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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.

BRIEF OF APPELLANT

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I. INTRODUCTION

On February 3, 2012, Becky Anderson went to the hospital for minor, elective surgery that was supposed to last ten minutes, using a laser to remove a polyp on her vocal cords.[1] In the past, her surgeon had always used a special endotracheal tube with two "cuffs" to seal off the patient's trachea during the procedure, while the anesthesiologist administered oxygen through the lumen of the tube so the patient could breathe. The purpose of the double-cuff design is to protect the patient. The upper cuff is filled with saline, and, if struck by the laser, it acts like a shield, absorbing energy from the laser, and preventing the lower cuff from being inadvertently struck by the laser. The lower cuff will continue to hold the seal on the airway, so the surgeon can stop the procedure and swap out the damaged endotracheal tube for a new one before continuing. The lower cuff prevents oxygen-enriched air from escaping from the lungs to the site where the laser is being used. One of the risks of laser surgery, especially in the presence of

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

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

On the day of Ms. Anderson's surgery, the surgeon used a Laser Shield II endotracheal tube manufactured by Medtronic Xomed, Inc., and its parent corporation, Medtronic, Inc., a major manufacturer of medical devices (collectively Medtronic).[3] The Laser Shield II employs a single-cuff design. Medtronic criticizes the double-cuff design as giving the surgeon a "false sense of security," contending that it may lead the surgeon to continue the surgery even though the second cuff is vulnerable to a laser strike and resulting airway fires.[4] However, since 2000, there is a history of eight airway fires with the single-cuff Laser Shield II, including two known reports in the State of Washington. During the same

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[2] Regarding the blowtorch effect, *see* RP 30:15-33:4 (10/29/13 PM); RP 32:15-19 (10/30/13 AM).

[3] The jury instructions did not distinguish between the Medtronic defendants, and the superior court denied a pretrial motion for summary judgment filed by Medtronic, Inc., contending that it is not liable as a manufacturer.

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

period of time, there is only one reported airway fire with the double-cuff design, occurring outside of Washington.[5]

The Laser Shield II comes in a plain white box that lacks any warning or reminder that, despite its name, the Laser Shield does not actually shield the patient from laser energy, nor does it contain any reminder to protect the single cuff from a laser strike with small saline-soaked wads of absorbent cotton known as "pledgets," nor does it contain any reminder about the risk of endotracheal tube fire in the presence of concentrations of oxygen greater than room air, nor does it even contain a reminder to read or request a copy of the product's instructions.[6]

During the operation on Ms. Anderson, the surgeon struck the cuff of the Laser Shield II with the laser, while the anesthesiologist was administering 100% oxygen. Without any protection from a second cuff, 100% oxygen leaked into the surgical site where the laser was being used. The endotracheal tube caught on fire, creating a blowtorch effect, and Ms. Anderson suffered horrific burns in her respiratory tract. Fragments of the Laser

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[5] There is reason to believe that the history of adverse events may be underreported. *See* RP 7:4-16 (11/4/13 PM); RP 50:24-52:1 (11/4/13 PM).

[6] *See* CP 4137 (photocopy of the surface of the box).

Shield II were embedded in her trachea, and the tip of the tube lodged in the lower left lobe of her lungs. She was hospitalized for more than five months, undergoing multiple surgeries, and ultimately placed in a nursing home.

Ms. Anderson originally went in for surgery so she would not get hoarse when she sang. Now, she is unable to speak or even breathe for more than 30 minutes at a time without ventilator assistance.

Ms. Anderson filed suit against her health care providers for negligence, and against Medtronic for defective design of the Laser Shield II endotracheal tube and failure to warn her health care providers about the dangers of the product. Following trial, the jury returned a verdict against the health care providers, but in favor of Medtronic. Beforehand, the superior court dismissed Ms. Anderson's failure-to-warn claim against Medtronic on summary judgment. With respect to her design defect claim, the court instructed the jury that Ms. Anderson had the burden of proving that the Laser Shield II was not reasonably safe, but declined to give the pattern jury instruction containing the statutory tests for determining whether a product is reasonably safe. The health care providers have filed two separate appeals of the judgment entered

against them, and Ms. Anderson cross appeals the judgment in favor of Medtronic.[7]

II. ASSIGNMENTS OF ERROR

1. With respect to her defective design claim, the superior court erred in refusing to give Becky Anderson's proposed jury instruction regarding the statutory tests to determine whether a product is reasonably safe as designed.[8]

2. The superior court erred in dismissing Ms. Anderson's failure-to-warn product liability claim on summary judgment. CP 4491 (summary judgment order).

3. The superior court erred in awarding costs against Ms. Anderson. CP 4495 (judgment).

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[7] *See* CP 4471-84 (notice of appeal); CP 4485-96 (amended notice of appeal). The health care providers appeals have been consolidated, and Ms. Anderson's cross appeal has been linked to the consolidated cases. In motion practice regarding superseding the judgment, counsel for Ms. Anderson described her cross appeal as "protective," to prevent the health care providers from allocating fault to an empty chair in case they obtain reversal and remand for a new trial in their consolidated appeals. This description relates solely to Ms. Anderson's reasons for pursuing the cross appeal, rather than the merits of her claims against Medtronic.

[8] CP 4463 (proposed jury instruction); CP 2546-77 (court's instructions to the jury, omitting proposed instruction); CP 4468-69 (written exceptions to the court's instructions); RP 10:11 (12/3/13 AM) (incorporating written exceptions by reference). The proposed jury instruction, CP 4463, and the pattern jury instruction on which it is based, WPI 110.02, are reproduced in the Appendix to this brief.

III. ISSUES PERTAINING TO ASSIGNMENTS OF ERROR

1. Where the superior court instructs the jury that Becky Anderson has the burden of proving that Medtronic's Laser Shield II is not reasonably safe, but declines her request to give an instruction regarding the statutory tests to determine whether the product is reasonably safe, do the instructions properly inform the jury of the law applicable to Ms. Anderson's design defect claim? (Assignment of Error No. 1).

2. Where the Laser Shield II comes in a plain white box lacking any warning or reminder (a) that it does not actually shield the patient from laser energy, (b) that the single cuff should be protected from a laser strike with pledgets, (c) that there is a risk of fire in the presence of high concentrations of oxygen, and/or (d) that the user should read or request a copy of the product's instructions, does a surgeon's failure to read the instructions relieve Medtronic of its duty to warn as a matter of law? (Assignment of Error No. 2).

3. Under RCW 4.84.010(7), is Medtronic entitled to an award of costs for entire depositions, without regard for the extent to which they were used at trial? (Assignment of Error No. 3).

IV. STATEMENT OF THE CASE

A. The superior court dismisses Ms. Anderson's failure-to-warn claim against Medtronic on summary judgment.

Before trial, Medtronic moved for summary judgment, seeking dismissal of Ms. Anderson's failure to warn claim, among other things. *See* CP 3769-3800. In response, Anderson pointed to evidence in the record from engineer and human factors expert, George Samaras, Ph.D, and testimony from Ms. Anderson's surgeon, Donald Paugh, M.D. *See* CP 4430, 4441.

Dr. Samaras is a professional engineer and human factors expert. *See* CP 3916-28 (curriculum vitae). Approximately 10-15% of his work involves drafting instructions for use (IFUs) and warnings for medical devices.[9] Dr. Samaras opined in part that the "labeling of the modified Laser-Shield II endotracheal tube was

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[9] *See* Videotaped Deposition of George Michael Samaras, Ph.D., Aug. 28, 2013, at 204:14-21 (hereafter "Samaras Depo., Aug. 28, 2013), attached as Exhibit 15 to the Supplemental Declaration of Victoria Lockard Re Motions to Strike Experts Causation Opinions Against the Medtronic Defendants (Sub No. 299H), filed Sept. 4, 2013. The supplemental declaration of Ms. Lockard was before the superior court and cited by Anderson in response to Medtronic's motion for summary judgment. *See* CP 4430 (citing deposition transcript). It is being transmitted to the Court of Appeals via a supplemental designation of Clerk's Papers.

inadequate."[10] The labeling includes both the IFU inserted into the box containing the product and the box itself.[11] With respect to the IFU, Dr. Samaras noted the following:

- The IFU violates 21 C.F.R. § 801.15(a)(15), because it is in an "essentially unreadable" 6-point font, in a 36-page multi-language booklet that "makes the package insert, on its face, impenetrable and effectively inhibits utilization by end users, especially those under time pressure."

- The lack of readability is confirmed by standard measures of readability employed by human factors experts, including the Gunning-Fog Index, the Flesch Reading Ease Score, and the Flesch-Kinkaid Grade Level Score.

- The instructions contain nonsensical text, i.e., "[t]he 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."

- Reported test data conflicts with statements in the IFU.

- The IFU violates 21 C.F.R. § 801.109(c), because it recommends a questionable procedure for managing surgical fire.

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[10] *See* Summary of Certain Opinions by George M. Samaras, PhD, DSc, PE, CPE, CQE, July 22, 2013, at 2 (hereafter Samaras Summary of Opinions), which is attached as Exhibit 16 to the supplemental declaration of Victoria Lockard, transmitted via supplemental designation of Clerk's Papers. *See also* CP 4430 (citing Samaras Summary of Opinions).

[11] *See* Samaras Depo., Aug. 28, 2013, at 260:6-7.

