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JOSETTE TAYLOR, as Personal Representative of the Estate of FRED E.
TAYLOR, deceased; and on behalf of the Estate of FRED E. TAYLOR;
and JOSETTE TAYLOR,

Plaintiffs/Petitioners,

vs.

INTUITIVE SURGICAL, INC., a foreign corporation doing business in
Washington,

Defendant/Respondent.

FILED E
MAY - 6 2016
WASHINGTON STATE
SUPREME COURT

h/h

BRIEF OF AMICUS CURIAE
WASHINGTON STATE ASSOCIATION FOR JUSTICE FOUNDATION

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 ORIGINAL

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I. IDENTITY AND INTEREST OF AMICUS CURIAE

The Washington State Association for Justice Foundation (WSAJ Foundation) is a not-for-profit corporation under Washington law, and a supporting organization to Washington State Association for Justice (WSAJ). WSAJ Foundation is the new name of Washington State Trial Lawyers Association Foundation (WSTLA Foundation), a supporting organization to Washington State Trial Lawyers Association (WSTLA), now renamed WSAJ. WSAJ Foundation, which operates the amicus curiae program formerly operated by WSTLA Foundation, has an interest in the proper interpretation and application of the Washington Products Liability Act, Ch. 7.72 RCW (WPLA).

II. INTRODUCTION AND STATEMENT OF THE CASE

This case presents questions regarding whether a manufacturer of a medical device must provide adequate warnings to a hospital purchasing the device, and the proper standard of liability for failure to provide such warnings under RCW 7.72.030(1)(b). The case also presents the opportunity for the Court to clarify how the "proper directions and warning" requirement for invocation of Restatement (Second) of Torts, §402A comment *k* (1965) (comment *k*) is applied under the WPLA.

Josette Taylor, individually and as Personal Representative of the Estate of Fred E. Taylor (Taylor), brought this action against Intuitive Surgical, Inc. (ISI), surgeon Dr. Scott Bildsten and his partner and medical

practice (Bildsten), and Harrison Medical Center, a hospital (Harrison). The underlying facts are set forth in the Court of Appeals opinion and the briefing of the parties. See Taylor v. Intuitive Surgical, Inc., 188 Wn. App. 776, 355 P.3d 309 (2015), *review granted*, 184 Wn.2d 1033 (2016)¹; Taylor Supp. Br. at 2-6; ISI Supp. Br. at 3-6; Taylor Pet. for Rev. at 1, 3-11; ISI Ans. to Pet. for Rev. at 1-2, 3-7; Taylor Br. at 1, 4-39; ISI Br. at 1-3, 4-15.²

For purposes of this brief, the following facts are relevant: ISI sold a sophisticated medical device, a robotic surgical instrument, to Harrison. Harrison credentialed physicians to perform prostate surgery at the hospital using the ISI device. Fred Taylor's robotic surgery was performed by Bildsten at Harrison and went poorly. Ultimately, his estate sued Bildsten, Harrison and ISI under various theories of liability, including a product liability claim against ISI as manufacturer of the device. Taylor settled with Harrison and Bildsten and proceeded to trial solely against ISI for failure to provide adequate warnings regarding the device. The jury returned a verdict for ISI, and Taylor appealed.

In a split decision, the Court of Appeals affirmed. The majority opinion synthesizes the key issues and holdings as follows:

¹ The Court of Appeals opinion below is published in part. See Taylor, 188 Wn. App. at 780, 794. The issues discussed in this brief are addressed in the published portion of the Court of Appeals opinion.

² The Washington State Hospital Association (WSHA) filed an amicus curiae brief in this case in the Court of Appeals.

Taylor argues that the trial court erred by not instructing the jury that (1) ISI, manufacturer of the system used to perform the surgery, owed a duty to warn the hospital in addition to the surgeon, and (2) strict liability governed the duty to warn. In the published portion of this opinion, we hold that under the learned intermediary doctrine, ISI only had a duty to warn the surgeon and not the hospital. We further hold that a negligence standard governs the duty to warn a learned intermediary about a medical product.

188 Wn. App. at 779-80. The majority determined that Taylor was not entitled to an instruction that ISI had a duty to warn Harrison, see id. at 790-92, but the dissent disagreed, reasoning that "ISI's failure to warn Harrison could harm Harrison, the physicians, and the patient." Id. at 797 (Worswick, J., dissenting in part). Both the majority and dissent/concurrence seem to apply a negligence-based duty to warn under their comment *k* analysis. See Taylor at 792-94 (majority); id. at 794-98 (dissenting in part).

