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No. 71411-2-I
(Linked with Nos. 71315-9-I and 71316-7-I)

COURT OF APPEALS OF THE STATE OF WASHINGTON
DIVISION I

BECKY S. ANDERSON, a single person,

Plaintiff-Appellant,

vs.

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

Defendants-Respondents.

REPLY BRIEF OF APPELLANT

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I. REPLY

A. Where the superior court instructed the jury that Becky Anderson had the burden to prove Medtronic's product was not "reasonably safe" in order to prevail on her negligent design claim, her request for the pattern jury instruction containing the statutory tests to determine whether a product is reasonably safe did not improperly interject strict liability principles, and the court's failure to give the instruction warrants a new trial.

With respect to Becky Anderson's design claim, Medtronic[1] does not dispute the following:

- The superior court instructed the jury that Anderson had the burden of proving the Laser Shield II was not "reasonably safe" in order to prevail on her claim against Medtronic.[2]

- The phrase "reasonably safe" is a legal term of art under the WPLA and is defined in terms of a risk-utility balancing test and a consumer expectations test.[3]

- The ordinary meaning of reasonably safe differs from the risk-utility and consumer expectations tests, and suggests a less exacting standard of safety than would otherwise be imposed under these tests—i.e., the

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[1] As in prior briefing of both parties, "Medtronic" denotes both defendants/respondents, Medtronic Xomed, Inc., and its parent company, Medtronic, Inc.

[2] *See* CP 2567-68 (instructions); *see also* App. Br., at 12-13 (discussing instructions); *id.*, Appendix (reproducing instructions).

[3] *See* RCW 7.72.030(1)(a) (stating risk-utility test); RCW 7.72.030(3) (stating consumer expectations test); *Falk v. Keene Corp.*, 113 Wn. 2d 645, 654, 782 P.2d 974 (1989) (holding risk-utility and consumer expectations tests are independent and alternative basis for imposing liability for design defects); WPI 110.02 (pattern instruction containing both tests); *see also* App. Br., at 20-22 (discussing risk-utility and consumer expectations tests).

ordinary meaning of the phrase is "moderately" or "fairly" safe.[4]

- Anderson objected to the superior court's failure to define "reasonably safe" for the jury, and proposed an instruction defining the phrase in accordance with the statutory definition based on the pattern instruction.[5]

- "As with a superior court's instruction misstating the applicable law, a court's *omission* of a proposed statement of the governing law will be 'reversible error where it prejudices a party.'"[6]

- Counsel for Medtronic focused almost exclusively on the issue of whether the Laser Shield II was reasonably safe in closing argument, and the jury returned a verdict in the company's favor.[7]

The foregoing should be dispositive and result in reversal and remand for retrial of Anderson's design claim against Medtronic.

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[4] *See Merriam-Webster Online, s.v.* "reasonably" (available at www.m-w.com); *see also* Anderson App. Br., at 24 (discussing ordinary meaning).

[5] *See* CP 4463 (Anderson's proposed instruction); CP 2546-77 (court's instructions, omitting Anderson's proposal); CP 4468-69 (written exception to omission of proposed instruction); RP 10:11 (12/3/13 AM) (incorporating written exceptions by reference); *see also* App. Br., at 5 (assigning error to failure to give instruction); *id.*, Appendix (reproducing proposed instruction).

[6] App. Br., at 18 (quoting *Barrett v. Lucky Seven Saloon, Inc.*, 152 Wn. 2d 259, 266, 96 P.3d 386 (2004), with emphasis added; internal quotation omitted). Medtronic does not cite *Barrett*, nor does it contest the principle for which it stands.

[7] *See* App. Br., at 14-15 (citing and quoting record); Resp. Br., at 29 n.17 (acknowledging focus on reasonably safe issue in closing).

1. Medtronic wrongly attempts to limit the risk-utility and consumer expectations tests to strict liability claims.

Underlying Medtronic's response is a type of syllogistic reasoning:

> *First premise*: Liability for defective design of a medical device requires proof of *negligence* under the Restatement (Second) of Torts § 402A cmt. *k* (1965) ("Comment *k*").[8]
>
> *Second premise*: The statutory risk-utility and consumer expectations tests for determining whether a product is reasonably safe serve as the basis for imposing *strict liability*.[9]
>
> *Conclusion*: The relevance of the risk-utility and consumer expectations tests to a claim sounding in strict liability renders them irrelevant to, and even incompatible with, a claim sounding in negligence.[10]

Anderson has accepted the first premise in this case, and the requirement to prove negligence is incorporated in the court's instructions to the jury and constitutes the law of the case. However, the second premise and the conclusion are wrong. While the risk-utility and consumer expectations tests are unquestionably relevant to determining whether a product is reasonably safe in a

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[8] *See* Resp. Br., at 21 (citing *Terhune v. A.H. Robbins Co.*, 90 Wn. 2d 9, 12, 577 P.2d 975 (1978); *Rogers v. Miles Labs., Inc.*, 116 Wn. 2d 195, 203, 802 P.2d 1346 (1991); *Ruiz-Guzman v. Amvac Chem. Corp.*, 141 Wn. 2d 493, 507-08, 7 P.3d 795 (2000)).