- Labeling the device a "Laser-Shield" is inaccurate and misleading because it "does not provide a means for shielding against laser energy."[12]

In light of the foregoing, Dr. Samaras concluded that "[t]his IFU, in my opinion, was not designed to be read by anybody."[13]

With respect to the box containing the Laser Shield, Dr. Samaras explained:

- "[L]abeling, as defined by the FDA and as generally accepted in the human factors profession, has to do with all physical labels, all instruction manuals, all advertisements related to the use and characteristics of the product and any statements made by agents of the manufacturing firm. The box that I was given that contained the Laser-Shield II that I cut apart and that you kept has a small label on it and also has a huge white space that could very easily have borne warnings and cautions to the end user that would also have been embedded in the IFU."[14]

- "[T]he white space on the box provides a reasonable person with an opportunity to post

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[12] Samaras Summary of Opinions, at 7-9.

[13] Samaras Depo., Aug. 28, 2013, at 354:19-20.

[14] Samaras Depo., Aug. 28, 2013, at 363:12-23 (brackets added); *accord id.* at 387:11-24 (stating "part of the risk communication process is the labeling. That includes the instructions for use on the outside of the box. And part of it is one of the agents and presumably, as — as do many other companies — and I've worked on basically presentations for not the sales folks but the technical folks that go out with them that do the in-services, that the agents for the companies can provide the information in a way so that either the end users are familiar with the contents of the instructions for use or are aware that they really need to take the time and review the instructions for use.")

> warnings. Since you don't know whether somebody is going to read or even understand your IFU, this is another example of a redundant safety system. Except in this case, it's not a design issue; it's a labeling issue."[15]

- "The only criticism I have [about the box] is that there is an obvious opportunity to provide warning .... that there could have been to good effect a redundant set of labeling on the outside of the box; that whoever picked up the box, unless they had their eyes closed, would probably have noticed."[16]

According to Dr. Samaras, "a reasonable and prudent manufacturer would have taken advantage of all possible ways of warning the end user[,]" specifically including the provision of warnings on the box.[17]

Becky Anderson's surgeon, Donald R. Paugh, M.D., did not see the IFU before he operated on Ms. Anderson, and he thought the box for the Laser Shield II might have been empty, although he could not say for sure.[18] However, he remembered seeing the box and explained his reaction as follows:

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[15] Samaras Depo., Aug. 28, 2013, at 368:3-9 (brackets added); *accord id.* at 362:8-11 (stating "the box that the device and the IFU is contained in has a huge, big white space on the front of it, and it was an ideal portion — place to place warnings. And it was white space. There were no warnings.").

[16] Samaras Depo., Aug. 28, 2013, at 370:9-21 (brackets & ellipses added).

[17] Samaras Depo., Aug. 28, 2013, at 368:19-22 (brackets added).

[18] CP 3888 (Paugh Depo., at 88:7-19, indicating he did not see a package insert); CP 3890 (Paugh Depo., at 95:5-9, indicating he thought the box was empty).

Q. [Y]ou understood completely that there was a risk of — potential risk of a surgical fire if there was some kind of an ignition from the laser, right?

A. [By Dr. Paugh:] No.

Q. You didn't understand that, anything about the risk of surgical fires?

A. That was the assumption I made when I saw the box.

Q. Tell me about that.

A. Because the box, you asked me about labeling.

Q. Yes.

A. And that's what — that's what kind of relaxed me a little bit is the label on the box describing as a laser shield tube.

Q. Right.

A. A tube that's able to be struck by the laser.

Q. Okay. So you took the title of LASER-SHIELD II as one that could be struck by the laser.

A. I did.[19]

Based on the foregoing testimony, Ms. Anderson's failure-to-warn claim focused on the manner in which Medtronic provided its

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[19] CP 3889-90 (Deposition of Donald R. Paugh, M.D., Dec. 17, 2012, at 92:25-93:19 [hereafter Paugh Depo.]); *accord* CP 3890 (Paugh Depo., at 9522-96:1, indicating "surprise" that the IFU warns users not to impact the Laser Shield with a laser beam).

warning. RP 87:19-24 (9/20/13). However, the superior court discounted the lack of warnings on the box, and dismissed the claim on grounds that Dr. Paugh did not read the IFU. RP 99:6-14 (9/20/13).

B. The superior court instructs the jury that Ms. Anderson has the burden of proving that the Laser Shield II is not reasonably safe as designed, but declines her request to give the pattern jury instruction containing the statutory tests to determine whether a product is reasonably safe.

During trial, there was conflicting testimony regarding the safety of Medtronic's design for the Laser Shield II. The superior court gave Instruction No. 19, adapting the pattern jury instruction regarding the elements of a defective design claim, WPI 110.21. *See* CP 2567. The court also gave Instruction No. 20, adapting the pattern instruction regarding negligent design in the medical context, WPI 110.02.01. *See* CP 2568. The court did not give any other instructions regarding the design claim.[20]

The court's instructions to the jury required Becky Anderson to prove "that the Medtronic defendants failed to exercise reasonable care in the design of the Laser-Shield II at the time the product left their control," and explained that "a medical device

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[20] Copies of the court's instructions to the jury regarding the design claim, CP 2567-68, are reproduced in the Appendix.

manufacturer has a duty to use reasonable care to design medical devices that are *reasonably safe*." CP 2567-68 (emphasis added). The instructions further required Ms. Anderson to prove "that the *unsafe condition* of the product was a proximate cause" of her injury. CP 2567 (emphasis added). However, the instructions did not define what constitutes a "reasonably safe" product.

Anderson brought the lack of definition to the court's attention, and proposed an instruction based on WPI 110.02, stating the risk-utility and consumer expectations tests for determining whether a product is reasonably safe under the Washington Product Liability Act (WPLA), RCW 7.72.030(1)(a) & (3). *See* CP 4463 (proposed instruction). When the court declined to give the instruction, she took formal exception. *See* CP 4468-69 (written exceptions); RP 10:11 (12/3/13 AM) (incorporating written exceptions by reference).[21]

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[21] At one point, Medtronic proposed an instruction apparently based on WPI 110.02, containing a form of the risk-utility test, but not the consumer expectations test. *See* Proposed Instruction No. 30, adapting WPI 110.02, in Defendants Medtronic Xomed, Inc.'s and Medtronic, Inc.'s Requested Jury Instructions (Sub No. 494), filed Oct. 8, 2013. Medtronic's proposed instructions are being transmitted to the Court of Appeals via a supplemental designation of Clerk's Papers.

C. During closing argument, counsel for Medtronic focuses almost entirely on the issue of whether the Laser Shield II is reasonably safe, and the jury returns a verdict in the company's favor.

Counsel for Medtronic began her closing argument by emphasizing what she believed to be the dispositive issue: "I want to start by saying that this case is complex, but I think what's clear is that the plaintiffs [sic] cannot prove that the Laser Shield II was not reasonably safe, which is the standard." RP 83:9-13 (12/3/13 PM) (brackets added).[22] "I am focusing on this first question, that is, did the plaintiff's [sic] prove, have they proven that the Laser Shield II is not reasonably safe?" RP 84:11-13 (brackets added).

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

> did the plaintiff prove ... that the Laser Shield II modified was not reasonably safe? Okay. And the answer — if the answer is no, then you stop there, and I will show you the verdict form as we go. You check no for no negligence and you stop. And it's a defense verdict for Medtronic/Xomed. No need to even proceed beyond the first question.

RP 90:7-15 (ellipses added); *accord* RP 85:8-10 ("if you find that the Laser Shield II, first question, question one, negligence. Is reasonably safe, then deliberations must end [sic]").

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[22] All citations to the closing argument of counsel for Medtronic are from the 12/3/13 PM session of court.

Throughout closing, counsel continually returned to the issue of whether the Laser Shield II is reasonably safe. *See, e.g.*, RP 88:23-24, 91:21-92:2, 92:21-93:1, 93:13-14, 96:9-12, 97:22-98:2, 98:20-22, 99:10-12, 100:4-6, 101:7-9, 102:10-15, 103:10-104:1, 109:7, 110:7-10, 112:19-21, 123:11-13, 128:14-16, 133:15-16. Counsel concluded, "Was this a reasonably safe design? *I think we have covered that extensively. I told you I wanted to spend the majority of my time on that and I have.*" RP 116:7-10 (emphasis added).

As requested, the jury returned a special verdict in Medtronic's favor, finding no negligence on the part of the company. CP 2544 (question 7).

D. The superior court awards costs to Medtronic.

The superior court entered judgment on the jury's verdict, including $13,968.47 in costs requested by Medtronic. CP 4495. Becky Anderson objected to all but $989.48 of the cost bill, because it requested reimbursement for the entire cost of nine depositions, rather than the pro rata share of the cost for the portions of the

depositions used at trial, and Medtronic made no attempt to establish the portions of the depositions used at trial.[23]

V. SUMMARY OF ARGUMENT

With respect to Becky Anderson's design defect claim against Medtronic, the superior court failed to properly instruct the jury regarding the applicable law when it declined her request to give the pattern jury instruction stating the statutory risk-utility and consumer expectations tests for determining whether a product is reasonably safe as designed. The question of whether the Laser Shield II is reasonably safe goes to the heart of the design defect claim. The lack of an instruction defining the phrase "reasonably safe" misled the jury because the ordinary meaning is "fairly" or "moderately" safe, and does not require consideration or balancing of the factors involved in the risk-utility test, nor does it require consideration of the expectations of the ordinary consumer.