This Court granted Taylor's petition for review.

III. ISSUES PRESENTED

Under the WPLA:

1. Does the duty to provide adequate warnings or instructions with a product under RCW 7.72.030(1)(b) require the manufacturer of a medical device to adequately warn a hospital that purchases the device, furnishes it for use on hospital premises, and credentials physicians to use it?
2. Does a manufacturer seeking to avoid strict liability for defective design of a medical device under Restatement (Second) of Torts §402A comment *k* (1965), have a duty to warn based upon the strict liability standard of RCW

7.72.030(1)(b), or does a negligence-based duty to warn apply?

IV. SUMMARY OF ARGUMENT

WPLA Duty to Warn: Under the WPLA, the manufacturer of a medical device must provide adequate warnings and instructions to a hospital that purchases the device, furnishes it for use on hospital premises, and credentials physicians to use it. RCW 7.72.030(1)(b) requires these warnings and instructions to be “provided *with* the product.” (Emphasis added.) With the exception of *post-manufacture* warnings—which must be calculated “to inform product *users*,” RCW 7.72.030(1)(c) (emphasis added)—the WPLA does not otherwise specify who must receive warnings. This is consistent with the product-oriented focus of strict liability under the act. Who should receive warnings will depend upon the intrinsic nature of the product, the manner of distribution, and the uses to which the product will be put. This is a case-by-case inquiry.

This analysis of the statutory duty to warn does not hinge upon application of the learned intermediary doctrine, or characterization of the hospital as a learned intermediary. Under the learned intermediary doctrine, the manufacturer of a medical device can satisfy the duty to warn by giving adequate warnings or instructions to the physician who uses the device on the patient. While the doctrine relieves the manufacturer of any obligation to give the warning directly to the patient, it should have no

bearing on the manufacturer's obligation to provide adequate warnings with the product to purchasers and others in a position to prevent harm to the patient.

Comment k Warnings under the WPLA: Comment *k* does not purport to eliminate the duty to warn, nor does it purport to alter the strict liability standard for failure to warn under the WPLA. Instead, comment *k* merely alters the strict liability standard for defective design claims involving unavoidably unsafe products, when certain preconditions are met. The reason for limiting comment *k* to design claims is that, by definition, it is impossible for an unavoidably unsafe product to satisfy the strict liability standard for reasonably safe design. Nonetheless, a manufacturer is obligated, even with respect to unavoidably unsafe products, to provide adequate warnings for the product. Consequently, comment *k* expressly requires that adequate warnings must be provided regarding unavoidably unsafe products.

Applying the strict liability standard to warning claims involving unavoidably unsafe products is dictated by the language and policy of the WPLA. While at common law the Court arguably fashioned a negligence-based standard for such warnings, the WPLA limits the negligence-based standard of liability to *post-manufacture* warnings, see RCW 7.72.030(1) (c), and certain product sellers other than a manufacturer, see RCW 7.72.040(1). This approach is consistent with the Court's

recognition in Ruiz-Guzman v. Amvac Chem. Corp., 141 Wn.2d 493, 506, 7 P.3d 795 (2000), that while comment *k* is implicit in the WPLA, its application should be "sparing" so as not to "defeat the letter or policy of the WPLA."

To the extent that Estate of LaMontagne v. Bristol-Myers Squibb, 127 Wn. App. 335, 111 P.3d 857 (2005) holds to the contrary, it should be disapproved.

V. ARGUMENT

Introduction: The two issues discussed in this brief are addressed in the parties' briefing, and are dealt with here only in the abstract. See e.g. Taylor Supp. Br. at 6-8 (regarding WPLA duty to warn) & 12-17 (regarding nature of comment *k* warnings); ISI Supp. Br. at 8-11 (regarding WPLA duty to warn) & 18-22 (regarding nature of comment *k* warnings); see also WSHA Am. Br. at 1-2, 11-14.

