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No. 92210-1

IN THE SUPREME COURT FOR
THE STATE OF WASHINGTON

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,

Petitioners,

v.

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

Respondent

PETITIONERS' RESPONSE TO FOUR *AMICI*

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 ORIGINAL

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INTRODUCTION

Amici are the Washington State Association for Justice Foundation (“the Foundation”), the Product Liability Advisory Council, Inc. (“PLAC”), the Washington State Hospital Association (“WSHA”), the Medical Device Manufacturers Association, and the National Association of Manufacturers (collectively “MDMA”).¹ Aside from the Foundation, which agrees that ISI had a WPLA duty to warn Harrison, Amici all but ignore the WPLA. But where no learned intermediary stood between ISI and Harrison, that doctrine cannot eliminate ISI’s duty to warn Harrison. The WPLA controls.

The Foundation also agrees with Taylor that comment *k* creates an exception to Washington’s strict-liability rule only where the manufacturer provides adequate warnings with the product. RESTATEMENT (SECOND) OF TORTS § 402A. Amici either ignore this issue or rely on foreign cases, many of which also apply strict liability to inadequate-warning claims under comment *k*. That some states have different strict-liability tests is neither surprising nor persuasive, particularly where ISI has not raised that issue.

This Court should reverse for trial with proper instructions.

¹ This brief refers collectively to PLAC, WSHA and MDMA as “amici.”

ARGUMENT

A. **As the Foundation agrees, ISI has a duty to warn Harrison under the WPLA.**

Taylor has argued throughout this matter that ISI has a duty to warn Harrison under the WPLA, where warning Harrison is the only way to provide “adequate warnings or instructions . . . with the product.” RCW 7.72.030(1)(b). ISI’s duty to warn Harrison derives not only from the fact that Harrison purchased the robot, but also from Harrison’s role in making the robot available for doctors to use on patients at Harrison. As the credentialing hospital, Harrison did not merely make the robot available, but established the standards for using the robot and, ultimately, determined who met the standards. It is beyond dispute that the robot could not have been used on Fred Taylor without Harrison first purchasing it, establishing credentialing requirements, and credentialing Fred’s surgeon.

Only the Foundation squarely addresses this argument. Foundation 14-16. As it notes, RCW 7.72.030(1)(b) governs the duty to warn at the time of manufacture, but does not specify who must be warned, providing only that “adequate warnings or instructions [must be] provided with the product.” *Id.* at 14 (quoting RCW 7.72.030(1)(b)). “[W]ith the product” suggests that every person receiving the product must also receive adequate warnings. *Id.* at 14.

By contrast, paragraph (c) of RCW 7.72.030(1) provides that *post-manufacture* duties to warn run to product “users.” *Id.* at 15. This specificity suggests that the Legislature intentionally declined to limit those who must receive warnings at the time of manufacture under paragraph (b). *Id.*

Further, as used in paragraph (b), warnings are “adequate” only if they render the product in question “reasonably safe.” *Id.* at 15-16. The risk-utility test, one of two tests used to determine whether warnings are adequate, requires the jury to consider whether the manufacturer’s warnings were “inadequate” and whether “adequate” warnings could have been given. *Id.* at 15 (*quoting* RCW 7.72.030(1)(b)). This test is sufficiently broad to allow the jury to consider *who* must be warned in determining whether a warning is adequate. *Id.* at 15-16.

Finally, the nature of the unavoidably unsafe robot itself dictates that ISI had to warn Harrison. In ***Macias v. Saberhagen Holdings, Inc.***, this Court held that the nature of the product and its intended use are relevant to the warning owed. 175 Wn.2d 402, 415-16, 282 P.3d 1069 (2012). Thus, the manufacturer of a respirator used to filter asbestos was not entitled to summary judgment that it had no duty to warn because it did not manufacture the injury-causing

asbestos products, where the very purpose of its product put the plaintiff in contact with asbestos. 175 Wn.2d at 417-18.