With respect to Ms. Anderson's failure-to-warn claim, the superior court erred in finding, as a matter of law, that Dr. Paugh's

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[23] *See* Defendants Medtronic, Inc. and Medtronic Xomed, Inc.'s Cost Bill (Sub No. 760A), filed Jan. 7, 2014; Plaintiff's Objection and Opposition to Medtronic Defendants' Notice of Presentation of Cost Bill (Sub No. 775), filed Jan. 13, 2014; Declaration of Andrew Hoyal in Support of Plaintiff's Objection and Opposition to Medtronic Defendants Notice of Presentation of Cost Bill (Sub No. 776), filed Jan. 13, 2014. These documents are being transmitted to the Court of Appeals via a supplemental designation of Clerk's Papers.

failure to read or request a copy of the instructions for the Laser Shield II absolved Medtronic of responsibility to provide appropriate warnings on the box. A warning on the box serves as a reminder of important warnings contained in the instructions, or of the need to read the instructions before use, comparable to, and at least as important as, a seat belt alarm in an automobile or speed limit signs along every few miles of road. The sufficiency and effect of the warnings are questions of fact that should have been submitted to the jury.

With respect to the award of costs, the superior court failed to follow the plain language of RCW 4.84.010(7), which provides "[t]hat the expenses of depositions shall be allowed on a pro rata basis for those portions of the depositions introduced into evidence or used for purposes of impeachment."

VI. ARGUMENT

A. The superior court erred in refusing to instruct the jury regarding the statutory tests for determining whether the Laser Shield II is reasonably safe as designed.

"Jury instructions are inadequate if they prevent a party from arguing its theory of the case, mislead the jury, or misstate the applicable law." *Barrett v. Lucky Seven Saloon, Inc.*, 152 Wn.2d

259, 266, 96 P.3d 386 (2004). The legal sufficiency of jury instructions is reviewed de novo. *See id.*, 152 Wn.2d at 266; *Hue v. Farmboy Spray Co.*, 127 Wn.2d 67, 92 & n.23, 896 P.2d 682 (1995).

"As with a trial court's instruction misstating the applicable law, a court's *omission* of a proposed statement of the governing law will be 'reversible error where it prejudices a party.'" *Barrett*, at 267 (emphasis added; quoting *Hue*, 127 Wn.2d at 92). In particular, refusal to instruct the jury regarding statutory or other technical definitions of words or phrases constitutes reversible error. *See Barrett*, at 267-75 (involving "apparently intoxicated" statutory standard for over service of alcohol); *Hub Clothing Co. v. City of Seattle,* 117 Wn.2d 251, 253-54, 201 Pac. 6 (1921) (involving standard for "reasonable inspection" of city water meters); *Williams v. Virginia Mason Med. Ctr.*, 75 Wn.App. 582, 880 P.2d 539 (1994) (involving definition of "voluntary retirement" in connection with eligibility for permanent total disability benefits under workers compensation laws).

For example, in *Hub Clothing* the occupier of a building brought a negligence action against the City of Seattle to recover damages sustained as a result of a burst water meter installed by the city in the basement of the building. *See* 117 Wash. at 252. One

claim was the city might have discovered the defect that caused the meter to burst if it had performed reasonable inspections. *See id.* at 253. The court instructed the jury that the city had a duty to perform a "reasonable inspection," but declined to give an instruction requested by the building occupier that such an inspection "is not confined to optical observation, but is ordinarily understood to embrace tests and examinations[.]" *Id.* at 253-54. On appeal, the Supreme Court held that the failure to define the phrase "reasonable inspection" was reversible error:

> This instruction should also have been given in order that the jury might have before it some standard by which to determine whether or not that which the city did amounted, under the circumstances of this case, to the performance of the duty which the law imposed.

Id. at 254.

The rationale for the rule applied in *Hub Clothing* is that courts cannot presume that jurors already know and understand the applicable law.[24] That is precisely why such care and effort is expended in instructing the jury. Jurors must be informed of the

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[24] This principle is evident in the instructions given to the jury in this case. *See, e.g.*, CP 2547 (Instruction No. 1, stating "[i]t also is your duty to accept the law as I explain it to you, regardless of what you personally believe the law is or what you personally think it should be. You must apply the law from my instructions to the facts ... and in this way decide the case"; brackets & ellipses added).

law in all relevant particulars before they can make a meaningful decision regarding the merits of a case.[25]

In this case, as in *Hub Clothing*, the superior court improperly failed to instruct the jury regarding the applicable legal standard. In particular, the superior court failed to instruct the jury regarding the statutory tests for determining whether a product is reasonably safe. The Legislature enacted the WPLA to reform product liability law. *See* Laws of 1981, Ch. 26, § 1. The legislative purpose underlying the reforms is to treat consumers and product manufacturers in a balanced fashion, without unduly impairing "the right of the consumer to recover for injuries sustained as a result of an unsafe product." *Id.*

Accordingly, the WPLA allows injured consumers to hold a manufacturer legally responsible if the product in question is "not reasonably safe as designed." RCW 7.72.030(1). The Act delineates

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[25] Compare the "technical term rule" applied in the criminal law context, which requires legal terms of art used in jury instructions to be defined for the jury upon request of a party. *See, e.g., State v. Scott,* 110 Wn.2d 682, 692-93, 757 P.2d 492 (1988) (Utter, J., concurring, summarizing the rationale for the rule). The technical term rule is limited to definitions of words or phrases that *differ* from common usage. *See, e.g., In re Detention of Pouncy,* 168 Wn.2d 382, 396, 229 P. 2d 678 (2010). In contrast, the rule of *Hub Clothing* seems to apply even when the definitions are *similar* to common usage. *See* 117 Wash. at 253-54 (involving definition of "reasonable inspection" derived from *Webster's* dictionary).

two tests for determining whether the product is reasonably safe. The first 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). This is often described as the risk-utility test. *See, e.g., Soproni v. Polygon Apartment Partners,* 137 Wn.2d 319, 326-27, 971 P.2d 500 (1999). The risk-utility test involves a balancing of the factors listed in the statute. *See, e.g., Ayers v. Johnson & Johnson Baby Prods. Co.*, 117 Wn.2d 747, 763, 818 P.2d 1337 (1991).[26]

The second test for whether a product is reasonably safe provides:

> In determining whether a product was not reasonably safe under this section, the trier of fact shall consider whether the product was unsafe to an extent beyond

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[26] Although the WPLA's risk-utility test is similar to Judge Learned Hand's formula for analyzing a duty grounded in negligence, *see United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2nd Cir. 1947), the focus under the risk-utility test is on the *product* rather than the conduct of the manufacturer. *See Ayers,* 117 Wn.2d at 762 (citing *Davis v. Globe Mach. Mfg. Co.*, 102 Wn.2d 68, 72, 684 P.2d 692 (1984)). The distinction is evident from the instructions in this case, where Anderson was required to prove both that Medtronic was negligent and that the Laser Shield II is not reasonably safe. *See* CP 2567-68.

> that which would be contemplated by the ordinary consumer.

RCW 7.72.030(3). This is often described as the "consumer expectations" test. *See, e.g., Soproni,* 137 Wn.2d at 326-27. It is based on the reasonable expectations of an ordinary consumer. *See id.* at 327.

An injured consumer may rely on either one or both of these statutory tests to show that the manufacturer's product was not reasonably safe. *See Soproni,* at 326-27. Both tests have been incorporated into the pattern jury instruction that Anderson adapted for use in this case. *See* WPI 110.02. The "Note on Use" for the pattern instruction states: "[u]se this instruction if there is a claim against a manufacturer that the product was not reasonably safe as designed." *Id.* (brackets added).

The superior court's refusal to give the instruction Anderson proposed is reversible error, no less than in *Hub Clothing,* because it deprived the jury of knowledge of the applicable law. No explicit

showing of prejudice was required for reversal in *Hub Clothing*, and none should be required here.[27]

To the extent that an analysis of prejudice is required, Ms. Anderson should be entitled to a presumption of prejudice. Prejudice is presumed from a clear misstatement of the law, as distinguished from a merely misleading statement of the law. *See Anfinson v. FedEx Ground Pkg. Sys., Inc.*, 174 Wn.2d 851, 860, 281 P.3d 289 (2012). Although a misstatement of the law would seem to be inherently misleading, the distinction between a clear misstatement and a merely misleading statement is imprecise at best. Failing to instruct the jury regarding the applicable law should be considered more akin to a clear misstatement than a merely misleading statement. *See Barrett,* 152 Wn.2d at 267 (equating "omission of a proposed statement of the governing law" with "misstating the applicable law"). As noted above, jurors must be informed of the applicable law in all its particulars before they can make a meaningful decision regarding the merits of a case. It should therefore be incumbent upon Medtronic to establish that the

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[27] *Williams,* 75 Wn. App. at 584-85, is in accord because the court omitted any mention of prejudice in connection with the failure to define the phrase "voluntary retirement." At most, the court noted that the reason for retirement was "a significant issue in the case." *Id.* at 585. The court did explicitly address prejudice in connection with other instructional issues, suggesting that the omission was not inadvertent. *See id.* at 587-88.

failure to instruct the jury regarding the statutory tests for determining whether a product is reasonably safe is harmless.[28]

Medtronic cannot satisfy this burden because there is ample evidence of actual prejudice in the record. The ordinary meaning of the undefined phrase "reasonably safe," as used in the court's instructions, is misleading in the context of a product liability case based on defective design. The dictionary definition of "reasonably" safe is "moderately" or "fairly" safe. *See Merriam-Webster Online, s.v.* "reasonable" (viewed May 18, 2014; available at www.m-w.com). This definition is less detailed than the WPLA tests for determining whether a product is reasonably safe, and it suggests a less exacting standard of safety than would otherwise be imposed under the risk-utility or consumer expectations tests.[29] The dictionary definition does not identify the relevant factors or the required balancing involved in the risk-utility test, nor does it

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[28] Although *Barrett* indicates that an analysis of prejudice is required, *see* 152 Wn.2d at 267, and finds prejudice based on the fact that the trial court gave a jury instruction regarding "obvious" intoxication that conflicted with the one that should have been given regarding "apparent" intoxication, *see id.* at 274-75, the case does not preclude a presumption of prejudice in other circumstances.