A. **Brief Overview Of Washington Product Liability Law Under The Common Law And WPLA, Including Application Of Comment *k* With Respect To "Unavoidably Unsafe Products."**

Common Law Strict Liability: In 1969, this Court adopted strict product liability (strict liability) in Washington in Ulmer v. Ford Motor Co., 75 Wn.2d 522, 525-32, 452 P.2d 729 (1969), a case involving a manufacturing defect. In Ulmer, the Court abandoned the fiction of

warranty liability in favor of strict liability based upon the Restatement (Second) of Torts §402A (1965). See 75 Wn.2d at 532.³

Washington common law of strict liability was next refined in Seattle-First Nat'l Bank v. Tabert, 86 Wn.2d 145, 147-49, 542 P.2d 774 (1975), which extended strict liability for unreasonably dangerous products to other actors in the chain of distribution, including suppliers or sellers of the product. Tabert also clarified two additional points. First, strict liability was extended to claims based on defective design. See id., 86 Wn.2d at 149-50. Second, citing §402A and comment *i*, Washington's conceptual approach to strict liability was settled as focusing on "the consumer's expectation of buying a product which is reasonably safe." Id. at 152-54. The Court later characterized this standard as "a buyer-oriented standard based on the reasonable expectations of an ordinary user." Ryder v. Kelly-Springfield Tire, 91 Wn.2d 111, 117, 587 P.2d 160 (1978).⁴

In a frequently referenced passage from Tabert, the Court explained the focus of Washington common law strict liability as follows:

This evaluation of the product in terms of the reasonable expectations of the ordinary consumer allows the trier of the fact to take into account the *intrinsic nature of the product*. The purchaser of a Volkswagen cannot reasonably expect the same degree of safety as would the buyer of the much more expensive Cadillac. *It*

³ Section 402A allows for strict liability based upon manufacturing defect, defective design, and failure to warn. See Simonetta v. Viad Corp., 165 Wn.2d 341, 355 & n.7, 197 P.3d 127 (2008).

⁴ In choosing this conceptual path, the Court rejected a seller-oriented standard favored elsewhere. See Ryder, 91 Wn.2d at 117-18.

must be borne in mind that we are dealing with a relative, not an absolute concept.

In determining the reasonable expectations of the ordinary consumer, a number of factors must be considered. The relative cost of the product, the gravity of the potential harm from the claimed defect and the cost and feasibility of eliminating or minimizing the risk may be relevant in a particular case. In other instances the *nature of the product* or the nature of the claimed defect may make other factors relevant to the issue.

Id. at 154 (emphasis added).

In Teagle v. Fischer & Porter Co., 89 Wn.2d 149, 155, 570 P.2d 438 (1977), and Ryder, 91 Wn.2d at 117-18, the Court extended the principles announced in Tabert to the duty to warn context. In so doing, it noted that “[w]hile *Tabert* discussed the test in a defective design case, the standard would be the same where the product is claimed to be defective because of a failure to warn.” Ryder at 117 (citation omitted).

This common law buyer-oriented strict liability standard, with its focus on the product, was generally referred to as a “consumer expectations” test. Baughn v. Honda Motor Co., 107 Wn.2d 127, 134, 727 P.2d 655 (1986). However, as Baughn explains:

the *Tabert* rule actually combines the consideration of consumer expectations with an analysis of the risk and utility inherent in a product’s use. Thus, some commentators find it more accurate to call the *Tabert* test “a consumer expectations test with a risk-utility base.”

Id. (footnote citing quoted commentator and other commentary omitted).⁵

⁵ The last two sentences of the Tabert quote in the main text set forth the risk-utility factors.

WPLA Strict Liability: The WPLA was enacted in 1981. See Laws of 1981, ch. 27 (codified in RCW 7.72.010 et seq).⁶ In WWP v. Graybar Electric Co., 112 Wn.2d 847, 853-56, 774 P.2d 1199 (1989), the Court held the WPLA preempts the common law of product liability. Nonetheless, the Washington Legislature carried forward in the WPLA the principles animating Washington’s common law strict liability, with few modifications. See RCW 7.72.020(1); Macias, 175 Wn.2d at 409.

RCW 7.72.030 codifies the three basic theories of strict product liability—manufacturing defect, defective design, and failure to warn. Post-manufacture failure to warn is treated differently under the WPLA, imposing a *negligence* standard on manufacturers, in contrast to the strict liability standard that applies at the time of manufacture. See RCW 7.72.030(1)(b)-(c).⁷

In interpreting RCW 7.72.030 this Court has held that notwithstanding preemption of common law remedies: 1) the buyer-oriented risk-utility/consumer expectations principles developed at common law are carried forward in this statute, see Falk v. Keene Corp., 113 Wn.2d 645, 651-54, 782 P.2d 974 (1989); Macias at 409-10; and 2) the conceptual underpinnings for design defect liability and failure to warn

⁶ The WPLA governs product liability claims arising on or after July 26, 1981. See RCW 4.22.920(1); Macias v. Saberhagen Holdings, Inc., 175 Wn.2d 402, 408, 282 P.3d 1069 (2012).