[9] *See* Resp. Br., at 21 (citing *Falk*, 113 Wn. 2d at 653; *Seattle-First Nat'l Bank v. Tabert*, 86 Wn. 2d 145, 154, 542 P.2d 774 (1975)).

[10] *See* Resp. Br., at 16, 21-23 (arguing the risk-utility and consumer expectations tests are applicable only to strict liability claims, not negligence claims).

strict liability claim, they are not limited to such claims. They are also relevant to negligence claims, especially where the instructions impose a burden to prove that the product in question was not reasonably safe.

The authorities on which Medtronic relies do not support its reasoning. *See* Resp. Br., at 21 (citing *Falk,* 113 Wn. 2d at 653; *Tabert,* 86 Wn. 2d at 154). Medtronic describes *Falk* as "finding that consumer expectation and risk-utility tests of the WPLA were appropriate for strict liability claims, but not claims based on negligence." Resp. Br., at 21. This description incorrectly implies that *Falk* precludes application of the tests to negligence claims, when in fact the case does not address their application to negligence claims. Medtronic similarly describes *Tabert* as "adopting the consumer expectation test as an element of strict liability under Washington common law." Resp. Br., at 21-22. However, as with *Falk*, the Court did not discuss application of the consumer expectations test to negligence claims. In other words, neither *Falk* nor *Tabert* foreclose application of the risk-utility and consumer expectations tests in negligence cases.

The Washington Product Liability Act (WPLA), Ch. 7.72 RCW, expressly recognizes that the consumer expectations test

applies to claims sounding in negligence. In particular, RCW 7.72.030(1)(c) describes a claim for post-manufacture failure to warn in terms of negligence:

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

Accord Falk, at 653 (stating "[s]ubsection (1)(c) ... sets forth a standard consistent with a traditional negligence approach"; ellipses added). Along with the express incorporation of negligence principles, a claim for post-manufacture failure to warn is also phrased in terms of whether the product is "reasonably safe." RCW 7.72.030(1)(c). The consumer expectations test is not just relevant in determining whether a product is reasonably safe, the language of the statute indicates that it is mandatory, i.e., "the trier of fact *shall* consider whether the product was unsafe to an extent beyond that which would be contemplated by the ordinary consumer." RCW 7.72.030(3); *see Eubanks v. Brown,* 180 Wn. 2d 590, 596 n.1, 327 P.3d 635 (2014) (stating use of the word "shall" indicates

statutory language is mandatory). This illustrates the essential compatibility between a negligence claim and the definition of "reasonably safe" in terms of the consumer expectations test. If the compatibility exists in a negligence-based claim for post-manufacture failure to warn, there is no reason why it should not also exist in a negligence-based claim for defective design. This refutes Medtronic's claim that the consumer expectations test cannot be considered in the context of a negligence claim.

Moreover, while it is not expressly stated in the WPLA, there is a natural affinity between the risk-utility test for determining whether a product is reasonably safe as designed and the analysis of negligence. *See Ruiz-Guzman,* 141 Wn. 2d at 513 (Talmadge, J., concurring/dissenting, noting similarity with Judge Learned Hand's analysis of negligence in *United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947)); *see also* App. Br., at 21 n.26 (citing *Carroll Towing*). As it pertains to a WPLA design claim, the risk-utility test provides:

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

RCW 7.72.030(1)(a). Similarly, a determination of negligence involves consideration of the probability of harm, the gravity of the resulting injury, and the burden of adequate precautions. *See Carroll Towing*, 159 F.2d at 173.[11] While the focus of strict liability is the product, and the focus of negligence is the conduct of the defendant, both types of claims still involve consideration of whether the product is reasonably safe. Given the congruency between the risk-utility test of reasonable safety and the analysis of negligence, Medtronic cannot show (nor has it attempted to explain) why the risk-utility test should be confined to cases of strict liability and unavailable in cases of negligence.