Here, the robot's intended use mandated adequate warnings and instructions to Harrison. The da Vinci robot is not a drug that a doctor directly prescribes, or a vaccine that she directly administers. The robot is a complex surgical device that surgeons may access only with Harrison's credential. ISI plainly knew that, as three ISI employees sat on the steering committee addressing Harrison's credentialing requirements. RP 720. Indeed, ISI recommended that two proctored procedures were sufficient, without any medical support, and contrary to numerous studies. *Infra*, Argument § A 4. Knowing that Harrison would determine credentialing requirements and who met them, ISI had a duty to adequately warn and instruct Harrison. See *Macias*, 175 Wn.2d at 417-18.

1. The other Amici all but ignore the WPLA.

Following ISI's lead, PLAC and WSHA fail to even address the duties owed under the WPLA. While MDMA ostensibly addresses the WPLA, it ignores Taylor's arguments and the Court of Appeals dissent, arguing only that the WPLA forecloses any duty to warn Harrison (or any hospital) where it "supplants all common law claims or actions based on harms caused by a product." MDMA 9

(citing *Macias*, 175 Wn.2d at 409). That is a non-sequitur. Taylor agrees that the WPLA preempts the common law, but her claim that ISI has a duty to warn Harrison is based on the WPLA, not on the common law. MDMA apparently misunderstands this, claiming that “Plaintiffs cannot create a separate duty of care on the manufacturer outside of the WPLA.” MDMA at 9. Taylor never attempted to do so.

MDMA next argues that many states have adopted statutory schemes similar to the WPLA, consolidating all common law theories of recovery into one products liability statute. MDMA at 9-10. Taylor does not disagree, nor does she disagree that “in Washington, the source of that liability law is solely the WPLA.” MDMA at 11. But it simply does not follow that Taylor is “attempting to circumvent the WPLA to create new common law theories of liability directly against manufacturers.” MDMA at 11. The opposite is true – ISI has a duty to warn Harrison under the WPLA, and the learned intermediary doctrine – a common law creation – does not change that.

To the extent that MDMA is referring to ISI's argument that Taylor lacks “standing,” the argument is meritless. *Id.*; ISI's Amended Supp. Brief at 11-12. Taylor is not asserting a claim on Harrison's behalf. Her claim is based on Fred's injuries, which were caused (in part) by ISI's failure to warn and instruct Harrison.

2. The learned intermediary doctrine does not govern ISI's WPLA duty to warn Harrison.

Amici turn to the learned intermediary doctrine to eliminate ISI's WPLA duty to warn Harrison. They contradict the learned intermediary doctrine itself. This Court should reject such misdirection.

The WPLA requires manufacturers to provide adequate warnings with unavoidably unsafe prescription drugs and medical devices. RCW 7.72.030, comment *k*; *Terhune v. A. H. Robins Co.*, 90 Wn.2d 9, 12-14, 577 P.2d 975 (1978). The learned intermediary doctrine then provides that manufacturers of “drugs, vaccines, and the like” . . . which cannot be legally sold except to a physician,” may “satisf[y]” their duty to warn by adequately warning prescribing physicians. *Terhune*, 90 Wn.2d at 13. Permitting a manufacturer to warn a gatekeeper standing between the manufacturer and the patient is permissible because a relationship always exists between physicians and patients, no relationship normally exists between manufacturers and patients, and the law assumes physicians will act reasonably to pass warnings onto patients. 90 Wn.2d at 14.

Thus, the issue here, properly framed, must assume that ISI has a duty to warn Harrison, and then ask whether the presence of

a learned intermediary permits ISI to satisfy its duty to warn Harrison by instead warning the learned intermediary. This is consistent with the learned intermediary doctrine's original and *only* current application: to permit a manufacturer to satisfy its duty to warn by adequately warning a prescribing doctor. *Terhune*, 90 Wn.2d at 14.

An analogy to another non-prescription product shows the fallacy in WSHA's and MDMA's arguments that the learned intermediary doctrine governs the duty to warn where, as here, there is no gatekeeper standing between the manufacturer and hospital. WSHA at 2-6; MDMA at 6-12. Manufacturers have a duty to warn a hospital when it purchases any number of products made reasonably safe only by adequate warnings, such as modern hospital beds. No learned intermediary "prescribes" a bed. A hospital purchases a bed and makes it available to a patient. The fact that the patient might be in the hospital using the bed through his doctor/patient relationship with a learned intermediary does not alter the manufacturer's duty to warn the hospital of the potential dangers of misusing a modern hospital bed. The same is true for this robot.