⁷ A negligence-based standard is also retained as to certain product sellers other than a manufacturer. See RCW 7.72.040(1). The current versions of RCW 7.72.010, 7.72.020, 7.72.030 and 7.72.040 are reproduced in the Appendix.

liability remain substantially the same, see Ayers v. Johnson & Johnson, 117 Wn.2d 747, 762-64, 818 P.2d 1337 (1991); Macias at 409.⁸

The WPLA differs from prior common law in one key respect. RCW 7.72.030(1) and (3) establish two independent grounds for imposing strict liability, based on either a risk-utility or a consumer expectations analysis, whereas, as noted above, the common law imposed strict liability based on a combined risk-utility consumer expectations analysis. See Falk, 113 Wn.2d at 654. Otherwise, the nature of the duties owed by manufacturers under the WPLA and the common law are similar. Common law strict liability under §402A, as interpreted by Tabert and its progeny, requires manufacturers to produce products that are not “unreasonably dangerous” or, stated another way, that are “reasonably safe.” See Tabert at 154. Whether products are reasonably safe was determined by the combined risk-utility and consumer expectations test. See Baughn, 107 Wn.2d at 134. For its part, the WPLA repeatedly frames the manufacturer’s duty in terms of the obligation to provide a “reasonably safe” product. RCW 7.72.030(1)-(3). With respect to claims based on defective design and failure to warn at the time of manufacture, a manufacturer breaches its duty if its product is unsafe under either the

⁸ Strict liability based upon a claim that the product is not reasonably safe in construction is governed by RCW 7.72.030(2). See generally Washington Pattern Instructions (WPI), WPI 110.01 & Comment (defect in construction); WPI 110.02 & Comment (defective design); WPI 110.03 & Comment (failure to warn).

risk-utility or consumer expectations test. RCW 7.72.030(1)(a)-(b) & (3); Falk at 654.⁹

In determining breach under the common law strict liability test, the inquiry focused on the intrinsic nature of the product, and the analysis was product and risk specific. See Tabert at 154. This same analysis applies under the WPLA risk-utility balancing and consumer expectations test in RCW 7.72.030. See Falk at 654; WPI 110.03 (setting forth separate considerations for risk-utility and consumer expectations tests based on failure to warn).

The above overview demonstrates that generally under both common law strict liability and the WPLA the principal focus of the inquiry is on the intrinsic nature of the product and the reasonable expectations of the ordinary consumer or user with respect to whether the product in question is reasonably safe.

Application of Comment k Under the Common Law and WPLA:

In Terhune v. A.H. Robins Co., 90 Wn.2d 9, 577 P.2d 975 (1978), this Court adopted the Restatement's comment *k* as a limitation on common law strict liability for defective design where an "unavoidably unsafe product" is involved. Under comment *k* certain unavoidably unsafe products are not considered defectively designed based upon a

⁹ Under the common law, the consumer expectations standard considered "the reasonable expectations of the ordinary consumer." Ryder, 91 Wn.2d at 117; see also Teagle, 89 Wn. 2d at 155. In Soproni v. Polygon Apt. Partners, 137 Wn.2d 319, 327, 971 P.2d 500 (1999), this Court holds that under the WPLA, consumer expectations "are judged against the reasonable expectations of the ordinary consumer."

determination that such products are "fully justified, notwithstanding the unavoidable high degree of risk which they involve." However, such products must be "accompanied by proper directions and warning" to be eligible for the exemption.¹⁰

In Terhune, the Court applied comment *k* to an intrauterine contraceptive device. Subsequently, the Court recognized comment *k* operated as a limitation on Washington common law strict liability in Rogers v. Miles Laboratory, 116 Wn.2d 195, 197-98, 207-08, 802 P.2d 1346 (1991), involving a blood product, stating that the manufacturer of a comment *k* product that fails to give adequate warning is subject to negligence liability, not strict liability. Subsequently, in Young v. Key Pharmaceuticals, 130 Wn.2d 160, 178-79, 922 P.2d 59 (1996) (Guy, J., lead opinion, joined by 3 justices); id., 130 Wn. 2d at 179 (Madsen, J., dissenting, joined by 3 justices), involving comment *k* and a prescription drug, the Court was unable to resolve by a majority whether the adequacy of warnings required to invoke comment *k* is judged by a negligence or strict liability standard.¹¹

This Court has only discussed comment *k* in one case governed by the WPLA. See Ruiz-Guzman v. Amvac Chem. Corp., 141 Wn.2d 493, 7

¹⁰ The full text of comment *k* is reproduced in the Appendix to this brief. The text of comment *k* does not specify whether the required directions and warnings are evaluated under a negligence or strict liability standard

¹¹ While both Rogers and Young were decided after enactment of the WPLA, in each instance it appears the WPLA was not in effect at the time of injury. See Rogers, 116 Wn. 2d at 198-99; Young, 130 Wn.2d at 162; see also n.6, supra.

