and performance specifications or that it deviated in any material way from other Laser-Shield II endotracheal tubes. Nor can Plaintiff present any evidence, expert or otherwise, that any alleged defect in construction or manufacturing caused her injuries. Therefore, to the extent that the complaint pleads a viable claim under RCW 7.72.030(2)(a), it must be dismissed. Plaintiff's sole liability expert against the Medtronic Defendants has given two declarations, two expert reports, and two depositions in this case, and at each opportunity he has failed to articulate any cognizable basis for an unsafe construction or manufacturing defect claim.

b. Plaintiff does not have a claim for breach of express warranty or breach of implied warranty.

Under RCW 7.72.030(2)(b), a manufacturer may be liable if its product "did not conform to the manufacturer's express warranty," meaning that a warranty was made, was part of the "basis of the bargain and relate[d] to a material fact or facts concerning the product," and "proved to be untrue." Plaintiff has not presented any evidence that the Medtronic Defendants breached any express warranty made to Ms. Anderson or her health care providers. Therefore, to the extent that her complaint asserts a viable claim under RCW 7.72.030(2)(b), it must be dismissed.

Under RCW 7.72.030(2)(c), a manufacturer may be liable if its product "did not conform to the implied warranties under Title 62A RCW." Allowing an implied warranty claim would be inconsistent with the rationale of the *Terhune* line of decisions, because it would not make sense to absolve a manufacturer of liability because it adequately warned a patient's health care provider, but hold it liable for breaching an *implied* warranty running to the patient. However, even if a claim under RCW 7.72.030(2)(c) is theoretically available with respect to medical devices, Plaintiff cannot present any evidence that the Medtronic Defendants breached either the UCC's implied warranty of merchantability, RCW 62A.2-314,

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or the implied warranty of fitness for particular purpose, RCW 62A.2-315. There is no evidence that Ms. Anderson's Laser-Shield II was not "merchantable," and a warranty of fitness arises only if "the seller at the time of contracting has reason to know . . . that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods . . ." RCW 62A.2-315. Because under comment k, Ms. Anderson relied on her health care providers, rather than on the Medtronic Defendants, to furnish suitable goods, no implied warranty of fitness for particular purpose arose as a matter of law.

Further, even if Plaintiff's Complaint asserted a viable claim for breach of express or implied warranties, such claims fail because Plaintiff is not in privity with the Medtronic Defendants. To maintain an action for breach of express or implied warranty, a plaintiff must be in contractual privity with the defendant. *Thongchoom v. Graco Children's Products, Inc.*, 117 Wn. App. 299, 307, 71 P.3d 214, 219 (2003). Here, Becky Anderson did not purchase the Laser-Shield II from Medtronic or Xomed. Therefore, there was no privity between her and the Medtronic Defendants, and any claims for breach of express of implied warranty fail. *See id.*

4. Plaintiff Cannot Prevail on a Negligence/Res Ipsa Loquitur Claim Because the Claim Is Preempted by the WPLA and Plaintiff Cannot Satisfy the Requirements of Res Ipsa Loquitur in Any Event.

a. Negligence claims are preempted by the WPLA.

Res ipsa loquitur is not a cause of action, but merely a "rule of evidence" in a negligence action that "allows an inference of negligence from circumstantial evidence . . . where (1) the plaintiff is not in a position to explain the mechanism of injury, and (2) the defendant has control over the instrumentality and is in a superior position to control and to explain the cause of injury." *Robison v. Cascade Hardwoods, Inc.*, 117 Wn. App. 552, 565,

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72 P.3d 244 (2003), *review denied; see also Pacheco v. Ames*, 149 Wn.2d 431, 436, 69 P.3d 324 (2003). The WPLA preempts all common law product liability causes of action not preserved by the statute. RCW 7.72.010(4); *see also Washington Water Power Co. v. Graybar Elec. Co.*, 112 Wn.2d 847, 854-55 774 P.2d 1199 (1989). Therefore, Plaintiff may not maintain claims for common law negligence, via application of res ipsa loquitur or otherwise, in product liability cases. *See Washington State Physicians Ins. Exchange & Ass'n v. Fisons Corp.*, 122 Wn.2d 299, 323, 858 P.2d 1054 (1993).

b. Plaintiff cannot show that the Medtronic Defendants had exclusive control over the Laser-Shield II.

Whether res ipsa loquitur applies is a question of law. *Tinder v. Nordstrom, Inc.*, 84 Wn. App. 787 791, 929 P.2d 1209 (1997); *Jackson v. Washington State Criminal Justice Training Comm'n,* 43 Wn. App. 827, 829, 720 P.2d 457 (1986). Because the doctrine allows a plaintiff to avoid establishing an otherwise complete prima facie case, courts apply the doctrine "sparingly" and only to "peculiar and exceptional cases . . . where the facts and the demands of justice make its application essential." *Morner v. Union Pac. RR. Co.*, 31 Wn.2d 282, 293, 196 P.2d 744 (1948). Courts may permit the res ipsa loquitur inference only where:

(1) the accident or occurrence producing the injury is of a kind which ordinarily does not happen in the absence of someone's negligence;

(2) the injuries are caused by an agency or instrumentality within the *exclusive control of the defendant*, and

(3) the injury-causing accident or occurrence is not due to any voluntary action or contribution on the part of the plaintiff.

Pacheco, 149 Wn.2d at 436 (emphases added).

Here, there is at least a question of fact as to the first criterion and Plaintiff certainly cannot satisfy the second criterion. The "instrumentality" at issue, the Laser-Shield II, was not in the

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control, let alone the *exclusive* control, of the Medtronic Defendants. Rather, the Laser-Shield II left the Medtronic Defendants' possession long before Ms. Anderson's procedure, and was in the control of one or more of the healthcare providers at the time of the fire. Thus, Plaintiff's res ipsa loquitor claim fails as a matter of law.

5. Plaintiff's Claims Fail Because the Administration of 100% Oxygen was an Intervening Cause of Plaintiff's Injuries

Plaintiff's claims related to the Laser-Shield II also fail because Dr. Schatz's administration of 100% oxygen was an unforeseeable, intervening cause of Plaintiff's injuries. As detailed above, the Laser-Shield II contained clear, unequivocal, and redundant warnings regarding the administration of elevated levels of oxygen. Further, Dr. Schatz, Dr. Paugh, and Nurse Vandoren were all well aware that administering elevated levels of oxygen increased the risk of an airway fire. This Court has found that Dr. Schatz's administration of 100% oxygen was negligent as a matter of law, and Plaintiff does not dispute that the administration of 100% oxygen was a proximate cause of the fire and Ms. Anderson's injuries. It was therefore unforeseeable, in light of the product warnings and the well-known risks, that a clinician would administer 100% oxygen during Ms. Anderson's laser surgery. As Dr. Schatz's administration of 100% oxygen during Plaintiff's procedure was an unforeseeable, independent cause of the fire, the causal connection between any alleged negligence on the part of the Medtronic Defendants and Plaintiff's injuries is broken. *See McCoy v. Am. Suzuki Motor Corp.*, 136 Wn. 2d 350, 357-58, 961 P.2d 952 (1998) ("If... the intervening cause was unforeseeable then it will break the causal connection between the defendant's negligence and the plaintiff's injury and negate a finding of cause in fact") (internal quotations omitted). Plaintiff's claims against the Medtronic Defendants fail as a matter of law for this reason alone.