Notwithstanding Amici's repeated unsupported references to the robot as a "prescription medical device," it is not. A doctor does not "prescribe" a robot. A robot is a surgical tool – like a scalpel – not

a drug, or personal medical device. Doctors are not “credentialed” to prescribe drugs (they are *licensed* to do that). This matter is thus unlike *Terhune*, where a prescription device reached a patient through a doctor’s prescription, without the hospital’s intervention. The doctrine does not apply here.

3. No Washington case suggests that the learned intermediary doctrine eliminates the duty to warn a credentialing hospital like Harrison.

Amici read too much into existing precedents, drawing unsupported and often illogical conclusions. No Washington case suggests that the learned intermediary doctrine eliminates the duty to warn product purchasers like Harrison. None provides that manufacturers must warn doctors only, and no other entity.

WSHA and MDMA read into *Terhune* that only a prescribing physician must receive adequate warnings with an unavoidably unsafe product. WSHA at 4; MDMA at 7-8. *Terhune* does not say that. There, the unavoidably unsafe medical device reached the patient through her doctor’s prescription, not through a credentialing hospital. 190 Wn.2d at 12-14. Thus, the Court was asked only whether warning the doctor was sufficient, or whether the manufacturer also had to warn the patient. *Id.* Whether manufacturers had to warn an entity like Harrison was not at issue.

This Court did not state – in what could only have been *dicta* – that manufacturers must warn “only” prescribing doctors.

MDMA also mistakenly relies on *Terhune* for the proposition that “the patient-physician relationship alone . . . should be the focal point of any liability.” MDMA at 12 (quoting *Terhune*, 90 Wn.2d at 16, “concluding that the treating physician is [sic] ‘who finally controls the dispensing of the product’”). But unlike in *Terhune*, here the *hospital* “finally control[ed] the dispensing of the product.” 90 Wn.2d at 16. The robot could not have been used on Fred without Harrison’s credential. And only ISI could have warned Harrison. *Terhune* is inapposite.

WSHA and MDMA similarly over-read *McKee v. Am. Home Prods. Corp.*, 113 Wn.2d 701, 782 P.2d 1045 (1989). WSHA at 5; MDMA at 6, 8-9. WSHA relies on *McKee* for the proposition that “the only party with the ability to evaluate and appropriately act on the manufacturer’s warnings is the prescribing physician.” WSHA at 5. *McKee* does not support that assertion, and the facts contradict it.²

² Nor does *Ruiz-Guzman v. Amvac Chemical Corp.* support WSHA’s claim. WSHA at 5 (citing 141 Wn.2d 493, 7 P.3d 795 (2000)). *Ruiz-Guzman* addresses pesticides, and nowhere says that only a prescribing doctor has the ability to evaluate and act on warnings.

Harrison had "the ability" to act on warnings, had ISI provided them. WSHA at 5. ISI sold itself as an expert and a partner in building a successful robotics program. RP 550, 657, 679-80, 1669, 1694; CP 4587-88; Ex 281, p. 5. It placed three people on the steering committee addressing the credentialing requirements Harrison adopted. RP 720. Harrison acted on ISI's unsupported recommendation that two proctored procedures were sufficient, adopting that as its credentialing requirement. RP 711-12, 840, 1956. Harrison is nothing like a pharmacist filling a prescription.

McKee does not support WSHA's position in any event. **McKee** holds that neither a manufacturer nor a pharmacist have the medical education or knowledge of a patient's medical history to justify the "imposition of a duty to intrude into the physician-patient relationship." 113 Wn.2d at 711. Thus, this Court correctly held that pharmacists have no duty to warn patients, where imposing such a duty would require pharmacists to undermine a doctor's medical judgment. *Id.* No similar concern is present here.

While MDMA and WSHA both claim that warning Harrison would somehow require it to intrude on the physician-patient relationship, neither says how. MDMA at 8-9; WSHA at 5-6. The purpose of warning Harrison is to allow it to determine appropriate

credentialing requirements based on complete and accurate information, and to decide who has met those requirements. *Infra*, Argument § A 4. WSHA at 5. Credentialing is not an intrusion, and even if it were, the Legislature demands it to protect patients.