[29] For example, compare "reasonably safe" to "reasonably priced," "reasonably smart," or "reasonably good-looking."

prompt the jury to consider the consumer-oriented perspective of the consumer expectations test.[30]

Prejudice is established when a misleading instruction "was actively urged upon the jury during closing argument." *Anfinson,* 174 Wn.2d at 876. "No greater showing of prejudice from a misleading instruction is possible without impermissibly impeaching a jury's verdict." *Id.* at 876-77. In this case, the undefined and misleading phrase "reasonably safe" formed the centerpiece of Medtronic's closing argument. Thus, in the final analysis, even if a showing of prejudice were required, it is present in this record, warranting reversal and remand for retrial.

B. The superior court erred in dismissing Ms. Anderson's failure-to-warn claim on summary judgment.

Summary judgment is only appropriate when there are no genuine issues of material fact in dispute, and the moving party is entitled to judgment as a matter of law. CR 56(c). An appellate court reviews a grant of summary judgment de novo, and performs the same inquiry as the trial court, viewing the evidence in the light most favorable to the nonmoving party and drawing all reasonable

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[30] *Cf. McKay v. Sandmold Sys., Inc.*, 482 A.2d 260, 265-66 (Pa. Super. 1984) (holding in a products liability case that failure to define the term "defective" misleads the jury and requires a new trial).

inferences from the evidence in that party's favor. *See Lakey v. Puget Sound Energy, Inc.*, 176 Wn.2d 909, 922, 296 P.3d 860 (2013). In product liability actions based on failure to warn, the adequacy and effect of warnings (or lack of warnings) will generally be questions of fact. *See Estate of LaMontagne v. Bristol-Myers Squibb,* 127 Wn. App. 335, 343, 111 P.3d 857 (2005) (evaluating adequacy of warnings on summary judgment); *Ayers v. Johnson & Johnson Baby Prods. Co.*, 117 Wn.2d 747, 752-58, 818 P.2d 1337 (1991) (reviewing effect of warnings for substantial evidence post-trial).

The evidence before the superior court in this case creates a genuine issue of material fact regarding Medtronic's failure to warn. Under the WPLA, the adequacy of warnings is determined by an analysis of the warnings "as a whole," including the "context" and "manner of expression" together with the meaning of the language used. *See LaMontagne,* 127 Wn. App. at 344. "The question is, *Was the warning sufficient to catch the attention of persons who could be expected to use the product*; to apprise them of its dangers and to advise them of the measures to take to avoid those dangers?" *Little v. PPG Indus., Inc.,* 92 Wn.2d 118, 122, 594 P.2d 911 (1979) (emphasis added); *accord LaMontagne,* 127 Wn. App. at 344

(citing *Little*).[31] Under this standard, the lack of any warnings on the Laser Shield box creates a genuine issue of material fact for the jury. This is especially so in light of the fact that the name "Laser Shield" misleadingly connotes protection from surgical lasers that Medtronic's product does not actually provide, as confirmed by Ms. Anderson's human factors expert and Dr. Paugh's testimony.

The superior court improperly focused on the fact that Dr. Paugh did not read or request a copy of the IFU before using the Laser Shield II as absolving Medtronic of its duty to warn. The court's focus is too narrow to the extent that it ignores the lack of warnings on the box. While failure to read or request a copy of the IFU may be relevant, it is not dispositive.[32] Even if the physician is generally aware that medical devices have IFUs, a warning on the box serves as a reminder of important warnings contained in the

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[31] One of the objectives that warnings must accomplish is to "attract attention," which may require "a printed statement on a container box." Kenneth R. Laughery, *Safety Communications: Warnings,* 37 Applied Ergonomics 467, 468 & 469 (2006). A copy of the Laughery article is reproduced in the Appendix to this brief.

[32] *Cf. Baker v. St. Agnes Hosp.*, 70 A.D.2d 400, 403-04 & 406, 421 N.Y.S.2d 81 (1979) (finding question of fact regarding failure-to-warn claim, even though physician "did not consult the package insert," in part because "[t]here is no system for insuring, or even making it likely, that the physician sees the insert"). *Baker* is cited with approval in *Martin v. Hacker,* 83 N.Y.2d 1, 8, 607 N.Y.S.2d 598, 628 N.E.2d 1308 (1993), which is in turn cited with approval in *LaMontagne,* 127 Wn. App. at 344.

IFU, or of the need to read the IFU before use. As explained by one commentator:

> The reminder function of warnings can be thought of in terms of the distinction between knowledge and awareness. A person may have knowledge about a product hazard, the potential consequences, and the appropriate safe behavior in using it, but the important issue is being aware of it at the proper time. Hence, a purpose of warnings may be to call into awareness information that may be latent in long-term memory or unavailable due to other demands on attention. The auditory signal and visual symbol in vehicles that remind occupants to fasten seat belts are examples of reminders.

Laughery, *supra*, at 469 (in the Appendix). An appropriate reminder on the Laser Shield II box is comparable to, and at least as important as, a seat belt alarm in an automobile. *See* RP 89:5-90:17 (9/20/13); *see also* RP 92:5-93:2 (9/20/13) (drawing analogy to speed limit signs at intervals along the road).[33] As a result, the superior court erred in granting summary judgment in Medtronic's favor and dismissing Ms. Anderson's failure-to-warn claim.

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[33] Contrast *Throngchoom v. Graco Children's Prods., Inc.*, 117 Wn. App. 299, 306, 71 P.3d 214 (2003), *rev. denied*, 151 Wn.2d 1002 (2004), where the court affirmed summary judgment in part because the product itself contained a warning directing the user to read the instruction sheet and contact the manufacturer if an instruction sheet is not otherwise available.

C. For the guidance of the superior court on remand, the court should hold that strict liability is the standard for failure-to-warn claims in the medical context.

Under the WPLA, it is not settled whether failure-to-warn claims in the medical context are based upon strict liability or negligence. *See Young v. Key Pharms., Inc.*, 130 Wn.2d 160, 922 P. 2d 59 (1996) (4-4 split decision); *see also* WPI 110.03 comment (discussing *Young*). The superior court below did not address the standard of liability, and regardless of the standard that applies, Ms. Anderson has produced sufficient evidence to withstand summary judgment on her failure-to-warn claim. However, this court should address the standard in order to provide guidance to the superior court on remand. *See Caruso v. Local Union No. 690,* 100 Wn.2d 343, 352, 670 P.2d 240 (1983) (addressing issues subject to remand).

Although the Court of Appeals decision in *LaMontagne* applies a negligence standard to failure-to-warn claims in the medical context, *LaMontagne* should be overruled as incorrect and harmful. *See State v. Stalker,* 152 Wn. App. 805, 219 P.3d 722 (2009) (noting incorrect and harmful standard for Court of Appeals to overrule its own precedent). A negligence standard is applied to

at least some design claims in the medical context, based on the "learned intermediary doctrine" described in the Restatement (Second) of Torts § 402A comment *k* (1965). *See Ruiz-Guzman v. Amvac Chem. Corp.*, 141 Wn.2d 493, 505-09, 7 P.3d 795 (2000). The negligence standard is justified because a physician presumably has training that enables him or her to assess the adverse health effects of a medical product prescribed for a patient. *See id.* at 508.[34]

However, a negligence standard should *not* be applied to failure-to-warn claims in the medical context, for the reasons stated in the dissenting opinion in *Young, supra*. The dissent, authored by Justice Madsen and joined by three other justices, points out that application of the learned intermediary doctrine is premised on the fact that the product is "*accompanied by proper directions and warning*." *See Young,* 130 Wn.2d at 181 (Madsen, J., dissenting; quoting comment *k*; emphasis in original). "By its express terms,

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[34] Although comment *k* has been described as a "blanket exemption from strict liability for design defect claims on all prescription medical products," *Transue v. Aesthetech Corp.*, 341 F.3d 911, 916 (9th Cir. 2003), this is not entirely correct. The Washington Supreme Court has never held that there is a "blanket exemption." While the lead opinion in *Young,* 130 Wn.2d at 170, rejected a product-by-product approach, the opinion was not joined by a majority of the Court. *See also Ruiz-Guzman*, 141 Wn.2d at 508 (declining to determine whether comment *k* should be applied on a product-by-product basis). Ms. Anderson did not contest application of comment *k* in this case, and the issue of a blanket versus product-by-product exemption is thus not before the court.

comment *k* protection from strict liability is not available to a manufacturer who fails to adequately warn." *Id.* at 181.

In addition, the purpose of comment *k* does not encompass failure-to-warn claims. As explained by Justice Madsen:

> In addition to the express language of comment k requiring adequate warnings as a prerequisite to immunity from strict liability, the theoretical underpinnings of that exclusion support a rule of strict liability for defects in warnings. Considering the usefulness of certain products which are unavoidably unsafe by nature, relieving the manufacturer of such products from strict liability, which would otherwise attach to a product which cannot be made safe even for its intended use, may be justified. The risk of using a product which cannot be made safe then shifts to the user. When the risk of use is shifted, however, it must be a risk which is fully appreciated. The consumer is in no position to know these risks and thus, comment *k* requires the manufacturer to adequately warn and properly manufacture such products to justify the reduced liability for placing an unavoidably unsafe product into the stream of commerce.

See id. at 187-88. In sum, comment *k* establishes a "very limited" exception to the rule of strict liability. *Id.* at 181.