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6. Any Purported Claims Regarding Alleged Failure to Follow FDA Regulations Are Impliedly Preempted

Plaintiff's expert witness George Samaras has opined that Xomed failed to comply with FDA Quality System Regulations regarding the Laser-Shield II, specifically, due to a perceived failure to maintain an adequate Design History File or Risk Management File during the device's design and marketing. Though such claims are not alleged in the Complaint, to the extent that Plaintiff seeks to argue noncompliance with FDA or other federal regulations, such claims are impliedly preempted by *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001), which prohibits private plaintiffs from usurping the FDA's exclusive authority to enforce its own regulatory scheme.

The plaintiffs in *Buckman* claimed that the defendant medical device manufacturer had made fraudulent representations to the FDA in its 510(k) application. *Id.* at 346-47. The Supreme Court concluded that "fraud-on-the-FDA" claims were impliedly preempted by the Medical Devices Amendments of 1976 because they improperly infringed upon the FDA's regulatory authority. *Id.* at 347-48. In reaching that conclusion, the Supreme Court noted its profound concern that permitting state tort claims to proceed when they were based upon a duty that existed solely by virtue of the federal statutory scheme would upset the regulatory balancing and were, thus, impliedly preempted. *Id.* at 350-51. The Court advanced a number of reasons why that was so, including: (1) the risk that permitting plaintiffs' claims to proceed would infringe upon the FDA's broad discretion to police violations of its regulations as it sees fit; and (2) the risk that permitting plaintiffs' claims to proceed would cause applicants to fear that the adequacy of their disclosures to the FDA would be second guessed by state juries, even when they had been deemed adequate by the FDA, thereby causing applicants to flood the FDA with voluminous, unnecessary information through which the agency would then have to sift. *Id.* at 349-51. The Court foresaw that state tort claims would exercise an

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"extraneous pull" on the regulatory scheme and concluded that resulting interference with the federal regulatory scheme meant that such claims were impliedly preempted. *Id.* at 353. In at least one other case, the Court has emphasized the importance of the FDA's "complete discretion" in deciding "how and when [its enforcement tools] should be exercised." *Heckler v. Chaney*, 470 U.S. 821, 835, 105 S. Ct. 1649, 84 L. Ed. 2d 714 (1985).

There is no pre-existing state-law duty to comply with the FDA's Quality System Regulations cited by Dr. Samaras. If Plaintiff is seeking to impose liability for any purported violation of federal regulations relating to the development, design and regulatory clearance of the Laser-Shield II, she will either be (1) trying to usurp the FDA's regulatory oversight role for policing purported violations of the agency's regulations; or (2) basing her various tort claims solely on a violation of federal law. Either way, Plaintiff's claims would run afoul of *Buckman* and therefore fail, as a matter of law. To allow Plaintiff's claims to proceed on the basis of alleged inadequacies in its Design History File or Risk Management File or noncompliance with the FDA's Quality System Regulations, and to have those functions and records second guessed by a jury, is precisely the scenario that the Supreme Court expressed concern over in its decision in *Buckman*. *See* 531 U.S. at 349-51. Thus, any of Plaintiff's claims based on Dr. Samaras' cited failures to comply with federal regulations are preempted and should be dismissed as a matter of law.

V. CONCLUSION

All of Plaintiff's claims against the Medtronic Defendants[5] should be dismissed on summary judgment, for the reasons stated above.

DATED: September 3, 2013.

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[5] Plaintiff has not asserted a claim for punitive damages, and no such claim could be sustained under Washington law in any event. Also, while Plaintiff's Complaint does not specify to which Defendants her claim regarding Informed Consent (¶¶11.1-11.3) is directed, the Medtronic Defendants submit that any duty of informed consent does not run to the manufacturer of a medical device who has no patient-provider relationship with Plaintiff.

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DESCRIPTION

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

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

INDICATIONS FOR USE

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

CONTRAINDICATIONS

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

WARNINGS

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

INSTRUCTIONS FOR USE

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

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

Prior to Intubation

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

Intubation

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

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Q. And the next entry is a memo entry timed at 8:40, which is your entry, correct?
A. Yes.
Q. When the surgery is started at 8:29, what level of oxygen is being administered to Ms. Anderson?
A. 100 percent.
Q. And did the 100 percent oxygen remain being administered up until the time of the fire?
A. Yes.
Q. I take it the 8:40 time when you put in that memo is not necessarily contemporaneous with what's happening, it's after you've dealt with the fire?
A. Yes.
Q. Let's go off of this record and go into your memory at this point in time. Do you recall that the surgery was near completion when the fire occurred?
A. I don't know that.
Q. What do you recall being your first indication that there was a complication with Ms. Anderson?
A. I heard a pop. I heard Dr. Paugh ask for saline.
Q. Did you see smoke?
A. I turned -- I wasn't looking at the patient at the time -- I turned, I saw smoke.
Q. Let me try and get this in order. When you

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heard the pop you were not looking at the patient, you were looking at the --
A. The monitors.
Q. -- the monitors. And the pop, did the pop sound like what you would expect to hear if the laser perforated the cuff?
A. I have no idea what a laser perforating a cuff sounds like.
Q. Can you describe the pop in any more detail?
A. No.
Q. Loud pop?
A. Moderately loud.
Q. And you turned to the patient and when you turn to the patient do you see smoke coming out of the airway?
A. I can't recall if I saw the smoke before or after the saline went in.
Q. Who poured in the saline solution?
A. I'm not sure.
Q. Do you recall what kind of a container the saline solution was in when it was poured?
A. No.
Q. What did you do in response to the realization that there was an airway fire?
A. Turned the oxygen all the way down and the air

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up.
Q. In your memo submission at 8:40, it says, "airway fire with laser, ETT cuff perforated." That means the endotracheal cuff was perforated, correct?
A. That was my interpretation.
Q. And that's that cuff we're talking about that has the blue saline in it?
A. Yes.
Q. And if that cuff was in fact perforated, wouldn't that mean that the 100 percent oxygen would be leaked into the surgical field?
A. Yes.
Q. Was one of the things you were monitoring her oxygenation level, that is, her O2 level sat rate?
A. Yes. That's not exactly how we'd term it but, yes.
Q. Tell me what terms I should be using to be on the same page with you.
A. Oxygen saturation.
Q. Okay. You'd be monitoring her oxygen saturation rate?
A. Yes.
Q. Wasn't her oxygen saturation rate at 100 percent during the entire procedure?
A. I don't recall if it was 100 percent the

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entire time but it was in the high 90s at the --
Q. It's in -- take a look.
A. Yes. It's close to 100 at least. You don't have the page in here that's the easiest to see it on. Here it is right here. Yeah. It's very close to 100.
Q. So oxygenation status was not a concern of yours, correct?
A. At this point, no.
Q. And there was no reason from an oxygenation standpoint not to have turned the oxygen administration down, correct?
A. At this point, no.
Q. At this point we're talking about during the laser surgery?
A. At this point in the operation, yes. That's what I'm talking about.
Q. If you had been trained that you want to have a reduced level of oxygen administration during a laser procedure, why was she being administered 100 percent oxygen during this procedure?
A. I don't know.
Q. Would you agree she should not have been administered 100 percent oxygen during a laser procedure?
A. This patient at this time with her oxygen

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pulled and you're sitting there in the OR and it's on the tray or on whatever it's on and you look at it, did it appear to be a -- did it appear to have burned?