MDMA's and WSHA's reliance in *McKee* revolves around a series of misunderstandings or mischaracterizations of Taylor's claims. MDMA at 8-9; WSHA at 5-6. Taylor's argument has always been that ISI had to warn Harrison because it purchased the robot, established credentialing requirements for its use, and ultimately determined which physicians met those requirements. Taylor has never argued that ISI had to warn "hospital personnel," or that personnel would be "required to be an intermediary between patients and physicians." MDMA at 8-9 (citing 113 Wn.2d at 711); *see also* WSHA at 5-6. Nor has she ever suggested that Harrison had to make patient-specific decisions. *Id.* Taylor agrees that Harrison does not make medical judgments regarding specific patients, but that is beside the point. WSHA at 6. Again, the issue is credentialing, and credentialing plainly involves the exercise of medical judgment.

Further, Taylor has always maintained that the learned intermediary doctrine does not govern ISI's duty to warn Harrison, a point that MDMA and WSHA somehow overlook. Taylor argues only

in the alternative that if this Court is persuaded that the learned intermediary doctrine governs all duties to warn with unavoidably unsafe medical devices, then Harrison must be a second learned intermediary. BA 46-48; Reply 5-12. Like the prescribing doctors in *Terhune* and *McKee*, Harrison also stood between ISI and Fred Taylor. But unlike those physicians, Harrison never received the manufacturer's warnings that could have protected Fred.

4. Applying the learned intermediary doctrine to eliminate the WPLA duty to warn a credentialing hospital like Harrison decreases patient safety.

The learned intermediary doctrine is plainly concerned with increasing patient safety by making sure warnings are directed to gatekeepers standing between manufacturers and patients, in a superior position to communicate with patients, and to help patients make sound treatment decisions. *Terhune*, 90 Wn.2d at 12-14. The doctrine makes good sense when the product is a drug, or vaccine, or as in *Terhune*, a prescription medical device inserted in a patient's body. 90 Wn.2d at 13-14. It makes no sense here.

MDMA and WSHA lose sight of patient safety, arguing that under the learned intermediary doctrine, credentialing hospitals do not need adequate warnings and instructions with the unavoidably

unsafe medical products they credential doctors to use. WSHA at 7-8; MDMA at 12-13. That is both false and frightening.

The need to warn Harrison is made plain by WSHA's own description of the credentialing process:

Hospitals make decisions about the products they purchase and make available to physicians who practice at the hospital. [They] are responsible for credentialing physicians and for granting physicians privileges to perform specific types of procedures. WSHA at 5-6.

Hospitals are required to adopt credentialing guidelines in order to be accredited. WSHA at 10.

Credentialing is 'the collection, verification, and assessment of whether a health care provider meets relevant licensing, education, and training requirements.' WSHA at 10 (quoting RCW 4.24.810).

To secure clinical privileges to perform specific procedures, the hospital must evaluate the applicant's qualifications to perform the procedures, which includes a review of the physician's education, licensure, training, experience, current competence, and abilities. WSHA at 12.

The hospital then evaluates the information and makes a recommendation for membership and clinical privileges to the hospital's governing body for action. WSHA at 12 (citing WAC 246-320-161(2)).

In short, Harrison adopted credentialing requirements to determine who should be permitted to operate using the robot, and decided who met those guidelines by evaluating, among other things, the applicant's training, experience, competence and ability. WSHA 5-6, 10-12. Seemingly at odds with WSHA's position, MDMA

summarily dismisses credentialing as “a generalized process based on objective checklists, *e.g.*, whether the physician observed the right number of procedures, performed procedures proctored by credentialed physicians, and attended specific training sessions.” MDMA at 11. This misses the key point: Harrison needed adequate warnings to establish the “checklist” in the first instance.