P.3d 795 (2000). In Ruiz-Guzman, involving a federal certification by the Ninth Circuit Court of Appeals, the Court essentially read comment *k* into the WPLA, absent an express adoption by the Legislature, concluding: "it is implicit that products that are 'unavoidably unsafe' are not products that ever *could* be 'reasonably safe as designed' RCW 7.72.030(1)." 141 Wn.2d at 506 (emphasis & ellipses in original). The Court notes that, in the absence of express adoption of comment *k*, its application "must be sparing ... lest we defeat the letter or policy of the WPLA." Id. Ultimately, the Court holds that the product involved, a pesticide, may qualify for comment *k* treatment if all prerequisites are met, and that this determination is for the trier of fact if reasonable minds may differ. See id. at 505-11. Notably, while the Court references the dispute in Young, supra, regarding the nature of the duty to warn standard regarding comment *k*, it does not appear to resolve what warning standard applies under the WPLA.

B. Under The WPLA, A Manufacturer Of A Medical Device Has A Duty To Warn A Hospital That Purchases The Device, Furnishes It For Use On Hospital Premises, And Credentials Physicians To Use It.

The Court of Appeals held and amicus curiae Washington State Hospital Association argues in its Court of Appeals brief that a manufacturer of a prescription medical device purchased by a hospital has *no* duty under the WPLA to warn the hospital under RCW 7.72.030(1),

and that such a holding would be inconsistent with application of the learned intermediary doctrine. See Taylor, 188 Wn. App. at 779-80; WSHA Am. Br. at 1. WSHA further urges that: "[t]he most logical reading [of RCW 7.72.030] is that the warnings must be communicated to the ultimate user of the product, not every person in the supply chain." Id. at 2. WSHA's view of RCW 7.72.030 and the relevance of the learned intermediary doctrine to this question should be rejected.

RCW 7.72.030(1)(b) delineates a manufacturer's duty to warn "at the time of manufacture" of the product in question:

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

This provision "does not expressly specify who must receive the manufacturer's warnings." Taylor, 188 Wn. App. at 788. Instead, under this provision adequate warnings must be "provided *with* the product." RCW 7.72.030(1)(b) (emphasis added). This language suggests every person who receives the product must also receive adequate warnings, although the recipients of such warnings may depend upon the intrinsic nature of the product, the manner of distribution, and the use to which the product is put in each case. See Macias at 419 (stating whether the product is unreasonably unsafe in the absence of adequate warnings always

involves consideration of “the use to which the product will be put”); cf. Little v. PPG Indus. 92 Wn.2d 118, 127-28, 594 P.2d 911 (1997) (Utter, J., concurring, noting in pre-WPLA case “the jury focuses its attention on the product itself and the dangers inherent in its condition and manner of distribution”).

The duty to warn at the time of manufacture contrasts with the duty to warn under RCW 7.72.030(1)(c) “after the product was manufactured where a manufacturer learned or where a reasonably prudent manufacturer should have learned about a danger connected with the product after it was manufactured,” which *does* specify who must receive the manufacturer’s warnings. In this circumstance, post-manufacture warnings must be reasonably calculated “to inform product *users*.” Id. (Emphasis added). The fact that the Legislature specified the recipients of post-manufacturer warnings indicates that the omission of specified recipients for the initial warnings was intentional.

Just as importantly, the concept of “adequacy,” incorporated into the risk-utility balancing test for evaluating warnings, is sufficiently broad to include consideration of the proper *recipients* of warnings in addition to the *substance* of warnings and the *manner* in which they are provided. The risk-utility test involves consideration of whether the manufacturer’s warnings were “inadequate,” and whether “adequate” warnings could have been given under the circumstances. RCW 7.72.030(1)(b). The terms

“inadequate” and “adequate” are undefined. Undefined statutory terms should be given their ordinary meaning as discerned from common dictionaries. See Filmore LLLP v. Unit Owners Ass’n, 184 Wn.2d 170, 174, 355 P.3d 1128 (2015). The ordinary meaning of the term “adequate” is “sufficient for a specific requirement.” Merriam-Webster Online, s.v. “adequate” (viewed Apr. 20, 2016; available at www.m-w.com). In the context of the duty to warn under the WPLA, the specific requirement for warnings under RCW 7.72.030(1)(b) is that they must be adequate to render the product in question “reasonably safe.” A jury should be entitled to find that warnings are inadequate to render a product reasonably safe because they were not provided to a person who received the product and was in a position to prevent harm to the claimant if adequate warnings had been given.¹²