A. I can't remember. I don't remember seeing that.

Q. Were you involved at all with her transfer to Harborview?

A. No.

Q. One of the Harborview transfer records suggests that she suffered an explosion type burning injury. Do you have any idea where the term explosion came from in the Harborview transfer documents?

MS. DELISA: Objection as to form.

A. No.

Q. What percentage of the anesthesia cases are at Central Washington Hospital?

A. That I perform?

Q. Yeah.

A. Between 60 and 70 percent, probably.

Q. And you told me you work various hours, ballpark, how many cases a week do you perform anesthesia on?

A. I perform around 70 a month.

Q. 70 a month. Okay. Those are all the questions I have. Thanks.

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MR. MERRELL: Do you want to take a break first or do you want to just go?

MR. YOSHIDA: No. That's fine.

THE VIDEOGRAPHER: Can we pass his microphone down?

EXAMINATION

BY MR. MERRELL:

Q. Dr. Schatz, my name is Cliff Merrell. We met earlier. I represent Medtronic and Medtronic XOMED. And I just have a few questions for you. I don't think it will take very long. And I'm going to sort of bump around because when you go second it's hard to go in a very organized manner. So excuse any confusion in terms of the manner I go in but I just want to ask you a few more questions.

Do you know -- you testified earlier that you filled the cuff with the saline?

A. Yes.

Q. Do you recall how much saline you put into the cuff?

A. No.

Q. Do you have a standard amount of saline you typically put in a cup for a laser -- or a laser assisted endotracheal tube?

A. Usually I would have a syringe with 5 mills in

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it but I would only put enough in to fill the cuff to where it occludes the airway.

Q. So you wouldn't know the precise amount, you just do it until it seems to be an amount that's enough to occlude the airway?

A. Yes.

Q. Do you know if 3 cc's if that sounds about what you would probably put in one or if that's in the range or does it vary?

MR. YOSHIDA: Object to form.

A. I don't know. It varies.

Q. Did you see the blue dye in the cuff when you filled the saline?

A. I tested it before putting it in the patient and I saw the blue dye in the cuff.

Q. Were you in a position during the procedure to be able to see the blue dye if there was a rupture of the cuff from the endotracheal tube?

A. No.

Q. Do you know if anybody saw the blue dye from the endotracheal tube cuff during the procedure after the fire?

A. No.

Q. Or before or after the fire?

A. No. I don't know.

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Q. Did you review the instructions for use for the -- I'm not sure if you answered this earlier -- did you review the instructions for use for the LASER-SHIELD II endotracheal tube prior to using it on -- in February of 2012?

A. No.

Q. Had you ever reviewed the instructions for use for the two cuff endotracheal tube that you had used before?

A. Boy, I don't know. That would have been a long time ago.

Q. I'm going to mark as an exhibit the instructions for use for the LASER-SHIELD endotracheal tube.

A. Looks like we have one.

MR. BRINDLEY: It's Exhibit 7 to Dr. Paugh's deposition.

Q. Okay. Exhibit 7 to Dr. Paugh's deposition, could you take a look at that quickly, and just for your reference, it looks like a long document but only the first -- the second and third pages are in English and the rest of the instructions are in another language so I'm just going to be asking you questions about those sections. And you're welcome to look at this before I ask you questions but I'm going to point

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enough for everybody.

(Deposition Exhibit Number 2 marked for identification.)

Q. Exhibit 2 is a document prepared by an outfit called ECRI. Are you familiar with ECRI?

A. Yes.

Q. What's ECRI?

A. Well, they're an organization that educates hospitals and medical groups about laser and fire safety.

Q. Have you ever seen this ECRI publication before? Feel free to take a minute to take a look at it.

A. I don't remember seeing this particular publication, no.

Q. And you don't recall seeing this posted anywhere in the hospital?

A. I do not.

Q. Are you involved in choosing when you're doing a laser procedure the type of endotracheal tube that's to be utilized?

A. I am involved.

Q. Tell me what your involvement is.

A. Well, the endotracheal tube that I've always used in the beginning at my very first case that I

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observed and throughout my residency training and for every case prior to this one was a metal tracheostomy tube. I believe it's made by Mallinckrodt but I'm not definite on that. But it's a metal endotracheal tube with two cuffs on it.

Q. Those are inflatable cuffs?

A. They are.

Q. And it's -- the entire tube is metal, the external portion of the entire tube is metal?

A. Yes.

Q. Does it have rings around -- are there kind of rings on the tube as they go down?

A. Well, I think a metal is designed to give it flexibility so that -- like a slinky kind of a -- yeah.

Q. You said that's the one you always used up to this particular procedure?

A. That is correct.

Q. Which type of endotracheal tube did you use in this particular procedure?

A. This was a -- I believe the box stated it was a Medtronic Laser Shield.

(Deposition Exhibit Number 3 marked for identification.)

Q. I'm looking at Exhibit 3. Does that appear to be the -- to refer to the type of endotracheal tube you

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utilized in this particular procedure?

A. Yes, it does appear to be that.

Q. And I don't want to represent to you that that's the actual product insert related to this particular tube, but this looks at least similar to the tube that you used, correct?

A. Well, I would have to match this with the tube that I examined prior to doing it but the title looks approximately the same.

Q. Why was it you decided to use a different tube and not the metal tube but use the Medtronic tube in this particular procedure?

A. Well, when I arrived for surgery that morning the metal tube wasn't to be seen and we were told it was not available and that this was the new tube that we had to use for laser surgery.

Q. And who told you that the metal tube was not available?

A. It was some member of the nursing staff who was helping to put the materials in the room for the procedure.

Q. Did you follow up and question why your regular old metal tube was not present?

A. Well, I did. I asked that question, yes.

Q. And you told me who you thought was the

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manufacturer, and I didn't write it down. Can you -- of the old metal tube.

A. Well, and, again, I believe it's Mallinckrodt. And I've always just called it the double cuff metal tracheostomy tube kind of descriptively.

Q. After this incident did you question the people that supplied you with the Medtronic endotracheal tube whether the Mallinckrodt tube was still stored or in place at the hospital?

MR. AIKEN: I'm going to object and advise him not to answer if any of these discussions took place in the quality assurance meeting.

MR. BRINDLEY: Let's do this, assume any question I ask you is not going to ask you about anything that happened in a QA meeting.

A. Right. I understand.

Q. And I will go down that road somewhere later to try and find out if there are any QA meetings and all that stuff, but I don't want to know anything that was said at the QA meeting.

So after this incident did you check and question whether the old type metal tube was still being utilized and available at the hospital?

A. I don't remember asking that question at that time.

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then, or if it's changed or what it's now, how many days a week do you do surgery or is there any set schedule?

A. Surgery is Tuesday, Thursday and Friday.

Q. And, in general, how many procedures do you perform a week?

A. 15 to 20.

Q. Do you know in this particular day, this Friday, whether there were surgeries scheduled after the Anderson case?

A. I don't recall.

Q. And I asked whether there were any scheduled. Did you perform any surgeries later that Friday?

A. I don't recall that either.

Q. Who was the anesthesiologist?

A. Dr. Schatz.

Q. Had you worked with Dr. Schatz before?

A. Yes.

Q. Roughly how long has Dr. Schatz been on the staff?

A. Approximately as long as I have been here.

Q. And has she -- had she been an anesthesiologist in other laser procedures that you performed, do you recall?

A. I don't recall.

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Q. You mentioned the two technicians and there's usually two nurses present in the operating room when you do a laser procedure, or in this particular case, there were two nurses as well present?