Adequate warnings are inarguably necessary to the credentialing process. Harrison could not make a sound purchasing decision without knowing that many surgeons lack the patient volume to become proficient at robotic prostatectomy or that robotic prostatectomy has high complication rates and often high rates of cancer being left behind (or “margin” rates). BA 18-20; RP 1951-52, 1954-55. Harrison could not evaluate an applicant’s training and experience without knowing that ISI told the FDA that robotic surgeons should have basic *and* advanced laparoscopic skills or that ISI dramatically reduced its training program after obtaining FDA clearance. BA 7-16; RP 1915-16; Ex 20, p. 55.³ It could not evaluate an applicant’s experience, competence or ability, without knowing that the learning curve is 20-25 robotic prostatectomies (even when

³ At the time, only about 10 or 15 surgeons in the United States performed laparoscopic prostatectomy. RP 876-77.

margin rates are discounted), that it may take 150 procedures to achieve results comparable to routine open surgery, and that it may take 250 procedures to achieve comparable surgical “comfort and confidence.” RP 567-69, 628, 804, 1947, 1949-50. Without that information, Harrison could not vet ISI’s medically unsupported claim that two proctored procedures are sufficient to operate independently. Ex 511; RP 573, 711-12, 716, 840, 1036, 1827, 1956.

WSHA’s and MDMA’s arguments that warning Harrison would undermine the physician-patient relationship misconstrue Harrison’s role. WSHA at 7-8; MDMA at 8, 12. Taylor has never argued that Harrison should have second-guessed the physician-patient decision to operate, nor is there any logical nexus between warning Harrison and “second-guessing” physician-patient decisions. MDMA at 12; WSHA at 7-8.⁴

WSHA’s position should concern anyone using one of the hospitals WSHA represents. WSHA correctly acknowledges that

⁴ In claiming that Hospitals ensure only that a doctor properly obtained informed consent, but do not otherwise obtain informed consent from patients, WSHA again misconstrues Taylor’s argument. WSHA 16. The only reason Taylor mentioned informed consent was to correct ISI’s false assertion that Harrison did not obtain separate informed consent. Reply 8-9. Taylor never argued that Harrison obtaining informed consent showed that it “exercised judgment about the use of the da Vinci System for Mr. Taylor’s surgery.” WSHA at 16-17.

hospitals have a statutory duty, through the credentialing process, to decide the minimum standards that must be met to use an unavoidably-unsafe medical device, and to decide whether a particular doctor meets those standards. WSHA at 5-6, 10-12. It is frankly dangerous for WSHA to claim that hospitals need no adequate warnings with such devices to protect their patients.

5. Requiring manufacturers to “warn and instruct” hospitals is not undue influence over the credentialing process, but omitting warnings while supplying incomplete and medically unsupported information is.

It is illogical at best for WSHA to argue that providing hospitals with the information necessary to determine adequate credentialing requirements intrudes in their credentialing process. WSHA at 17-19. Warning a credentialing hospital is no more of an “intrusion” than is warning a doctor. WSHA at 17. And while Taylor does not argue that ISI is “required to develop credentialing criteria” with hospitals, this argument ignores the facts of this case. *Id.*

Again, ISI marketed itself to Harrison (and others) as a “partner” in creating a successful robotics program, and three ISI employees sat on the steering committee where credentialing requirements were discussed. RP 550, 657, 679-80, 720, 1669, 1694; CP 4587-88; Exs 48, 281, p. 5. It is not just a coincidence that

Harrison decided to credential doctors after only two proctored procedures, consistent with ISI's recommendation. RP 840.

WSHA also mistakenly relies on a set of guidelines published by The Society of American Gastrointestinal and Endoscopic Surgeons, noting that they "did not identify a particular number of cases or clinical experience recommended for privileging, leaving the decision to individual hospitals to develop their own criteria." WSHA at 12-13. Again, ISI made the very "recommendation" that these guidelines omit: two proctored procedures are sufficient. RP 840.

It is unclear why WSHA seems to think that warning Harrison would have unduly burdened ISI. WSHA at 18. No one is suggesting that ISI would have to tell Harrison everything that it told the FDA to obtain clearance. *Id.* But ISI certainly should not be permitted to withhold from Harrison relevant information that it gave to the FDA, such as that robotic surgeons should have basic and advanced laparoscopic skills. RP 1915-16; Ex 20, p. 55.