Application of the risk-utility and consumer expectations test is entirely compatible with and should be required for negligence-based design claims under Restatement § 402A Comment *k*. Although adopted in Washington before enactment of the WPLA, Comment *k* continues to be followed afterward. *See Terhune*, 90 Wn. 2d at 12-18 (pre-WPLA); *Ruiz-Guzman v. Amvac Chem. Corp.*, 141 Wn. 2d 493, 505-11, 7 P.3d 795 (2000) (post-WPLA).

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[11] *Accord Bodin v. City of Stanwood*, 130 Wn. 2d 726, 733-34, 927 P.2d 240 (1996) (stating "[i]n assessing the standard of reasonable care, a risk-benefit analysis is usually part of the determination .... balancing the risk of harm , 'in the light of the social value of the interest threatened, and the probability and extent of the harm, against the value of the interest which the actor is seeking to protect, and the expedience of the course pursued").

Nonetheless, following enactment of the WPLA, the liability and the limits of liability described in Comment *k* are not free standing principles of product liability law, applied independently of the WPLA. *See Ruiz-Guzman*, at 506. The principles enunciated in Comment *k* are deemed to be implicit in RCW 7.72.030(1), and courts must be "sparing" in application of Comment *k* to avoid defeating the "letter or policy of the WPLA." *Id.*[12]

In particular, Comment *k* does not eliminate consideration of whether the product in question is reasonably safe as designed, nor does it supplant the statutory risk-utility and consumer expectations tests on which the issue of reasonable safety turns. In cases involving strict liability, proof that a product is not reasonably safe is both necessary and sufficient to impose liability. Under Comment *k,* proof that the manufacturer is negligent is required in addition to proof that the product is not reasonably safe. *See Rogers v. Miles Labs., Inc.*, 116 Wn. 2d 195, 207-08, 802 P.2d 1346 (1991). In this way, proof that a product is not reasonably safe is not sufficient, although it is still necessary, for liability under Comment *k*. Because proof that a product is not reasonably safe is

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[12] *See also* RCW 7.72.020(1) (indicating "[t]he previous existing applicable law of this state on product liability is modified only to the extent set forth in this chapter").

still necessary, Comment *k* should not be interpreted or applied in a way that effectively eliminates consideration of the statutory tests to determine whether a product is reasonably safe. Medtronic's attempt to limit the risk-utility and consumer expectation tests to the strict liability context should be rejected.[13]

2. Medtronic incorrectly characterizes Anderson's proposed instruction regarding the risk-utility and consumer expectations tests as a merely "augmenting instruction," rather than a statement of governing law.

Medtronic does not address the rule stated in *Barrett*, 152 Wn. 2d at 266, that a court's omission of a statement of the governing law from jury instructions—including failure to instruct the jury regarding statutory definitions of terms—is reversible error. *See* App. Br., at 17-18 (discussing *Barrett*). The decision of the superior court below in refusing to instruct the jury regarding the definition of a "reasonably safe" product in terms of the statutory risk-utility and consumer expectations tests falls within this rule, and warrants a new trial.

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[13] Since the risk-utility and consumer expectation tests for determining whether a product is reasonably safe are compatible with and required in a negligence-based design case, Anderson's acknowledgment of the need to prove negligence does not implicate the invited error doctrine. *See* Resp. Br., at 17-19. In proposing a correct instruction and objecting to the superior court's failure to give the instruction, Anderson fully complied with CR 51(f) and the error is preserved for review.

Rather than dealing with this authority, Medtronic improperly equates the superior court's decision below with a refusal to give a merely "augmenting instruction." *See* Resp. Br., at 23 (citing *Havens v. C&D Plastics, Inc.*, 125 Wn. 2d 158, 165-66, 876 P.2d 435 (1994); *Gammon v. Clark Equip. Co.*, 104 Wn. 2d 613, 617, 707 P.2d 685 (1985)). Review of an augmenting instruction differs from review of an omission of a statement of governing law. *See Havens*, 125 Wn. 2d at 165-67; *Gammon*, 104 Wn. 2d at 616-18. While the decision to give an augmenting instruction is reviewed for abuse of discretion, the legal sufficiency of instructions is reviewed de novo. *See Barrett*, at 266.