A. That's what I recall.

Q. What's their role?

A. The operating room nurses tend to keep the room stocked with the right supplies, patient care transferring in and out of the operating room, any other nursing duties that may be required.

Q. Could you have said that morning, I don't like the looks of this Medtronic laser shield, I like the old metal ones I used, could one of your nurses go down to supply and bring me the metal ones I've used in the past?

MS. MOORE: Object to form.

MR. AIKEN: Join.

A. I could have. In fact, I did. That was the whole issue.

Q. Let's go through what you -- reconstructing that as best you can. Was the tube already installed by the anesthesiologist?

A. No.

MS. MOORE: Let him finish the question.

A. I'm sorry. I apologize. Pardon me.

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Q. That's human conversation. You know what I'm going to ask but you've got to wait for me to finish.

A. Right. Thank you.

Q. So the tube was externally -- was it still in the package when you realize that this was going to be a Medtronic endotracheal tube, not the kind you were used to?

A. No.

Q. Outside the package?

A. Yes.

Q. Was the package sitting there?

A. Yes.

Q. Tell me, you see that, what's your first response?

MS. MOORE: Object to form.

Q. That's a bad question.

MS. COHEN: Join.

Q. I'll object myself. Just tell me in your own words what was your response to seeing this different type of Medtronic tube present in the operating room when you're going to perform a laser procedure?

MS. COHEN: Objection.

A. Well, my first response was to ask where the tube I used was, simply because of my familiarity with the tube I had used.

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Q. And who responds?

A. I was told by a number of people in the operating room that we no longer had the metal tracheostomy tube and this was the tube that we were going to use for the laser surgery.

Q. And was it the nurses that told you that, the anesthesiologist, combination, or you don't remember?

A. I remember Dr. Schatz also questioning the same thing along, so I think she was wondering about that as well.

Q. Did she verbally raise the same issue that you did, that this isn't the type of tube we usually use?

A. I just recall us looking at each other kind of shrugging our shoulders.

Q. Did you examine the tube to see what it was made of and what kind of safeguards it had for a type of laser procedure?

A. I did have -- held the tube -- hold the tube in my hands, yes.

Q. And I think we went over this. One of your concerns was it was a single cuff versus a double cuff, correct?

MS. MOORE: Object to the form.

A. I don't know if I was thinking about that at that time.

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one out?
A. When I'm using the laser, I use it on an intermittent mode so you'll pop, pop, pop, and maybe you'll want to reposition something a little bit, you might pull them out and put some more pledgets in, so it's kind of a constant process where it's --
Q. Is one of the considerations whether the cotton pledgets are drying out as to whether they need to be replaced?
A. I always like new moist pledgets. I always replace them all the time. I don't think they dry out very quickly, actually, in someone's -- in that kind of moist, humid environment.
Q. And they're put in after the endotracheal tube was put in?
A. Yes.
Q. And the endotracheal tube is put in with kind of a blade instrument first and then the blade instrument is taken off and --
A. The anesthesiologist inserts the endotracheal tube.
Q. With a -- using a blade-type instrument?
A. They'll use a laryngoscope to visualize the larynx and place it.
Q. And after that, you actually have the

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container of saline with pledgets in it and you pick them up and put them below the vocal cords in the surgical field?
A. Yes.
Q. What kind of instrument do you use to transfer them from the bowl of saline into the surgical field?
A. There are a number of instruments that are long enough to insert down the whole length of the laryngoscope, some might have little cups or biting ends to them that are designed for grabbing these things and placing them under direct vision where you want to put them.
Q. And you talked about the number of laser procedures you performed. Can you tell me the type of laser procedures you performed? Obviously this one is on the vocal cords. What other type of laser procedures do you perform?
A. Vocal cords is the only place I've used the C2O laser.
Q. And was Ms. Anderson's case similar to the majority of other laser procedures you had performed?
A. It was similar.
Q. And how many of those soaked pledgets did you put in the surgical field ball park with Ms. Anderson?
A. I don't know.

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Q. More than 10?
A. Oh, no.
Q. No.
A. You're working down a very small cylinder and each of these pledgets, for ease of retrieval, has a little string that actually comes out the length of the tube, so you might have a couple in there at a time or something like that. It's not -- it's not like you're packing the area with it.
Q. You told me I think you expected the surgical procedure to last about 10 minutes. Is my recollection right?
A. Uh-huh.
Q. Yes?
A. Yes. I did tell you that.
Q. Where in the continuum of this procedure did the fire occur? Were you close to being done? Halfway?
A. Yes.
Q. Close to being done?
A. Close to being done.
Q. What percent of the way would you estimate you were to being done?
A. Oh, gosh, 90.
Q. Tell us what happened. How you first

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identified the surgical fire? What you saw?
A. I saw a, what looked like a spark just beneath the vocal cords.
Q. Did you at any time see the blue saline solution in the surgical field?
A. I did not.
Q. As we sit here today, do you believe that there had to have been a puncture of the cuff?
A. No.
Q. Why not?
MS. MOORE: Object to form.
A. You use the word "had."
Q. Oh. Okay. Fair enough. As we sit here today, do you believe there was or that there's a substantial probability that there was a puncture of the cuff?
A. No.
Q. Why not?
A. I'm listening to your words very carefully.
Q. That's what you're supposed to do. Let me ask you this: When you pulled the endotracheal tube out after the fire, was the cuff still inflated?
A. No.
Q. Explain to me your thought process and what role the cuff played in this particular fire, if any.

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your internship and residency, right?
A. Yes.
Q. Pretty basic tool. It's not to suggest what you did is basic, but that's the tool that everybody in your field uses, right?
A. Yes.
Q. And the Mallinckrodt, in particular, is that known to have any particular disadvantages or, you know, as compared to other tubes or, again, is that outside of your expertise?
A. None that I know of.
Q. Let me ask a real basic question. You talked about the fact that there were double cuffs on the Mallinckrodt endotracheal tube, right?
A. Uh-huh.
Q. That's yes?
A. Yes. Pardon me.
Q. Yes. The cuffs themselves are flammable, right, on the Mallinckrodt?
A. I don't know.
Q. You don't know either way?
A. I don't know.
Q. Could be?
A. I imagine everything is flammable at a certain point.

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Q. One of the things I think you mentioned earlier is that, in response to Mr. Brindley, is that if there's a perforation or a spark or some ignition in the first cuff, you know, whether you stop or not, again, I guess that's something you're not sure about; is that correct?
A. Correct.
Q. Because from your recollection, you're not sure if that's ever happened?
A. Well, I think it has happened. I think -- I think a cuff, a perforated cuff has happened, yeah.
Q. With the Mallinckrodt, I mean, in your hands?
A. Yeah.
Q. Okay. You just can't remember a specific instance or whether there was any spark or ignition?
A. I have no recollection of any spark or any ignition at any time prior to this case.
Q. And for lack of a better description, I could pull out my Ipad, although I put it away so I would stop creating interference with the video, the -- when I look at the Mallinckrodt endotracheal tube, is it fair to say the metal piece of it looks like that corrugated, almost the old telephone cord?
A. Yeah. It's kind of like that.
Q. Okay. And have you read any literature

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studies or taken any courses with ECRI or anyone else that the Mallinckrodt, in terms of disadvantages, to the Mallinckrodt is that that metal actually can reflect the laser onto a kind of non-targeted surfaces?
A. I am aware of that.
Q. So that's one of the things that's listed as, I guess, as a potential negative to the Mallinckrodt?
A. A potential negative.
Q. And is the other, I guess, another potential negative of the Mallinckrodt is that it has a relatively large outer diameter compared to, say, the Medtronic LASER-SHIELD II and some of the other tubes on the market?
A. I wouldn't say that. I think that -- no. I wouldn't say diameter is an issue with it.
Q. The Medtronic LASER-SHIELD II, I guess you said you haven't studied that device at all; is that right?
A. Correct. I have not.
Q. It was in your hands one day the day of Ms. Anderson --
A. Briefly for a minute.
Q. And you don't have any expertise on the design of the LASER-SHIELD II, correct?
A. That's correct.