Finally, WSHA elides the distinction between "undue influence," and positive influence through complete and accurate information. WSHA at 18-19. Amici cannot ignore that ISI was directly involved in Harrison's decision to purchase a da Vinci robot, and in establishing its credentialing requirements. Telling Harrison

that the learning curve for robotic prostatectomy ranges from 25 to 250 procedures and that many surgeons lack the patient volume to become proficient robotic surgeons would not have been “undue influence.” BA 20-25. Nor would reporting that margin rates and complications are often higher in robotic prostatectomies. BA 18-20. It was undue influence, however, to omit all of that relevant information, while recommending only two proctored procedures without any medical support. RP 711-12, 840, 1956.

In sum, the learned intermediary doctrine does not eliminate ISI’s WPLA duty to provide adequate warnings with the da Vinci robot. Failing to warn Harrison impermissibly decreased patient safety. This Court should reverse and remand for trial with proper instructions on the duty to warn.

B. Comment *k* does not change Washington’s long-held rule that strict liability governs inadequate-warning claims.

Comment *k*, governing “unavoidably unsafe” medical products, twice states that such products must come with “proper warnings.” RESTATEMENT (SECOND) OF TORTS § 402A, (hereinafter “comment *k*”). At issue here is what that plain language means, and more specifically, whether comment *k*’s narrow exception to Washington’s general rule of strict products liability applies, even

when the defect claimed is that warnings were inadequate – or non-existent. Holding in ISI’s favor on this point would be at odds with comment *k*’s plain language, and with this Court’s long tradition of applying a strict liability standard to claims that a manufacturer’s warnings are inadequate.

Aside from repeating ISI’s arguments on *Rogers, Young*, and *Ruiz-Guzman, infra*, PLAC and MDMA ignore much of Washington’s controlling precedent in this area, relying on foreign cases that often do not support their claims.⁵ This Court should hold that manufacturers are relieved from Washington’s strict-liability rule only when they provide adequate warnings necessary to mitigate the risk of placing an unavoidably unsafe product into the market.

1. Washington has long had a strict liability rule for inadequate-warning claims, both at common law, and under the WPLA.

Long before the WPLA, this Court held that strict liability governs inadequate-warning claims. *Ulmer v. Ford Motor Co.*, 75 Wn.2d 522, 532-33, 452 P.2d 729 (1969); *Ryder v. Kelly-Springfield Tire*, 91 Wn.2d 111, 117, 587 P.2d 160 (1978); *Teagle*

⁵ WSHA does not address this issue and the Foundation agrees with Taylor that strict liability governs inadequate warning claims under comment *k*. Foundation at 18-19.

v. Fischer & Porter Co., 89 Wn.2d 149, 155, 570 P.2d 438 (1977). At common law, strict liability focused on "the consumer's expectation of buying a product which is reasonably safe." *Seattle-First Nat'l Bank v. Tabert*, 86 Wn.2d 145, 152-54, 542 P.2d 774 (1975). In determining the reasonable expectations of an ordinary consumer, courts considered: (1) the relative cost of the product; (2) the gravity of the claimed harm from the potential defect; and (3) the cost and feasibility of eliminating or minimizing the risk. *Tabert*, 86 Wn.2d at 155. This test combined "the consideration of consumer expectations with an analysis of the risk and utility inherent in a product's use." *Baughn v. Honda Motor Co.*, 107 Wn.2d 127, 134, 727 P.2d 655 (1986). This approach focused on the buyer and the inherent nature of the product – not on the manufacturer's conduct. *Tabert*, 82 Wn.2d at 154; *Ryder*, 91 Wn.2d at 117-18.

Although the WPLA (enacted 1981) preempts common law on strict liability, it carried forward those principles. *Falk v. Keene Corp.*, 113 Wn.2d 645, 654, 782 P.2d 974 (1989). In *Falk*, this Court held that under RCW 7.72.030(1)(a), strict liability governs design-defect claims. 113 Wn.2d 645, 654, 782 P.2d 974 (1989). Following *Falk* in *Ayers v. Johnson & Johnson Baby Prods. Co.*, this Court held that strict liability also governs inadequate-warning claims. 117

Wn.2d 747, 762-63, 818 P.2d 1337 (1991); see also *Anderson v. Weslo, Inc.*, 79 Wn. App. 829, 836, 906 P.2d 336 (1995) (“standard for allegations of defective design and of inadequate warnings is . . . strict liability”).