LaMontagne is incorrectly decided to the extent that it ignores the split-decision in *Young*, and in particular, the reasoning of Justice Madsen's dissenting opinion in the case. Furthermore, the *LaMontagne* decision is harmful because it upsets the careful balance between the rights of consumers and product

manufacturers under the WPLA. *See* Laws of 1981, Ch. 26, § 1. For purposes of remand, the court should hold that the strict liability standard applies to Ms. Anderson's failure-to-warn claim.

D. The superior court erred in awarding costs to Medtronic for entire depositions, despite the language of RCW 4.84.010(7) allowing such costs only to the extent such deposition were used at trial.

RCW 4.84.010(7) provides:

> To the extent that the court or arbitrator finds that it was necessary to achieve the successful result, the reasonable expense of the transcription of depositions used at trial or at the mandatory arbitration hearing: PROVIDED, That the expenses of depositions shall be allowed on a pro rata basis for those portions of the depositions introduced into evidence or used for purposes of impeachment.

Medtronic sought and obtained an award of costs for, entire depositions, without any attempt to demonstrate that the costs were "necessary to achieve the successful result," nor to establish the pro rata cost for "those portions of the depositions" used at trial. In the absence of such a showing, the costs were awarded in error, and should be reversed.

VII. CONCLUSION

Based on the foregoing, Becky Anderson respectfully asks the Court to reverse the judgment in favor of Medtronic, including the

award of costs, and remand this case for retrial of her defective design and failure-to-warn product liability claims.

Respectfully submitted this 21st day of May, 2014.

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CERTIFICATE OF SERVICE

The undersigned declares under oath and penalty of perjury of the laws of the State of Washington:

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

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APPENDIX

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

BECKY ANDERSON, a single person,

Plaintiff,

vs.

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

Defendants.

No. 12-2-17928-0 SEA

COURT'S INSTRUCTIONS TO THE JURY

DATED this 3rd day of December, 2013

Judge Michael J. Trickey

NO. 19

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

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

Second, that the plaintiff was injured; and

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

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

NO. 20

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

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

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

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

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

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 SUPPLEMENTAL AMENDED PROPOSED INSTRUCTIONS [CITED]

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

DATED this 2nd day of December, 2013.

LUVERA, BARNETT,
BRINDLEY, BENINGER & CUNNINGHAM

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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)

WPI110.02Manufacturer's Duty—Design
Washington Practice Series TM
Washington Pattern Jury Instructions--Civil
6 Wash. Prac., Wash. Pattern Jury Instr. Civ. WPI 110.02 (6th ed.)

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

WPI 110.02 Manufacturer's Duty—Design

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

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

outweighed

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

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

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

COMMENT
RCW 7.72.030(1).
The instruction was rewritten in 2012 to improve the use of plain language. The changes are intended for ease of juror understanding; no substantive change is intended. The committee has used an unusual format in setting forth the balancing test in

the first part of the instruction. The committee isolated the word "outweighed" in order to emphasize which factors are being balanced against which.

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

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

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

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

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

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

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

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

117 Wn.2d at 763.

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

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

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

Enhanced injury. In Couch v. Mine Safety Appliances Co., 107 Wn.2d at 241–43, the court discussed enhanced injury instructions in a design defect action brought under RCW 7.72.030. See also Baumgardner v. Am. Motors Corp., 83 Wn.2d 751, 522 P.2d 829 (1974). See WPI 110.02.02, Crashworthiness—Manufacturing and/or Design Defect.

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

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

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

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

[Current as of January 2012.]

6 WAPRAC WPI 110.02

END OF DOCUMENT

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Safety communications: Warnings ☆

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Abstract

This paper has two objectives: to identify and review factors that research has shown to be most significant in determining the effectiveness of warnings; and, to offer suggestions regarding challenges and opportunities for future research on warnings. In order for warnings to be effective, they must accomplish two objectives: they must be noticed and encoded; and they must provide understandable information needed for recipients to make informed decisions regarding compliance. A number of variables or factors have emerged as being especially significant in determining whether or not a warning achieves these objectives. These factors include both warning system design variables as well as characteristics of the target audience and the situation in which the warning is presented. While there has been significant progress in understanding the factors that influence warning effectiveness, there are also remaining challenges and opportunities. Challenges include issues associated with growing international trade such as language barriers, literacy and cultural values. Innovative approaches and opportunities are offered by developing communication technologies.

Keywords: Warnings; Safety communications

1. Introduction

Since the mid 1980s there has been a significant increase in research on safety communications, more specifically, warnings. This research has encompassed safety issues associated with both products and environments. While people from various disciplines have contributed to this research activity, a substantial portion of the research has been carried out by ergonomists and published in the ergonomics literature. It is not surprising, of course, that ergonomists have been involved in warnings matters. Warnings are part of the interface between people using and maintaining a product or environment, and such interfaces are the domain of ergonomics.

Factors that influence whether or not a warning will be effective have been a focus of research questions. At the same time, there has been a generally accepted underlying theoretical context for warnings research. The theoretical orientation has drawn on communication theory and human information processing theory, and it has served both as a means for organizing the research and for explaining and predicting warning successes and failures.

At a general level, there are two objectives that warnings must accomplish. First, they must attract attention; that is, they must be noticed and encoded. People do not generally search for warnings; thus, warnings must be conspicuous and they must encourage encoding the content. The second objective or requirement for success is that warnings must provide understandable information needed for recipients to make informed decisions regarding compliance. There is general agreement in the research literature as well as in design standards and guidelines that warnings should contain information about hazards, consequences, and instructions.

Warning design characteristics that maximize conspicuity and encoding and provide the three categories of information, however, are not the only factors that influence whether warnings will be effective. Another category of factors or variables that influences effectiveness includes characteristics of the target audience to whom the warning is directed as well as situational variables. People's familiarity with the product or environment and the perceived costs and benefits of complying or not complying are examples of such factors that play an important role in warning effectiveness.

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It is also important to note the concept of a warning system. The notion of a warnings being a label, a statement or picture in a manual, a posted sign, or an auditory alarm is much too narrow a view of how such safety information does or should get transmitted. There may be many components of a warning system for a given product or environment. The warning system for a product may include a printed statement on a container box, a package insert, a user's manual, and a verbal message at the point of purchase. How such components interact and compliment each other is an important consideration in warning design. For example, different components may play different roles in the communication. Some components may be intended to capture attention and then direct the user to another component for detailed information. Also, different components may be intended for different target audiences. Prescription drug warnings in communications to physicians may employ language more technical than the language on the label on the pill container that gets to the consumer.

There have been several published reviews and collections of the warnings research literature. A book by Edworthy and Adams (1996) provided a general review of visual and auditory warnings. Other reviews published include Laughery and Wogalter (1997), Rogers et al. (2000), Wogalter et al. (1999), and Wogalter and Laughery (press a and b). Two collections of papers published in the *Proceedings of the Human Factors and Ergonomics Society* have also been assembled and published (Laughery et al., 1994; Wogalter et al., 2001). Finally, Wogalter (2006) has edited a substantial handbook collection of papers reviewing the warnings literature.

It is not the purpose of this paper to provide another general review of the research literature on warnings. Rather, the intent is briefly to provide some context for examining warnings research, and then to identify and describe those factors that have been shown to be most significant in determining warning effectiveness. The context to be presented includes the following topics: where warnings fit in the general field of safety; the purpose of warnings; a brief history of recent warnings research; and a brief summary of relevant theory. The presentation of significant research findings will be organized on the basis of factors or variables that; (1) influence noticing and encoding warnings, and (2) factors that influence compliance decisions. Within each of these two warnings objectives, the discussion will be organized on the basis of warning system design factors and target audience/situational factors.

The last section of the paper will explore challenges and opportunities for future warning research. While warning research to date has resulted in substantial progress in understanding design and effectiveness issues, it has had a somewhat traditional focus. The issues and variables explored have merited the time and attention they have received, but there are challenges and opportunities that can and should move closer to the center of the research stage. For example, growing international trade creates issues of greater target audience diversity, language barriers, illiteracy and cultural considerations. The ever-accelerating sophistication and availability of technology creates opportunities for applying that technology to warnings.

2. Where do warnings fit in?

In the field of safety, as well as in ergonomics, there is a concept usually referred to as the *safety hierarchy* or the *hazard control hierarchy* (Sanders and McCormick, 1993). This hierarchy is a set of priorities for dealing with hazards. There are three approaches in the priority sequence; design, guard and warn. If there is a hazard associated with a product or environment, the first and preferable approach is to design it out; that is, to eliminate it through an alternative design. Eliminating a pinch point in industrial equipment or substituting a non-toxic chemical for a toxic component in a solvent are examples of alternative design solutions. Of course, it is not always technologically and economically feasible to design out hazards.

The second priority in the hierarchy is guarding. The intent of guarding is to prevent contact between people and the hazard. This approach may take the form of physical guards such as personal protective equipment (goggles, hard hats, rubber gloves, etc.), highway barricades, and fences around electrical stations and swimming pools. Guarding may also be procedural such as controls on a punch press that require simultaneous inputs by the two hands, thus preventing one of the hands being under the piston when it strokes. There are still other forms of guarding, such as the physician's prescription needed to purchase certain medications. But guarding, like alternative design, is not always a feasible solution to hazards.

The third line of defense against hazards is warning. Warnings, of course, are intended to provide people with information needed to use a product safely or to function safely in some environment. There are reasons why warnings are third in the safety hierarchy behind design and guard. People may not see or hear a warning, they may fail to understand it, or they may simply not be sufficiently motivated to comply. Influencing or controlling behavior is often difficult and seldom foolproof. However, such concerns are not a basis for not warning. Rather, warnings should be regarded as one tool or approach available to designers and manufactures for addressing product and environmental safety.