This reading of the duty to warn imposed by RCW 7.72.030(1)(b) does not hinge upon application of the learned intermediary doctrine, or characterization of the hospital as a learned intermediary.¹³ Under the learned intermediary doctrine, manufacturers of certain sophisticated medical devices may satisfy their duty to warn patients by providing adequate warnings and instructions to physicians who use the devices on

¹² Liability under this interpretation is not unduly expansive. It must be proven that the manufacturer “could have provided the warnings or instructions which the claimant alleges would have been adequate,” RCW 7.72.030(1)(b). It must also be established that the failure to provide such warnings was a proximate cause of the claimant’s harm.

¹³ Taylor argues, in the alternative, that Harrison was entitled to warnings as a second learned intermediary. See Taylor Supp. Br. at 11-12. This issue is not addressed in this brief.

their patients. See Washington St. Physicians Ins. Exch. & Ass'n v. Fisons Corp., 122 Wn. 2d 299, 313 & n.3, 858 P.2d 1054 (1993) (citing Terhune, 90 Wn. 2d at 13). The rationale for the doctrine is that the patient does not have the expertise to comprehend the warnings, and instead relies on the physician, who has an independent duty to obtain informed consent. See Terhune at 13-14. While the doctrine relieves the manufacturer of the duty to warn the patient directly, it does not relieve the manufacturer of the obligation under RCW 7.72.030(1)(b) to provide adequate warnings and instructions with the product to others, including the purchaser, who receive the product and are in a position to prevent harm to the patient. See Taylor at 796-97 (Worswick, J., dissenting in part, noting hospitals that purchase equipment are in a position to protect the patient). If the learned intermediary doctrine served to eliminate the duty of a manufacturer of medical products to warn anyone other than the physician, it would be contrary to the duty imposed by the WPLA to provide warnings with the product and would undermine the concept of adequacy by which warnings are evaluated. Moreover, as noted by the dissent below, it would also create “an environment that encourages manufacturers to refrain from disclosing dangers or defects to the actual purchaser of the medical equipment.” Taylor at 798 (Worswick, J., dissenting in part).

C. Under the WPLA, A Manufacturer Seeking To Avoid Strict Liability For Defective Design Based Upon Comment *k* Must Provide Adequate Warnings In Accordance With The Strict Liability Standard Of RCW 7.72.030(1)(b), Rather Than The Negligence-Based Warnings That May Have Sufficed At Common Law.

Comment *k*, addressing "unavoidably unsafe products," may apply to shield a manufacturer from defective design strict liability, but it requires as a prerequisite that the product is accompanied by proper directions and warnings. Comment *k* does not expressly state whether such warnings are based on a negligence or strict liability standard. This Court was unable to reach consensus regarding the proper standard under the common law, see Young, supra, and has yet to address the issue under the WPLA. See generally §A, supra.

In Ruiz-Guzman, this Court essentially read comment *k* into the WPLA because under the act "it is implicit that products that are unavoidably unsafe are not products that ever *could* be 'reasonably safe as designed....' RCW 7.72.030(1)." 141 Wn.2d at 506 (emphasis and ellipses in original). However, at the same time the Court recognized that in order to not "defeat the letter or policy of the WPLA" application of comment *k* "must be sparing." Id.

Under the WPLA, the standard for the requisite comment *k* warnings should be the strict liability standard set forth in RCW 7.72.030(1)(b), not a negligence standard. This is the principal

warning standard that applies under the WPLA, with the exception of the post-manufacture warning context. See RCW 7.72.030(1)(c).¹⁴ To the extent that the Court applied a negligence standard to comment *k* warnings at common law, this should not be determinative as to the WPLA, which codifies a strict liability warning standard in all instances but the post-manufacture context.¹⁵ The statute's strict liability standard should also be controlling because of the preemptive effect of the WPLA, in supplanting the common law. See Macias, 175 Wn.2d at 409 (collecting cases). Lastly, this reading of the WPLA also serves to assure that comment *k* is applied sparingly so as not to undermine the letter and policy of the act. See Ruiz-Guzman at 506.