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Q. You don't have any -- any expertise or opinion on the manufacturing of it, correct?
A. Correct.
Q. You don't have any opinion or expertise on the labeling or the warnings that go with the Medtronic LASER-SHIELD II; is that correct?
A. I do have an opinion on the labeling.
Q. Okay. Have you read the labeling?
A. Well, just on the box.
Q. So you looked at the box, the outer box itself?
A. The outer box.
Q. And did you -- did you look at the instructions for use or the actual, I think it was called package insert earlier today, that was contained within the box?
A. I never saw the package insert.
Q. Did you know what happened to it --
A. No.
Q. -- that day? You assume it was in the box, correct?
A. I didn't --
MS. MOORE: Object to form.
A. I didn't assume anything regarding the insert.
Q. Did you ask whether you could see the -- since

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it was the first time you were using it -- did you ask whether you could look at and review the instructions for use that were contained in the box?

A. I did not.

Q. And let me just for recordkeeping and logistics. I'm going to go ahead and mark the -- what I'm calling the instructions for use on the package insert.

(Deposition Exhibit Number 7 marked for identification.)

Q. And I have copies I describe here. And I'll let you take a look at it as well. And I'll just put on the record that we actually -- I was just going to state for recordkeeping purposes, we actually produced this with our discovery responses, so it's Medtronic Bates No. 5 through 39 so everybody has it. It's been made part of the record.

And I was just going to confirm, and you can take as much time as you need to look at that, Doctor, but have you ever gone through and looked at this instructions for use?

A. I have not.

Q. Have you ever looked at the Mallinckrodt instructions for use or package insert?

A. Not since the mid '80s.

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Q. Okay. So you don't know -- do you know whether the Mallinckrodt instructions for use, the double cuff type or any other type contained any specific warnings or labeling related to surgical fires?

A. I don't know that.

Q. Do you know whether -- I know you haven't looked inside, which is Exhibit 7, but do you know whether this LASER-SHIELD II endotracheal tube instructions for use contained specific warnings and risks related to surgical fires?

A. I do not know what it says inside.

Q. You said the only thing you looked at that day was the box from which the endotracheal tube came from?

A. Correct. That is correct.

Q. Did you -- I guess you -- did you understand that if you wanted to look at the instructions for use you could have asked for them?

MS. MOORE: Object to form.

A. I did not understand that.

Q. Did you understand that if you wanted to look at the instructions for use, you probably could have looked at them online? Is that something that you've done before?

A. I have not.

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MS. MOORE: Object to form.

Q. Have you ever looked at instructions for use for any medical device that you've used?

A. No.

Q. And is that because, I guess, the information you have about a medical device and the potential risks come from your training and your experience and your background?

A. Well, most of the devices it comes from sitting down with the representative and going through what probably is in the insert and hopefully more with the representative.

Q. And just so we're clear on the record, prior to Ms. Anderson's procedure you did not meet with any Medtronic representative; is that right?

A. That is correct.

Q. Did you ask anyone, any other than what you've already told Mr. Brindley today, did you ask anyone any specific questions about the LASER-SHIELD II that you haven't already talked about today?

A. No. No. Not that I recall.

Q. Now, when the ECRI group came into the CME presentation that you described, did they talk at all about differences between the different endotracheal tubes in that session?

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A. I don't recall any specific endotracheal tubes being identified.

Q. Did they just generally talk about the fact that with every endotracheal tube there are risks of surgical fires?

A. Yes. That's what I recall.

Q. And there are -- I'll state on the record so it's not confusing later that the Exhibit 7 that we marked, the instructions for use, starts with the information in English then goes on to different languages, so in case you're all wondering later what I've marked and why, you may not understand the latter part of it. But the first couple of pages, you can take a look, Doc, is in English and covers specifically the description of the LASER-SHIELD II as an endotracheal tube with a laser resistant overwrap of aluminum, and that's what you understood at the time anyway, right?

A. Uh-huh. Yes.

Q. I mean, that's something you gleaned from just looking at it visibly, right?

A. Yes.

Q. And I guess you knew, even on the day of this procedure, even without looking at this IFU specifically, I think you said this earlier, you

The airway fire which injured Becky Anderson began when her surgeon, Dr. Donald Paugh, struck the single cuff of the Medtronic Laser Shield endotracheal tube [ETT or tube] with the laser he was using to remove a polyp from her vocal cords. The purpose of the cuff was to seal the airway in order to prevent oxygen administered to the patient during surgery from coming back into the surgical field where the laser was employed.

The laser perforated the cuff, deflating it. With the cuff down, one hundred percent oxygen poured back into the field. In the oxygen rich atmosphere, a spark from the laser created a blowtorch effect, horribly burning Ms. Anderson's airway into her lungs.

The use of one hundred percent oxygen in this procedure was a misuse of the product; Dr. Schatz, the anesthesiologist who administered the oxygen, has conceded her negligence. But this tragic event, the use of 100% oxygen resulting in a horrendous airway fire was entirely foreseeable by Medtronic. It had happened again and again and again, twice in Washington state alone, and Medtronic knew that. Medtronic knew that its ETT designed with a single cuff sometimes failed, resulting in airway fires.

Medtronic had a duty as a responsible medical device manufacturer to design a product which would prevent a devastating airway fire, if that design was practical and feasible. It was practical and feasible. And such a design was and is practical and feasible; it has existed for years; and it exists today. It is a double cuff design, in which two cuffs are inflated to seal the airway from the oxygen administered to the patient's lungs below the surgical site. If the upper cuff fails, if it is inadvertently struck by the laser, the lower cuff maintains the seal, and gives the surgeon the opportunity to stop the procedure and change the tube. It was the design that Dr. Donald Paugh, the surgeon, ordinarily used, but which was not available to him that day.

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however, that the strict liability standard applied to claimed manufacturing defects in this comment k product. *Id.* at 917-919. Medtronic's position is contrary to *Transue*.

Finally, the WPI instruction on design defects involving comment k products adopts a negligence standard. WPI 110.02.01 and comments (Attached as Appendix A). If Medtronic is right, the WPI is wrong in adopting any standard for comment k products in design defect cases.

B. Under the Facts Taken in the Light Most Favorable to Plaintiffs, Medtronic is Liable for the Defective Design of its Product under RCW 7.70.030(1)(a).

The Washington Products Liability Act (WPLA) imposes liability upon a manufacturer for damages caused by a product which is unsafe in its design. RCW 7.70.030 (1)(a) provides:

> (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 . . .