3. Purpose of warnings

Warnings are safety communications, and they are intended to communicate information about safety issues or problems. There are four perspectives from which the purpose of warnings can be addressed. These perspectives are referred to as safer world, provide information, influence behavior, and reminder.

3.1. Safer world

At the most general level, a purpose of warnings is to make the world a safer place. Reduced accidents and injuries and improved health would be metrics for evaluating the effectiveness of warnings at this level. Warnings on cigarette packs are intended to reduce health effects of smoking. Warnings about using seat belts in vehicles are intended to make such travel safer.

3.2. Provide information

As a communication, a warning is intended to provide information for the target audience to whom it is directed. Considerable agreement has emerged that warnings should include information about the hazard, information about the potential consequences, and instructions regarding safe and unsafe behavior. This information can then be used to make informed decisions regarding compliance. Such decisions can be viewed as including a cost-benefit analysis that involves making judgments about the level of risk people are willing to accept or not accept.

3.3. Influence behavior

Warnings can also be viewed as an effort to influence or control behavior. If the person using a toxic solvent that can cause chemical burns on the skin does not wear the rubber gloves as instructed in the warning, the warning is considered a failure. In short, this purpose of warnings focuses on whether the behavioral intent of the warning is achieved.

3.4. Reminder

The reminder function of warnings can be thought of in terms of the distinction between knowledge and awareness. A person may have knowledge about a product hazard, the potential consequences, and the appropriate safe behavior in using it, but the important issue is being aware of it at the proper time. Hence, a purpose of warnings may be to call into awareness information that may be latent in long-term memory or unavailable due to other demands on attention. The auditory signal and visual symbol in vehicles that remind occupants to fasten seat belts are examples of reminders.

4. Brief history of warnings

In a brief but interesting history of warnings, Egilman and Bohme (2006) point out there were many examples of requirements, standards and guidelines for warnings prior to the 1980s, but relatively little formal research existed to serve as a basis for such efforts. However, as noted earlier, the mid 1980s witnessed a noteworthy upsurge in warnings research, and the past 20 years have produced a substantial body of knowledge regarding warning design and effectiveness. Initially during this period, research efforts tended to focus simply on the question "Do warnings work?" But the research quickly broadened to focus on design issues that influence when and how they work. Typical of the questions asked were how size, color, choice of signal word, and reading level influence warning effectiveness. Research further broadened to encompass other questions about effectiveness including the role of non-design issues such as target audience characteristics and situational factors.

Two other points can be noted about warnings research carried out during the past 20 years. The first point concerns methodology. Research on the design and effectiveness of warnings is neither simple nor easy. There are numerous ethical constraints and measurement issues. Ethics preclude exposing research participants to actual hazards. Dependent measures are often necessarily indirect, including assessments of comprehension, behavioral intentions and simulated performance. While necessary and important, such methodological approaches leave concerns such as the fidelity of simulations and the degree to which behavioral intentions predict behavior. Young and Lovvoll (1999), Wogalter and Dingus (1999), and Smith-Jackson and Wogalter (2006) have addressed these and other related methodological considerations. The second point about the 20 years of research is that there has been progress. While one can always cite the traditional statement "more needs to be done," a lot has been learned about when, where and why warnings work or do not work.

5. Theoretical approaches

Two theories or models have characterized most of the theoretical efforts regarding warnings: communications theory and human information processing theory. It is not the intent to discuss these efforts in detail in this paper. Rather, a brief description will indicate how these approaches have been employed for organizing and conceptualizing research on warnings. The typical, basic communication model has four components: the source, the medium, the message and the receiver (see Fig. 1).

These components can be viewed as follows:

Source—The designer, originator, sender of the warning message;
Medium—How the message is presented or displayed;
Message—The content of the warning;
Receiver—The target audience of the warning.

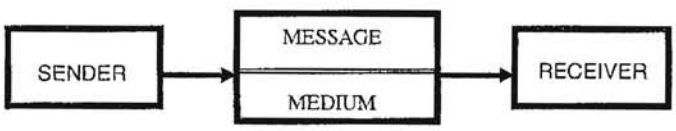


Fig. 1. Basic communication model.

The human-information processing framework a stages model, consisting of stages through which warning information flows. At each stage the information is processed and, if successful, "flows" to the next stage. Processing failure at any stage can block the flow and result in the warning not being effective. Wogalter et al. (1999) combined the communications and human-information processing models into a single theoretical framework for warnings (C-HIP). Their C-HIP model is displayed in Fig. 2. Similar models have been presented by others (Lehto and Miller, 1986; Rogers et al., 2000).

The feedback loops indicated on the right of Fig. 2 indicate that what happens at one stage can influence other stages. For example, if a warning is noticed and encoded (the attention stage), but the person did not understand the message, that person may read it again. Thus, the processing of a warning message may be more complex than a simple flow of information through a linear sequence of stages.

Models such as C-HIP have been useful in organizing the research literature. They have also been useful in diagnosing warning failures. Identifying where in the stages of processing failures occur enables the warning designer to focus on alternative designs that increase the likelihood of success. The following two sections present a discussion of factors that research has shown to be most significant in e success or failure of warnings in capturing attention noticing and encoding) and providing information needed to make informed compliance decisions.

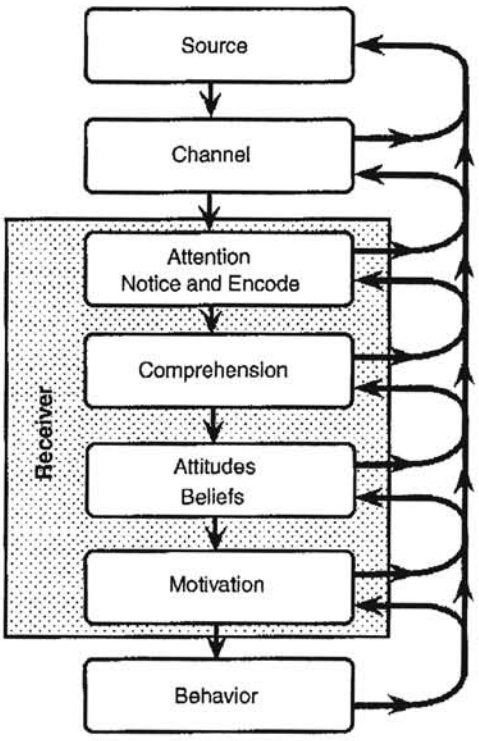


Fig. 2. The C-HIP model.

6. Attention (noticing and encoding)

As noted earlier, one of the objectives for warnings is to attract attention; that is to be noticed and encoded. Research reported during the last 20 years has shown a number of factors to be significant determinants of this objective. These factors include both parameters of the warning system design as well as characteristics of the target audience for whom the warning is intended and the situation is which it is presented.

6.1. Warning system design

Several design factors influence whether or not a warning will be noticed and encoded. Generally, they are factors that would be expected to matter: size, location, color/contrast, signal word, and a pictorial.

6.1.1. Size

Although bigger is usually better, the important design consideration is the size of the warning relative to other displayed information. Barlow and Wogalter (1991, 1993) found that bigger print enhanced later recall (encoding), and Young and Wogalter (1990) reported bigger, bolder print in owner's manuals led to improved memory for warnings. These and other similar findings are likely due to greater conspicuity with larger and bolder print.

6.1.2. Location

While typically warnings should be placed physically and temporally close to the hazard, the issue of where to place a warning can be somewhat more complex. For example, activities or tasks in which the target audience is likely to be engaged should be taken into account so as to maximize the likelihood the warning will be encountered. Laughery et al. (1993) found that a warning on the front label of an alcohol beverage container where the product identification is located is more likely to be noticed and read than a warning on a back or side label. Wogalter et al. (1987) reported that warnings located before instructions for carrying out a task were more likely to be noticed and encoded than warnings located after the instructions. Presumably people will stop reading after processing the needed instructional information.

Constraints such as container size may limit where a warning can be placed, such as the label on a small pharmaceutical container (bottle of pills). Barlow and Wogalter (1991) have studied tags and extended labels as techniques for increasing surface area to accommodate warnings. Another approach is to put attention getting warning information in a prominent location and direct the person to a secondary warning component for more detailed information. Examples of such secondary components are package inserts and manuals.

6.1.3. Color/contrast

A great deal of research has shown that color or other forms of contrast increases the noticeability of warnings as well as the likelihood the information will be encoded (e.g., Braun and Silver, 1995). Also, different colors have been shown to connote different levels of hazard (e.g., Klein et al., 1993) as discussed in the next section on signal words.

6.1.4. Signal word

There are three signal words commonly used in warnings to attract attention and to indicate hazard level. In order of increasing hazard level the words are CAUTION, WARNING and DANGER. CAUTION connotes hazards where minor injury or damage to property *might* occur. WARNING is intended for hazards that *might* result in serious injury. The word DANGER is for hazards that *will* cause serious injury.

The three signal words are typically associated with a particular color; specifically CAUTION, WARNING and DANGER go with yellow, orange and red, respectively. It is common, and consistent with various standards and guidelines, for the signal word–color combination to be embedded in a panel that also includes an alert symbol (triangle enclosing an exclamation point). Fig. 3 presents an example of such panels that would be part of a print warning.

Research shows the word DANGER is more likely to attract attention than CAUTION or WARNING (e.g., Adams et al., 1998). With regard to hazard level, people do not readily differentiate between CAUTION and WARNING; but both words are interpreted as connoting lower hazard levels than DANGER (Wogalter and Silver, 1995).