ISI may argue that because the Court has recognized comment *k* in a WPLA context this must mean that any negligence standard stated in common law cases must also apply. Any such argument should be rejected. Comment *k* does not dictate the standard for the prerequisite warnings. As a consequence, it was a proper function of the Court to articulate the common law warning standard as it saw fit. However, with enactment of the WPLA, the Legislature has codified the general strict

¹⁴ The only other negligence standard specified in the WPLA is with respect to product sellers who are not manufacturers. See RCW 7.72.040(1).

¹⁵ As revealed in the parties' briefing, there is uncertainty whether the statement in Rogers v. Miles Laboratories, 116 Wn.2d at 207-08, that the warnings required to invoke comment *k* involve a negligence standard, is a holding and, in any event, whether it is correct. Compare Taylor Supp. Br. at 14-16 with ISI Supp. Br. at 18-21; see also Young v. Key Pharmaceuticals, supra (lead and dissenting opinions; evenly divided court).

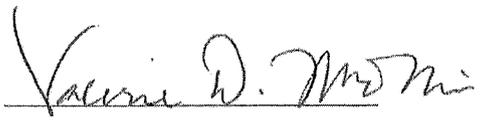
liability warning standard, with two exceptions, neither of which applies here.¹⁶ The Court should follow this standard.

VI. CONCLUSION

The Court should adopt the analysis provided in this brief to the extent relevant to resolving the issues on review.

DATED this 22nd day of April, 2016.


FOR BRYAN P. HARNETIAUX, *with authority*


FOR GEORGE M. AHREND, *with authority*


VALERIE D. McOMIE

On Behalf of WSAJ Foundation

¹⁶ The Court of Appeals decision in Estate of LaMontagne, 127 Wn. App. at 343-44, which states that a negligence standard applies to comment *k* warnings under the WPLA, should be disapproved. The court does not acknowledge Young, or the lack of consensus regarding this issue under the common law, but rather seems to assume without discussion that a negligence standard applied under the common law, and that this standard has been carried forward under the WPLA. The only authorities cited by the court are comment *k* itself, Terhune and Ruiz-Guzman, none of which address the proper standard for comment *k* warnings.

APPENDIX

Restatement (Second) of Torts §402A

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

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

West's RCWA 7.72.010

7.72.010. Definitions

Currentness

For the purposes of this chapter, unless the context clearly indicates to the contrary:

(1) Product seller. "Product seller" means any person or entity that is engaged in the business of selling products, whether the sale is for resale, or for use or consumption. The term includes a manufacturer, wholesaler, distributor, or retailer of the relevant product. The term also includes a party who is in the business of leasing or bailing such products. The term "product seller" does not include:

(a) A seller of real property, unless that person is engaged in the mass production and sale of standardized dwellings or is otherwise a product seller;

(b) A provider of professional services who utilizes or sells products within the legally authorized scope of the professional practice of the provider;

(c) A commercial seller of used products who resells a product after use by a consumer or other product user: PROVIDED, That when it is resold, the used product is in essentially the same condition as when it was acquired for resale;

(d) A finance lessor who is not otherwise a product seller. A "finance lessor" is one who acts in a financial capacity, who is not a manufacturer, wholesaler, distributor, or retailer, and who leases a product without having a reasonable opportunity to inspect and discover defects in the product, under a lease arrangement in which the selection, possession, maintenance, and operation of the product are controlled by a person other than the lessor; and

(e) A licensed pharmacist who dispenses a prescription product manufactured by a commercial manufacturer pursuant to a prescription issued by a licensed prescribing practitioner if the claim against the pharmacist is based upon strict liability in tort or the implied warranty provisions under the uniform commercial code, Title 62A RCW, and if the pharmacist complies with recordkeeping requirements pursuant to chapters 18.64,

69.41, and 69.50 RCW, and related administrative rules as provided in RCW 7.72.040. Nothing in this subsection (1)(e) affects a pharmacist's liability under RCW 7.72.040(1).

(2) Manufacturer. "Manufacturer" includes a product seller who designs, produces, makes, fabricates, constructs, or remanufactures the relevant product or component part of a product before its sale to a user or consumer. The term also includes a product seller or entity not otherwise a manufacturer that holds itself out as a manufacturer.

A product seller acting primarily as a wholesaler, distributor, or retailer of a product may be a "manufacturer" but only to the extent that it designs, produces, makes, fabricates, constructs, or remanufactures the product for its sale. A product seller who performs minor assembly of a product in accordance with the instructions of the manufacturer shall not be deemed a manufacturer. A product seller that did not participate in the design of a product and that constructed the product in accordance with the design specifications of the claimant or another product seller shall not be deemed a manufacturer for the purposes of RCW 7.72.030(1)(a).