See also, *Eastwood v. Horse Harbor Foundation, Inc.*, 170 Wn.2d 380, 395-96 (2010) ("a product manufacturer has a tort duty to avoid product designs and construction that are unreasonably dangerous. RCW 7.72.030.")

The United States District Court for West Virginia recently summarized the risk-utility test in terms of the duty to test and analyze products.

> "under the risk-utility analysis for design defects, the duty to exercise reasonable care includes the duty to test the product. *See, e.g., Lillebo v. Zimmer, Inc.*, No. 03–2919 (JRT/FLN), 2005 WL 388598, at *8 (D.Minn.2005); *Nicklaus v. Hughes Tool Co.*, 417 F.2d 983, 986 (8th Cir.1969); *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1089–90 (5th Cir.1973); *Dartez v. Fireboard Corp.*, 765 F.2d 456, 461 (5th Cir.1985); *Nicholson v. Am. Safety Util. Corp.*, 124 N.C.App. 59, 476 S.E.2d 672, 676 (N.C.App.1996); *Hensley v. Danek Med., Inc.*, 32 F.Supp.2d 345, 351 (W.D.N.C.1998); *see also* Restatement (Third) of Torts: Prod. Liab. § 2 cmt. m. (1998) ("Of course, a seller bears responsibility to perform reasonable testing prior to marketing a product and to discover risks and risk-avoidance measures that such testing would reveal.")."

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In re C.R. Bard, Inc., Pelvic Repair System Products Liability Litigation, 2013 WL 3821280, 4 (S.D.W.Va. 2013)

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: [6]

> 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 plaintiff's 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.[7]

Whether a product is unsafe under the risk-utility test is a jury question. *Ruiz-Guzman,* 141 Wn.2d at 504. A plaintiff may satisfy this burden by proving that another product of alternative design "more safely serve[s] the same function as the challenged product." *Ruiz-Guzman,* 141 Wn.2d at 504-05. A plaintiff is not required to show that the alternative design can

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[6] Plaintiff has modified the instruction by removing irrelevant brackets regarding pharmaceuticals, since the issue here involves medical devices or medical products as the WPI describes them.

[7] Whether the alternative theory of "consumer expectations," RCW 7.72.030(3), applies to a design defect case under comment k is a debatable point which Washington courts have not definitively decided. In order to avoid potential reversible error from an incorrect instruction, Plaintiff is presenting the design defect case under the WPI quoted above, and not under the consumer expectations test, unless Medtronic agrees that the case should also go to the jury under the consumer expectations theory. In another case, we may well choose to ask for an instruction under the consumer expectations theory.

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be incorporated into the existing product. *Id.*, at 503-04. Nor does it matter that one product may be under patent. It is sufficient to show that the alternative design exists and is safer. *Id.*

The seriousness of the risk in the present is beyond dispute. A patient is at risk of serious injury or death if for whatever reason, the ETT fails and oxygen comes into the airway, where there is an ignition source in operation and fuel for fire. A warning is insufficient protection, as this case and other cases demonstrate. Physicians make mistakes. Lasers do strike unintended targets in the very narrow confines of an airway; no warning can change this fact of surgery.

It is an unnecessary for the patient to pay with her life or a devastating injury for a mistake of the physician, inadvertent or negligent. ISO standards establish that the priority for making a medical device safer is to design for safety, to guard if design is not feasible, and to warn the human user as a last resort.

Here the design solution was practical and feasible. A two cuff system is safer, and would have prevented this tragedy from occurring. The lower or distal seal would have been preserved, and prevented the onrush of oxygen.

Medtronic's only argument is that Plaintiff's experts should be excluded and that no testimony would be left. The Court should properly admit the testimony of these experts for reasons argued elsewhere (though the testimony described above speaks for itself in cogency, coherency and its explanatory value), especially as compared to Medtronic's own proffered reason for not incorporating a two cuff design, the "false sense of security."

Moreover, the evidence shows that although Medtronic was fully aware of the safety problems with its product, it did absolutely nothing with regard to changing the design or otherwise to make its product safer. To the contrary, when it assessed the risk, Medtronic

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concluded that a risk-benefit "analysis [was] not required due to acceptable risk level." Cunningham Decl., Ex. 4, p. 1.

The facts show that Medtronic utterly failed in its duty to test, analyze, or properly assess the safety of its product in the face of the patent danger it posed. It's liability is a jury question.

C. Under the Facts Taken in the Light Most Favorable to Plaintiffs, Medtronic's Defective Design is a Proximate Cause of Ms. Anderson's Injuries.

In contesting proximate cause, Medtronic argues that cause of the fire and the result injures "are highly complex questions which involve 'obscure' medical and scientific factors." Motion at 12. Medtronic asserts that "with uncertainty over just how this event occurred and how the oxygen reached the surgical site, it would be entirely speculative for any of Plaintiff's experts to opine that a double cuff design would have made any difference." Motion at 13.

Medtronic's argument is without any foundation. As set out in detail in the facts, even Medtronic's own 30(b)(6) expert testified that the laser struck the cuff, and that with the cuff down, 100% oxygen flooded in. With a double cuff, the distal or lower seal would have remained intact. That is the purpose of the double cuff, to allow perforation of the first cuff, without exposing the patient to catastrophic harm.

Generally, issues of proximate cause are for a jury, including in cases involving medical care and surgical procedures. *Bauer v. White*, 95 Wn. App. 663, 669 (1999). While expert testimony is required (and is present here), it is not always necessary "to prove every element of causation by medical testimony if, from the facts and circumstances and the medical testimony given, a reasonable person can infer that the causal connection exists. . .." *Douglas v. Freeman*, 117 Wn.2d 242, 252 (1991).

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Plaintiff has argued elsewhere that her experts are qualified to testify on proximate cause. The jury will not be left to speculate as to proximate cause.

D. Under the Facts Taken in the Light Most Favorable to Plaintiffs, Medtronic's Warnings are Inadequate and Defective.

Plaintiff's warnings claim is simple and limited, but supported by the facts. Before undertaking the procedure on this product which he never used before, Dr. Paugh examined the box itself. The box described the product as a "Laser-Shield." It was this description of the product, appearing in large letters on the box itself, that led Dr. Paugh to believe that he could safely use this device. He did not know that the device was a single cuff ETT. But he knew from the information on the box that the device shielded the laser.

The adequacy of warnings is a jury question. *Little v. PPG Indus.*, 92 Wn.2d 118, 122 (1979); *Young v. Key Pharmaceuticals, Inc.*, 130 Wn.2d 160, 180 (1996). The device did not provide a shield from the laser on which Dr. Paugh could rely, and in his words "relax." Lockard Decl. Ex. 6 at 92-93. A jury question exists as to whether that warning was inadequate and deceptive.