6.1.5. Pictorials

Pictorials in warnings serve two functions; they attract attention and they convey content information. Pictorials may take different forms including actual photographs, representative drawings, and abstract symbols.

A number of studies have shown that pictorials in warnings contribute to capturing attention (e.g., Davies et al., 1998). Several studies have shown that they also enhance encoding and increase comprehension (e.g., Boersema and Zwaga, 1989). In terms of noticing and encoding warnings, pictorials are particularly useful where there are target audience concerns such as language barriers and illiteracy. Also, because a great deal of information may be obtained from a glance, pictorials can be important in situations where there are time constraints.

As with the text of a warning, pictorials may be used to communicate hazard, consequences or instructional information. Two pictorials intended to communicate hazards are shown in Fig. 4.

Fig. 5 shows two pictorials indicating consequences information.

Fig. 6 presents two pictorials indicating instructional information.

Fig. 3. Signal word panels.

(a) Fire hazard

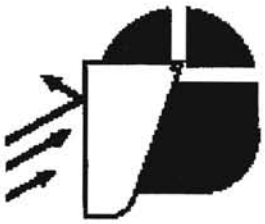
(b) Inhalation hazard

Fig. 4. Pictorials indicating hazards.

(a) Electrocution

(b) Hand injury

Fig. 5. Pictorials indicating consequences.



(a) Wear face mask

(b) Wash hands thoroughly

Fig. 6. Pictorials indicating instructions.

(a) Do not enter

(b) Biohazard

Fig. 7. Abstract information pictorials.

The pictorials in Figs. 4–6 are examples of direct representation; the information represented is expected to be recognized and understood from general experience and nowledge. The pictorials shown in Fig. 7, however, are abstract with respect to their meaning. The symbols for Do not enter and Biohazard must be learned in order to be understood. Generally, direct representation pictorials are preferred, particularly for general target audiences.

6.2. Target audience and situational factors

Characteristics of the target audience for whom the warning is intended and the situation in which it is presented are also factors in whether or not a warning will be noticed and encoded. Two factors that research has shown to be particularly important are perceived hazard and familiarity.

6.2.1. Perceived hazard

People's a priori perceptions of hazards associated with a product or environment are important determiners of whether or not they will look for and read warnings. Numerous studies (e.g., Otsubo, 1988; Wogalter et al., 1991) have shown that the greater the level of perceived hazard, the more likely people will look for, read, and encode warning information.

6.2.2. Familiarity

In the context of warnings, familiarity refers to experience with a specific or similar product or environment. Many studies have explored the role of familiarity in whether a warning is noticed and encoded. Generally the results (e.g., Godfrey and Laughery, 1984) have shown that people who are more familiar with products or environments are less likely to look for or read warning labels. This finding assumes, of course, that the persons have not had a related negative safety experience. A likely explanation for these findings is simply that greater familiarity has resulted in lower perceived hazardousness of the product or environment, and this perception, in turn, results in less motivation to seek or process safety information. Conversely, and more simply, if people are looking for a warning, they are more likely to notice and encode one that is present.

6.3. Summary

The warnings research reported over the past 20 years has provided a good basis for understanding the factors that are most significant is determining whether a warning gets noticed and encoded. The design factors are what one would expect. They include size, location, color/contrast, signal words, and the use of pictorials. But target audience variables also influence a warning's success in being noticed and encoded. Two that seem most important are perceived hazard and familiarity.

There are, of course, other factors that play a role in noticing and encoding warnings. With regard to design, these additional factors include message length, number of warnings (over warning), context (surrounding information), and multiple-modality presentations. Target audience factors that can potentially have a role are many. For example, two that have received significant research attention are gender and age. While there are somewhat consistent findings associated with their role in attending to warnings, the effects of gender and age have not been so

robust as perceived hazard and familiarity. Obviously, it is not suggested that these additional design and target audience factors be ignored in the design and implementation of warning systems. Rather, the intent here is to identify those factors that research has indicated are most significant so that the warning system designer can prioritize the various factors that must be considered in the design process.

7. Compliance decisions

Compliance decisions can be viewed as including a cost-benefit tradeoff analysis. On reason people may not comply with a warning is that the costs of compliance are perceived to outweigh the benefits. Costs may take the form of money, time, effort, and so on. Benefits may include avoiding accidents and injuries, negative health effects, and property damage. It should be recognized that carrying out the behaviors instructed in a warning may not always be the most rational decision outcome. If rubber gloves and goggles are not available and there are significant time and convenience costs to getting them, the homeowner cleaning a drain may decide to handle the drain cleaner (basically sulfuric acid) carefully instead of obtaining the two items of protective equipment prescribed by the warning.

Whether or not people using a hazardous product or performing some task in a hazardous environment decide to comply with a warning depends on both the design of the warning system and the characteristics of the people and the situation. In this section, these two categories of factors are examined, with the emphasis on those factors that research has shown to be most significant in influencing warning effectiveness.

7.1. Warning system design

Many aspects of the warning system design can influence compliance. Three to be discussed here are the factors that influence noticing and encoding, pictorials, and explicitness.

7.1.1. Noticing and encoding factors

Obviously, factors that influence noticing and encoding are important in determining whether compliance behavior occurs. If the warning is not noticed and encoded, it cannot have a direct effect on behavior. Hence, the factors reviewed earlier that influence noticing and encoding are expected to be positively correlated with likelihood to comply. Research results generally support this expectation. Reviews and analyses of these findings can be found in Kalsher and Williams, 2006, Rogers et al., 2000 and Silver and Braun, 1999.

7.1.2. Pictorials

In a previous section it was noted that pictorials play a significant role in warnings being noticed and encoded. A substantial number of studies (e.g., Jaynes and Boles, 1990; Wogalter et al., 1997) have also been reported showing the presence of pictorials increases compliance compared to warnings without pictorials.

Two explanations for the role of pictorials in compliance seem justified. First, pictorials enhance noticing and encoding, thus making it more likely the warning information is received. The second point concerns content. Pictorials provide information regarding the hazard, consequence or instruction, thus enabling the recipient to make better-informed compliance decisions.

7.1.3. Explicitness

The explicitness of content information has emerged as an important factor in warning effectiveness. Laughery and Smith (2006) have recently reviewed and summarized the findings of a number of studies dealing with this topic. Explicitness is defined as information that is specific, detailed, clearly stated, and leaving little or nothing implied.

For example, suppose a person works in an industrial environment and uses a chemical product that emits toxic fumes. Further, suppose the inhalation of the vapors can lead to severe and permanent lung damage and, therefore, it is important to wear a particular type of respirator when working with the chemical. The following warning text contains hazard, consequence and instruction information:

> Hazardous Environment
> Potential Health Effects
> Use Appropriate Precautions

The above warning will be of little or no use to the person exposed to the hazard. It is a classic example non-explicit warning. The hazard statement "Hazardous Environment" communicates little about what the safety problem is; the consequences statement "Potential Health Effects" only notes a potential problem having to do with health; and the instruction "Use Appropriate Precautions" is essentially useless in telling the user what to do or what not to do.

Consider the following alternative warning:

> Toxic Chemical Vapors
> Can Result in Severe Lung Damage
> Always Wear Type XYZ Respirator in Area

These two examples emphasize the importance of providing explicit information that will enable people to make informed judgments and decisions.

Laughery and Smith (2006) address the importance of explicit information for all three warning content categories; hazard, consequences and instructions. They conclude that explicitness of information in all three categories plays an important role in compliance.

From a motivational perspective it is foreseeable that more explicit information influences compliance. More specific information about hazards and consequences enables people to make better-informed costs-benefit tradeoff decisions regarding compliance. Further, explicit information should be especially significant when consequences are more severe. Research findings confirm this expectation. Also, more explicit instructions enable people to better understand and carry out appropriate actions, a common research outcome.

7.2. Target audience and situational factors

Several target audience and situational factors have been shown to influence warning compliance. Three factors that play a significant role are familiarity, modeling and cost of compliance.

7.2.1. Familiarity

The effects of familiarity on compliance are somewhat complex. It appears that the effect interacts with the nature of the experiences people have had with a product or environment. Assuming no negative safety experiences, a substantial amount of research generally indicates that greater familiarity leads to lower levels of compliance with warnings (e.g., Burnett et al., 1988; Harrell, 2003; Wogalter et al., 1995). However, some research has shown familiarity increases compliance. For example, Ortiz et al. (2000) found that when people were asked to apply pesticides to plants, familiarity with the product resulted in greater compliance with a warning to use personal protective equipment.

An explanation for the mixed effects of familiarity on compliance is that it may be mediated by perception of hazard. The idea that "familiarity breeds contempt" may be involved in the sense that greater familiarity leads to lower levels of perceived threat that, in turn, results in non-compliance. In terms of the costs/benefits tradeoff decision, familiarity results in lower costs associated with non-compliance.

7.2.2. Modeling

People's behavior is influenced by social context and the behavior of others around them. This effect includes compliance or non-compliance with warnings. Several studies have been reported in the warnings research literature that show a quite robust effect of modeling on compliance with warnings. For example, deTurck et al. (1999), Edworthy and Dale (2000) and Wogalter et al. (1989) reported greater compliance with warnings to use protective equipment when others were observed using such equipment.

How does the cost-benefit tradeoff analysis involved in the compliance decision take into account the modeling effect? A possible explanation is that the actions or behaviors of others is a form of instruction; that is, it provides information regarding the safe mode of behavior, thus enabling a more informed analysis. It may also be a form of social influence in the sense of being motivated to behave as others do.