(3) Product. "Product" means any object possessing intrinsic value, capable of delivery either as an assembled whole or as a component part or parts, and produced for introduction into trade or commerce. Human tissue and organs, including human blood and its components, are excluded from this term.

The "relevant product" under this chapter is that product or its component part or parts, which gave rise to the product liability claim.

(4) Product liability claim. "Product liability claim" includes any claim or action brought for harm caused by the manufacture, production, making, construction, fabrication, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging, storage or labeling of the relevant product. It includes, but is not limited to, any claim or action previously based on: Strict liability in tort; negligence; breach of express or implied warranty; breach of, or failure to, discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation, concealment, or nondisclosure, whether negligent or innocent; or other claim or action previously based on any other substantive legal theory except fraud, intentionally caused harm or a claim or action under the consumer protection act, chapter 19.86 RCW.

(5) Claimant. "Claimant" means a person or entity asserting a product liability claim, including a wrongful death action, and, if the claim is asserted through or on behalf of an estate, the term includes claimant's decedent. "Claimant" includes any person or entity that suffers harm. A claim may be asserted under this chapter even though the claimant did not buy the product from, or enter into any contractual relationship with, the product seller.

(6) Harm. "Harm" includes any damages recognized by the courts of this state: PROVIDED, That the term "harm" does not include direct or consequential economic loss under Title 62A RCW.

Credits

[1991 c 189 § 3; 1981 c 27 § 2.]

Notes of Decisions (78)

West's RCWA 7.72.010, WA ST 7.72.010

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West's RCWA 7.72.020

7.72.020. Scope

Currentness

(1) The previous existing applicable law of this state on product liability is modified only to the extent set forth in this chapter.

(2) Nothing in this chapter shall prevent the recovery of direct or consequential economic loss under Title 62A RCW.

Credits

[1981 c 27 § 3.]

Notes of Decisions (12)

West's RCWA 7.72.020, WA ST 7.72.020
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West's Revised Code of Washington Annotated
Title 7. Special Proceedings and Actions (Refs & Annos)
Chapter 7.72. Product Liability Actions (Refs & Annos)

West's RCWA 7.72.030

7.72.030. Liability of manufacturer

Currentness

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

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

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

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

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

(a) A product is not reasonably safe in construction if, when the product left the control of the manufacturer, the product deviated in some material way from the design specifications or performance standards of the manufacturer, or deviated in some material way from otherwise identical units of the same product line.

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

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

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

Credits

[1988 c 94 § 1; 1981 c 27 § 4.]

Notes of Decisions (194)

West's RCWA 7.72.030, WA ST 7.72.030

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West's RCWA 7.72.040

7.72.040. Liability of product seller other than manufacturer--Exception

Currentness

(1) Except as provided in subsection (2) of this section, a product seller other than a manufacturer is liable to the claimant only if the claimant's harm was proximately caused by:

(a) The negligence of such product seller; or

(b) Breach of an express warranty made by such product seller; or

(c) The intentional misrepresentation of facts about the product by such product seller or the intentional concealment of information about the product by such product seller.

(2) A product seller, other than a manufacturer, shall have the liability of a manufacturer to the claimant if:

(a) No solvent manufacturer who would be liable to the claimant is subject to service of process under the laws of the claimant's domicile or the state of Washington; or

(b) The court determines that it is highly probable that the claimant would be unable to enforce a judgment against any manufacturer; or

(c) The product seller is a controlled subsidiary of a manufacturer, or the manufacturer is a controlled subsidiary of the product seller; or

(d) The product seller provided the plans or specifications for the manufacture or preparation of the product and such plans or specifications were a proximate cause of the defect in the product; or

(e) The product was marketed under a trade name or brand name of the product seller.

(3) Subsection (2) of this section does not apply to a pharmacist who dispenses a prescription product in the form manufactured by a commercial manufacturer pursuant to a prescription issued by a licensed practitioner if the pharmacist complies with recordkeeping requirements pursuant to chapters 18.64, 69.41, and 69.50 RCW, and related administrative rules.

Credits

[1991 c 189 § 2; 1981 c 27 § 5.]

Notes of Decisions (12)

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Dear Mr. Carpenter:

On behalf of the WSAJ Foundation, a letter request to file an Amicus Curiae Brief and accompanying Amicus Curiae Brief (with Appendix) are attached to this email. Counsel for the parties are being served simultaneously by copy of this email, per prior arrangement.

Respectfully submitted,

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