The definition of "reasonably safe" in terms of the risk-utility and consumer expectations tests is not an augmenting instruction. An augmenting instruction clarifies or elaborates upon the statement of governing law already contained in other instructions. For example, in *Havens,* involving the question of whether there was just cause for an employment termination, the jury was instructed on the legal definition of just cause, which included "a fair and honest reason for dismissal." 124 Wn. 2d at 166. The defendant proposed an augmenting instruction stating that "an employer is entitled to consider such intangible attributes as

personality, initiative, ability to function as part of a management team and ability to motivate subordinates." *Id.* The Court characterized the defendant's proposal as an augmenting instruction because it was already encompassed within the language of the just cause definition given to the jury, and held that the lower court did not abuse its discretion in declining to give the instruction. *Id.*

Similarly, in *Gammon*, a product liability action, the jury was instructed on both strict liability and negligence claims. The plaintiff proposed a clarifying instruction stating that the exercise of all possible care does not preclude the imposition of strict liability. *See* 104 Wn. 2d at 616 (quoting instruction). The Court stated that it would not have been error to give the instruction, but held that the lower court did not abuse its discretion in refusing to do so because the instruction merely clarified others that adequately stated the law. *See id.* at 617-18.

In contrast to *Havens* and *Gammon,* the risk-utility and consumer expectations tests were not already encompassed within other instructions given to the jury in this case, and Anderson's proposed instruction cannot be considered in terms of merely augmenting or clarifying other instructions. The proposed

instruction was required to accurately and completely inform the jury of the applicable law.

Nonetheless, even if the instruction proposed by Anderson could be considered as merely augmenting or clarifying other instructions, the failure to give the instruction would still constitute reversible error. Medtronic acknowledges that augmenting instructions may be required where necessary to avoid misleading the jury. *See* Resp. Br., at 23. As pointed out in Anderson's opening brief, the undefined phrase "reasonably safe" is misleading because it suggests a less exacting standard of safety that would otherwise be imposed under the risk-utility and consumer expectations tests, i.e., "moderately" or "fairly" safe. *See* App. Br., at 24-25. Medtronic ignores this fact.

Rather than addressing the misleading effect of the failure to define "reasonably safe" in terms of the risk-utility and consumer expectations tests, Medtronic instead argues that the jury instructions were not misleading because they correctly informed the jury of the requirement to prove negligence, and allowed Anderson to present evidence and argument on the issue of negligence. *See* Resp. Br., at 24-29. This is beside the point, and

does not vitiate the misleading effect of the failure to define "reasonably safe."

3. Medtronic does not meaningfully address the prejudice resulting from the superior court's failure to define "reasonably safe": counsel for Medtronic used closing almost exclusively for the purpose of arguing that the Laser Shield II was reasonably safe, and her arguments were unconstrained by the risk-utility and consumer expectations tests of reasonable safety.

Medtronic does not meaningfully address the issue of prejudice in its response brief, and its argument that no prejudice occurred is based on the contention that defining "reasonably safe" in terms of the risk-utility and consumer expectations tests in a negligence case would have misstated the law. *See* Resp. Br., at 16. Because the instruction proposed by Anderson was necessary to accurately and completely inform the jury regarding the governing law, prejudice should be presumed from the failure to give the instruction, and it should be incumbent upon Medtronic to show the absence of prejudice. *See* App. Br., at 23-24.

Even if not presumed, however, ample evidence of prejudice exists in this record, based on the misleading effect of the superior court's failure to define "reasonably safe," noted above, and the closing argument of counsel for Medtronic, which focused on the

issue of reasonable safety, unconstrained by the statutory definitions of the phrase. *See* App. Br., at 14-15; *accord* Resp. Br., at 29 n.17 (acknowledging emphasis on "reasonably safe" in closing argument). With respect to the closing, in particular, Medtronic does not address the holding of *Anfinson v. FedEx Ground Pkg. Sys., Inc.*, 174 Wn. 2d 851, 860, 281 P.3d 289 (2012), that "[n]o greater showing of prejudice from a misleading instruction is possible" than when the instruction "was actively urged upon the jury during closing argument." Here, the instructional error involved omission of a statement of governing law, rather than a merely misleading instruction, but the evidence of prejudice is no less compelling. *See* App. Br., at 25 (discussing *Anfinson*). To the extent a showing of prejudice is required for reversal and remand, Anderson has made the requisite showing in this case.

II. CONCLUSION

Becky Anderson respectfully asks the Court to reverse judgment in favor of Medtronic, including the award of costs, and remand for retrial of her defective design claim against Medtronic.[14]

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[14] Anderson withdraws her assignment of error to the superior court's dismissal of her failure-to-warn claim on summary judgment. *See* App. Br., at 6 (assignment of error #2); *see also* RAP 2.4(a) (limiting scope of review to decisions designated in the notice of appeal "at the instance of the appellant").

CERTIFICATE OF SERVICE

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

On September 4, 2014, I served the document to which this is annexed by email and First Class Mail, postage prepaid, as follows:

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