E. The Use of 100% Oxygen was Reasonably Foreseeable and is not as a Matter of Law an Intervening Superseding Cause of Injury

Defendants wrongly argue that the administration of 100% oxygen was a superseding cause of Ms. Anderson's injury. At best, the issue of whether an intervening act was so foreseeable as to constitute an independent, superseding cause of injury is a question for the trier of fact. *See Crowe v. Gaston*, 134 Wn.2d 509, 520 (1998) ("The foreseeability of an intervening act, unlike the determination of legal cause in general, is ordinarily a question of fact for the jury."); *Johnson v. State*, 77 Wn. App. 934, 941 -943 (1995) ("The court may determine a

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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 AMENDED PROPOSED INSTRUCTIONS NO. 30
(Previously submitted as PLAINTIFF'S THIRD SUPPLEMENTAL PROPOSED INSTRUCTIONS DEALING WITH DESIGN CLAIM NO. 2)

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

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SUPERIOR COURT OF WASHINGTON IN AND FOR KING COUNTY

BECKY S. ANDERSON, a single person, Plaintiff, vs. 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.	12-2-17928-0 SEA

TRANSCRIPT OF PROCEEDINGS

BEFORE THE HONORABLE JEFFREY M. RAMSDELL

SEPTEMBER 20, 2013

TRANSCRIBED FROM RECORDING BY:

CHERYL J. HAMMER, RPR, CCR 2512

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simple that the Washington pattern -- excuse me -- the Washington Product Liability Act has a section, Your Honor, that allows evidence of FDA rules and regulations, evidence of government regulations, evidence of customs in the industry, standards and so forth into evidence on the issue of negligence.

All we're saying is that they're relevant on the issue of negligence under the statute.

THE COURT: Okay. So I'm going to deny the motion to dismiss the FDA claim because there isn't a claim, and then we can address the evidentiary issue prior to trial. Okay.

MS. COHEN: Thank you, Your Honor.

THE COURT: Okay. No problem. With regard to the design defect claim.

MR. CUNNINGHAM: Yes, Your Honor.

THE COURT: I'm satisfied that we've got a material issue of fact there. I understand counsel's argument completely. It may prevail in the long run. I guess my only question of you, Mr. Cunningham, is I think that pursuant to the comment K that is interlaced throughout the briefing here, that the standard that would have to be applied is a negligent standard there. And do you concur with that? I think you do.

MR. CUNNINGHAM: I got to be careful here, okay?

THE COURT: Okay.

MR. CUNNINGHAM: Because I'm a member of the plaintiffs bar, and we argue very vehemently that the standard should be the strict liability even for prescription (unintelligible).

That being said, and on the record, I'm willing to accept the negligent standard in this case, because I don't want error.

THE COURT: Okay. If it makes you feel any better, that's what you were going to get regardless of how hard you tried. So we'll say that you tried really hard and I said no, but it's negligence.

MR. CUNNINGHAM: You know, I have to go back and talk to my colleagues.

THE COURT: Yeah. You're covered. Don't worry. Blame me. Other people do. Okay. And with regard to res ipsa, again, I don't think that's an issue for us to resolve at this point in time. It's a theory of liability and it's going to be an evidentiary question, and ultimately it's going to be a jury instruction question and I don't think I can resolve that today.

instructions that are in the box.

But these folks are professionals. I think you have to assume that they're going to act in a professional manner, which would mean, in my mind, that they would make sure that they knew how to use the item before they used it.

So I'm going to grant the motion to dismiss on the failure to warn claim. I'll dismiss the breach of express and implied warranty claim, because that's basically been withdrawn. The design defect claim will go forward on the negligence standard despite Mr. Cunningham's vigorous opposition to that and advocacy for strict liability.

Res ipsa is reserved to the trial court as is the motion in limine on the FDA regulations.

So I'm not sure who the predominately prevailing party is. It's kind of a split decision.

MS. COHEN: We can craft something.

THE COURT: If you could do that, Counsel, that would be splendid. I'll be gone at conference until Wednesday of next week. So if you folks could craft something that you can all agree with by the end of next week, that would be great.

But I think we need to wrap up and get

SUPERIOR COURT OF THE STATE OF WASHINGTON

IN AND FOR THE COUNTY OF KING

BECKY S. ANDERSON, Plaintiff, vs. DONALD R. PAUGH; WENATCHEE VALLEY MEDICAL CENTER, P.S.; LINDA K. SCHATZ; WENATCHEE ANESTHESIA ASSOCIATES; MEDTRONIC, INC.; MEDTRONIC XOMED, INC.; and UNKNOWN JOHN DOES, Defendants)

VERBATIM REPORT OF THE PROCEEDINGS

Cause No. 12-2-17928-0 SEA

JURY VOIR DIRE

TRANSCRIPT

of the proceedings had in the above-entitled cause before the HONORABLE Michael Trickey, Superior Court Judge, on the 24th day of October, 2013, reported by Michelle Vitrano, Certified Court Reporter, License No. 0002937.

APPEARANCES:

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FOR THE DEFENDANT: (Paugh and Wenatchee Valley Medical Center)	JENNIFER MOORE, AMY DELISA & WILLIAM LEEDOM Attorneys at Law
FOR THE DEFENDANT: (Linda Schatz and Wenatchee Anesthesia Association)	DOUG YOSHIDA & TRACY GRANT Attorneys at Law
FOR THE DEFENDANT: (Medtronic and Medtronic Xomed)	STEPHANIA DENTON, LORI COHEN & VICTORIA LOCKARD Attorneys at Law

a statement of fact, but I share your concern, and we're not going to do it anymore. Okay.

MS. COHEN: And your Honor, again on that, I think the language, I know you've decided, but it says, they are not represented, which implies that they have not been represented. That is part of the issue.

THE COURT: That is one implication. I standby my ruling. The door is not opened. The settlement's still out.

All right. I'm going to look at that case.

MR. CUNNINGHAM: Your Honor, may I hand up the agreed remaining instructions to the Court? These are now all agreed. The damage instruction is in there. The additional instruction talking about all the corporations is in there. The two instructions dealing with the claim against Medtronic and the burden of proof on Medtronic are in there and agreed to by us.

THE COURT: All right. So I'm going to take this packet which was just handed up and join it to the packet for Mr. Leedom, and that is the preinstructions on the law?

MR. YOSHIDA: I have a comment, your Honor. Just got this here.

SUPERIOR COURT OF THE STATE OF WASHINGTON

IN AND FOR THE COUNTY OF KING

BECKY S. ANDERSON, a single person, Plaintiff, VERSUS DONALD R. PAUGH; WENATCHEE VALLEY MEDICAL CENTER, P.S.; LINDA K. SCHATZ; WENATCHEE ANESTHESIA ASSOCIATES; MEDTRONIC, INC.,; MEDTRONIC XOMED, INC.,; and UNKNOWN JOHN DOES, DEFENDANTS.	VERBATIM REPORT OF THE PROCEEDINGS CAUSE NO. 12-2-17928-0SEA MORNING SESSION

TRANSCRIPT

OF THE PROCEEDINGS HAD IN THE ABOVE-ENTITLED CAUSE BEFORE THE HONORABLE MICHAEL TRICKEY, SUPERIOR COURT JUDGE, ON THE 25TH DAY OF OCTOBER, 2013, TRANSCRIBED BY KIMBERLY GIRGUS, CERTIFIED COURT REPORTER.

APPEARANCES

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BECKY SUE ANDERSON

JOEL CUNNINGHAM
PAUL LUVERA
RALPH BRINDLEY
ANDREW HOYAL
STEVE PRUZAN
DAVID BENINGER
ATTORNEYS AT LAW

FOR THE DEFENDANTS:
DR. PAUGH & WENATCHEE VALLEY MEDICAL CENTER

WILLIAM LEEDOM
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FOR THE DEFENDANTS:
DR. SCHATZ AND WENATCHEE ANESTHESIA ASSOCIATES

DOUG YOSHIDA
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MEDTRONIC, INC., AND MEDTRONIC XOMED, INC.