7.2.3. Cost of compliance

There may be various types or forms of costs associated with complying with a warning, including time, effort, convenience, money, etc. There has been considerable research on the effects of such costs on warning compliance, and the results have shown consistent and quite robust effects. As already discussed, the decision to comply or not comply can be viewed as including a cost-benefit analysis in which compliance costs represent half the equation. Thus, it is not surprising that cost of compliance is a very important factor in warning effectiveness.

Several reviews of the cost of compliance research have been published, including Silver and Braun (1999) and Rogers et al. (2000). Specific studies will not be reviewed here except to note that the effects of this variable on compliance has been explored in a variety of settings. The outcome of the research clearly shows that lower costs lead to significantly greater compliance with warnings.

7.2.4. Summary

The past 20 years of research have contributed a great deal to our understanding of factors that influence warning compliance. Obviously, for a warning to be directly effective, it must be noticed and encoded. Therefore, design factors such as size, location, color/contrast, signal word, and pictorials are important. Of course, the content of the warning, a design factor, plays a critical role in compliance. As discussed, the explicitness of the hazard, consequence, and instructional information has been shown to be quite important. More explicit information leads to greater compliance. This conclusion seems especially valid for consequences information when the outcome of the hazard may be severe. The research also indicates that three target audience or situational factors warrant special emphasis regarding their effects on compliance decisions: familiarity, modeling and cost of compliance. Indeed, cost of compliance would appear to be one of the most important considerations for the warning designer as well as the system designer to keep in mind.

8. Where do we go from here?

Warning research during the last 20 years has provided substantial progress in understanding warning design and effectiveness issues. A goal of this paper has been to emphasize and to describe some of this progress. A lot has been learned that can and should lead to more effective warning systems that in turn contribute to product and environmental safety. However, while the issues and factors addressed by the research have merited the attention received, the focus has been somewhat traditional. There are several challenges and opportunities that can and should be the focus of future research. Among the

challenges in warning design is the need to communicate to more diverse audiences, a result of factors such as growing international trade. Opportunities for future warning design include greater use of increasingly sophisticated technology in warnings.

8.1. Target audience

Language barriers, illiteracy and social/cultural values are examples of potentially increasing concerns for the warning designer. These concerns are influenced by factors such as growing international trade. To date, there has been limited research effort addressing such matters.

Presenting warnings in more than one language is, of course, an approach to dealing with language barriers. Currently, this approach is employed for products that are marketed in different countries. The typical approach is to have a booklet or manual containing instructions and warnings printed in several languages. The consumer turns to the relevant language section to access the information. While this approach may work in most instances, it can represent a modest cost to the consumer in finding the information, and such costs may have the potential for defeating the effectiveness of warning information. How to organize and present such information merits some research attention to determine effective multi language warnings.

Pictorials, of course, are an approach to addressing language barrier and literacy concerns. Research is needed to better understand how pictorials are understood across cultures. Are there universals? That is, are there pictorials, including symbols such as the circle/slash negation sign, whose meaning is consistent across cultures?

The concern for literacy may require a broader perspective about how warnings are constructed and presented. Warnings presented in ways other than the printed, visual mode may represent necessary alternatives. Warnings presented verbally (speech) or by demonstration may play a greater role. The point here is that alternative approaches need to be developed and researched.

Social/cultural differences may represent a number of challenges for the warning designer. Different cultures may have different views regarding the responsibility individuals are expected to assume for their own safety. Such differences could have substantial implications for how warning systems are designed.

The above examples of target audience diversity issues are but a few ideas about the kinds of concerns of increasing importance to warning system design in the future. Research is needed to better understand these issues and to provide guidance for designing warning systems that effectively address them.

8.2. Technology and warnings

To date, technology has played a relatively limited role in the design of warning systems. While there are many exceptions, most warnings still take the form of static, printed language or pictorials. In today's vehicles, warnings are likely to be in the form of labels on the sun visor or statements/pictorials in the owner's manual. If the occupant does not fasten the seat belt, a temporary auditory signal may sound and a small light will come on, but with one or two exceptions, no vehicles will tell the occupant in spoken language to fasten the seat belt (a technology that has been available for at least a couple of decades).

Some of the exceptions to the static, printed format are warnings presented on television and on the Internet. In the United States TV commercials for prescription drugs typically contain warnings about contraindications and side effects. The form of the warning in the TV commercial may be spoken, printed on the screen, or both. Internet advertisements, particularly for products such as medications, may also include warning information.

Wogalter and his colleagues have explored a number of issues associated with applying technology to warning system design in several recent publications (Smith-Jackson and Wogalter, 2004; Wogalter and Conzola, 2002; Wogalter and Mayhorn, 2005, 2006). In this section, several ideas will be presented as to how technology might be explored and implemented for the design of warning systems. Specifically, these ideas include dynamic warnings using new technology displays, and hazard detection using sensors. At this point, these are examples of ideas that may be a basis for additional future research.

8.2.1. Dynamic warnings

Dynamic, changing warnings are more attention demanding than static warnings. Further, when a display such as a warning is static over time, it is subject to habituation; that is, it may no longer be noticed or processed. Dynamic warnings can reduce the problem of habituation. A visual warning can be dynamic in at least two respects. First, the warning may move or flash. Signs that consist of flashing lights are an example, such as the flashing street lights marking the beginning of a school zone. A warning may also be dynamic in the sense that the content changes over time. An example is the highway sign indicating road hazards (such as ice) that changes as the conditions change.

Technology for accomplishing dynamic displays is currently available. High-resolution plasma and liquid crystal displays (LCDs) are commonly available for computer displays and in high-definition televisions. Large flat-panel displays are used in sports stadiums and for advertisement billboards. These examples of electronic technologies can and should be explored for wider applications to communicating safety information (warnings).

An example of current technology being applied to warnings is shown in Fig. 8. The figure shows an in-vehicle navigation display with a warning shown on the screen.

Although this paper has focused on visual warnings, auditory warnings may also be enhanced by increased

Fig. 8. An in-vehicle navigation system displaying a warning.

dynamic qualities. For example, Haas and Edworthy (2006) and Edworthy and Hellier (2006) reported that the urgency of a simple fire alarm can be enhanced by adding more dynamic qualities such as varying the frequency and temporal aspects of the signal.

Recent, relatively inexpensive digitized voice technology has many potential applications in warnings design. Voice warnings have been shown to be a powerful method of conveying warnings and promoting compliance (Wogalter and Young, 1991). In a study by Conzola and Wogalter (1999), voice warnings were compared to print warnings for a task involving avoiding equipment damage. Results showed greater compliance with voice warnings than with print warnings.

Dynamic displays can be useful in influencing warning effectiveness in several ways. As noted, they can be more noticeable and reduce the problem of habituation. They are also valuable as a means for communicating hazard information that changes over time, thus enabling the receiver to be more adequately informed about safety information. Research is needed on the potential application of current technology to warning system design to develop more dynamic warning displays, as well as the role of such displays in achieving more effective warnings.

8.2.2. Hazard detection using sensors

A fundamental principle of warning system design is that warnings should be available when and where needed. Warnings too distant in location or time may not be recognized as relevant or may not be remembered. The use of hazard detectors in warning systems offer the potential for addressing several issues associated with warning effectiveness. Sensor systems are readily available for detecting heat, cold, wet, gas, vapors, motion, weight, and so forth. Examples of such detectors being integrated into current warning systems exist. The heat detector that is a component of a hotel fire alarm system and the gas detector that can be used in the home for signaling a possible gas leak are examples. There are several potential advantages of using such detectors as components of warning systems:

- Hazards could be warned only when they exist, reducing the problem of habituation to a permanent warning.
- The onset of a warning when the hazard is initially detected has the potential of more likely being noticed and encoded.
- Detectors can supplement people's sensory abilities, such as the detection of carbon monoxide or radiation.

The use of sensor technology combined with appropriate display technologies offers the potential for considerably more effective warning systems. In addition to the three advantages listed above, such warnings could employ content that varies and is appropriate to the magnitude of the hazard. For example, stronger and more explicit consequences information could be presented when the magnitude of the hazard is greater, such as a higher concentration of toxic fumes.

8.2.3. Summary

There are many potential applications of technology to the design of warning systems in addition to dynamic displays and hazard-sensing capabilities (see Wogalter and Mayhorn, 2006). These and other ideas warrant serious research activity to explore their potential for enhancing the contributions that good warnings systems can offer.

9. General discussion

This paper has had two objectives: to highlight the progress made by research on warnings design and

effectiveness over the past 20 years; and to suggest some challenges and opportunities for warnings research in the future. The perspective presented here is that warnings should be designed to be noticed and encoded and to provide the information needed for people to make informed decisions about compliance. The factors that research has shown to be most influential in determining whether or not warnings are successful in meeting these objectives can be placed into two categories; design parameters of the warning, and characteristics of the target audience and situation.

Considerable progress has been achieved. Design parameters most significant to warning success include format factors such as size, location, color/context, signal words and the use of pictorials. Content factors that are important are explicit information regarding hazards, consequences and instructions. Some of the most significant target audience and situation factors are the a priori perception of hazards and consequences, familiarity, modeling, and cost of compliance. It is not suggested that these factors are the only considerations relevant to warning success; but rather, the research seems to indicate that they are the more important ones. Stated differently, these are the factors the warning designer is well advised to carefully consider in designing a warning system.

Suggestions for future research directions are based on two considerations. First, growing international trade calls for a greater research emphasis on factors related to target audience diversity. This diversity may take the form of language barriers, illiteracy, and social/cultural norms. The second consideration is the availability of increasingly sophisticated technology applicable to warning system design. This technology could be applied to accomplish many objectives related to warnings, including more dynamic displays and detecting the presence and magnitude of hazards. Research progress on these fronts could and should result in more effective warning systems.

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