LORI COHEN
VICTORIA LOCKARD
STEPHANIA DENTON
EVAN HOLDEN
ATTORNEYS AT LAW

Dr. Schatz and was therefore negligence. But that's what I intended to use.

THE COURT: Do you have those exact words in a slide or is that just going to be part of your oral?

MR. BRINDLEY: It'll be part of my oral.

THE COURT: Okay. Any rebuttal to that?

MR. YOSHIDA: We argued this already, your Honor. I think -- I don't know that we want to bring up negligence right now. Certainly we would object to that. I thought earlier the language was going to be a violation, but what I hear Mr. Brindley saying is it's below the standard of care, and I think that's what we proposed. So I -- I object --

THE COURT: Read it to me again, please.

MR. YOSHIDA: Yes. It is undisputed that the administration of 100 percent oxygen by Dr. Schatz was below the applicable standard of care.

THE COURT: Applicable standard of care, is that -- any quibble with that?

MR. BRINDLEY: No. But that is negligence. I mean, that's defined as negligence.

THE COURT: Okay. I'm going to go with the stipulation at this point, and we will re-address it later. Okay.

MR. BRINDLEY: Okay.

verdict. Throughout the trial you should be impartial and permit neither sympathy, nor prejudice to influence to you.

That's my general instructions. 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 evidence that will be presented to you may be either direct or circumstantial. The term direct evidence refers to evidence that is given by a witness who has directly perceived something at issue in this case. The term circumstantial evidence refers to evidence from which, based on your common sense and experience, you may reasonably infer something that is at issue in this case. The law does not distinguish between direct and circumstantial evidence in terms of the weight or value in giving a findings of fact in a case. One is not necessarily more or less valuable than the other. The law treats all parties equally whether they are corporations or individuals. This means that corporations and individuals are to be treated in the same fair and unprejudiced manner. Wenatchee Valley Medical Center, Wenatchee Anesthesia Associates, Medtronic, Inc., Medtronic Xomed Inc. and Central

plaintiff was injured. Third, that the negligence of the defendant was a proximate cause of the injury to the plaintiff. If you find from your consideration of all the evidence that each of these propositions has been proved your verdict should be for the plaintiff. On the other hand, if any of these propositions has not been proved your verdict should be for the defendant.

As to 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 as to this claim. On the other hand, if any of these propositions has not been proved your verdict should be for the Medtronic defendants. As to plaintiff's claim against the Medtronic defendants. 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. The 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 medical product manufacturer knew or reasonably should have known at the time the medical product left its control. In determining what a medical product manufacturer reasonably should have gone 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 product themselves, 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 there by.

It is the duty of the Court to instruct you as to the measure of damages. By instructing you on damages the Court does not mean to suggest for which party your verdict should be rendered. If your verdict is for the plaintiff, then you must determine the amount of money that will reasonably and fairly compensate plaintiff for sufficient damages as you find were proximately caused by the defendant. If you find for plaintiff Becky Anderson, you should consider the following past economic damages.

must be governed by your own judgment, by the evidence in the case and by the these instructions.

Ladies and gentlemen, that concludes the preliminary instructions on the law. You will receive these instructions, and perhaps other instructions at the close of the case, and you will have those with you in the jury room to guide your deliberations.

We are now going to move to opening statements. I suggest everyone stand and stretch for a moment. Spectators too. Everybody stand and stretch. All right. Is the plaintiff ready to proceed with opening?

MR. BRINDLEY: We are, your Honor.

THE COURT: Mr. Brindley, are you going first?

MR. BRINDLEY: I will go first.

THE COURT: All right. Please be seated. Ladies and gentlemen of the jury, please direct your attention to opening statement on behalf of the plaintiff Becky Anderson by one of her attorneys Mr. Ralph Brindley. Mr. Brindley, you may proceed. You have 90 minutes.

MR. BRINDLEY: Thank you, your Honor. I appreciate it. Please the Court, and counsel, ladies and gentlemen of the jury, you are going to be hearing a lot of testimony in this case from doctors who will be up there on the witness stand. Now, the father or the grandfather of western medicine, and kind of the guru of western

SUPERIOR COURT OF THE STATE OF WASHINGTON

IN AND FOR THE COUNTY OF KING

BECKY S. ANDERSON, Plaintiff, vs. DONALD R. PAUGH; WENATCHEE VALLEY MEDICAL CENTER, P.S.; LINDA K. SCHATZ; WENATCHEE ANESTHESIA ASSOCIATES; MEDTRONIC, INC.; MEDTRONIC XOMED, INC.; and UNKNOWN JOHN DOES, Defendants)

VERBATIM REPORT OF THE PROCEEDINGS

Cause No. 12-2-17928-0 SEA

TRIAL

TRANSCRIPT

of the proceedings had in the above-entitled cause before the HONORABLE Michael Trickey, Superior Court Judge, on the 27th day of November, 2013, reported by Michelle Vitrano, Certified Court Reporter, License No. 0002937.

APPEARANCES:

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FOR THE DEFENDANT: (Linda Schatz and Wenatchee Anesthesia Association)	DOUG YOSHIDA & TRACY GRANT Attorneys at Law
FOR THE DEFENDANT: (Medtronic and Medtronic Xomed)	STEPHANIA DENTON, LORI COHEN & VICTORIA LOCKARD Attorneys at Law

Choppa.

THE COURT: Dr. Schatz.

MS. GRANT: No questions. Thank you.

THE COURT: Medtronic.

MS. LOCKARD: No questions. Thank you.

THE COURT: All right. Does the jury have any questions for this witness at this time?

Seeing none, you may step down. You are excused.

MR. LUVERA: We have no more witnesses, your Honor.

THE COURT: Plaintiff rests their rebuttal case. Ladies and gentlemen, I almost feel like we all deserve a round of applause here for finishing the case. We've worked you very hard and we've exhausted your patience, I'm afraid, and I want to apologize again for not getting this case to you yesterday, which was the goal, you would have been deliberating today. So things happen and it just happened in this case.

So I'm going to excuse you now. I hope you have a very pleasant Thanksgiving with your friends and family, and we'll be back here -- again I'm traveling on Monday, and unfortunately you can't do this without me, so you have to wait until Tuesday,

APPENDIX B

HON. MICHAEL TRICKEY

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

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

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

DATED this 24th day of October, 2013.

LUVERA, BARNETT,
BRINDLEY, BENINGER & CUNNINGHAM

/s/ Joel D.Cunningham
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CERTIFICATE OF SERVICE

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

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I declare under penalty of perjury, under the laws of the State of Washington that the foregoing is true and correct.

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

/s/ Dee Dee White
Dee Dee White

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PRE-INSTRUCTION NO. ____

It is the duty of the court to instruct you as to the measure of damages. By instructing you on damages, the court does not mean to suggest for which party your verdict should be rendered.

If your verdict is for the plaintiff, then you must determine the amount of money that will reasonably and fairly compensate plaintiff for such damages as you find were proximately caused by the negligence of the defendants.

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

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

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

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

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

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

In addition you should consider the following noneconomic damages elements:

1. The nature and extent of the injuries;

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

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

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

preponderance of the evidence.

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

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

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

PRE - INSTRUCTION NO. _____

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

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

Second, that plaintiff was injured; and

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

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

WPI 110.21 (modified)

PRE-INSTRUCTION NO. _____

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

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

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

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

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

WPI 110.02.01

PRE-INSTRUCTION NO. _____

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