The conceptual underpinnings for inadequate-warning claims remain substantially the same under the WPLA. *Ayers*, 117 Wn.2d at 762-64. The key difference is that a manufacturer can be strictly liable for failing to adequately warn at the time of manufacture under either the risk utility test or the consumer-expectation test. Foundation at 10-11 (citing *Falk*, 113 Wn.2d at 654). As at the common law, the WPLA remains focused on the consumer’s expectations and the inherent nature of the product, not on the manufacturer’s conduct. *Id.*

2. Comment *k*’s plain language creates an exception to the strict-liability rule only when the manufacturer provides adequate warnings with the product.

Comment *k* strikes a compromise between Washington’s strict-liability rule, and the desire to allow into the market products that are “incapable of being made safe for their intended and ordinary use.” § 402A, cmt. *k*. Foundation at 5, 11-12. This speaks to the

inherent nature of the product – no matter how well it is designed, it cannot be “made safe.” *Id.* This is where the warnings come in.

Comment *k* products, referred to as “unavoidably unsafe,” are neither defective, nor unreasonably dangerous, if “they are properly prepared and marketed, and proper warning is given”:

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. . . . **Such a product, properly prepared, and accompanied by proper directions and warning, is not defective**, nor is it *unreasonably* dangerous. . . . 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.

Id. (bold emphases added). In other words, a “proper warning” renders an unavoidably-unsafe product non-defective. § 402A, cmt. *k.* Foundation at 5, 11-12. In providing that a manufacturer of unavoidably-unsafe products “is not to be held to strict liability for unfortunate consequences attending their use,” comment *k* reminds a second time that with this reduced standard of liability comes “the qualification that [the products] are properly prepared and marketed, and proper warning is given.” *Id.*

Thus, by its plain language, comment *k* provides an exception to strict liability only where a manufacturer provides adequate warnings. Adequate warnings are a predicate to comment *k*, so comment *k* cannot govern whether the warnings themselves are adequate. Rather, whether the warnings are adequate is determined by the rule set forth in § 402A, measured by the ordinary consumer's reasonable expectations, or a risk-utility analysis. See *Falk*, 113 Wn.2d at 648, 654; *Ulmer*, 75 Wn.2d at 532.

Even MDMA recognizes that comment *k* requires “adequate warnings” to “make the product no longer defective”:

Because the design of the products cannot eliminate their risks, warnings are used to make the product no longer defective or unreasonably dangerous in the eyes of the law. . . . Thus, notwithstanding their medically recognized risks, these beneficial medical devices can be made available to treat patients so long as they are accompanied by adequate warnings.

MDMA at 14-15. This underscores Taylor's argument that adequate warnings are a predicate to applying comment *k*.

As this Court previously held, since the Legislature did not expressly provide for comment *k* in the WPLA, courts “must be sparing in its application lest [they] defeat the letter or policy of the WPLA.” *Ruiz-Guzman*, 141 Wn.2d at 505. To apply comment *k* sparingly, courts must follow its plain language: unavoidably unsafe

products are defective and subject to strict liability unless accompanied by proper warnings.

3. This Court should clarify *Rogers* and *Young* to be consistent with comment *k*'s plain language.

By its express terms, comment *k* protection from strict liability is not available to a manufacturer who fails to adequately warn. Comment *k* does not state whether the adequacy of its required warning is measured under a negligence or strict liability standard. This is so because the comment is intended to apply to a claim of design defect and assumes that adequate warnings were given. Adequate warnings are a predicate to application of comment *k*, but the adequacy of those warnings is not governed by comment *k*. Rather, warnings are measured under the rule set forth in § 402A, and the exception to that rule, outlined in comment *k*, applies only after the trier of fact determines whether the known or knowable risk was disclosed.

Young v. Key Pharmaceuticals, 130 Wn.2d 160, 182 (Madsen, J., dissenting), 922 P.2d 59 (1996). This Court should clarify *Young* and *Rogers v. Miles Labs., Inc.*, 116 Wn.2d 195, 203-04 802 P.2d 1346 (1991) to be consistent with comment *k*'s plain language.

In *Rogers*, this Court accepted a certified question from the Court of Appeals for the Ninth Circuit, holding that blood and blood products fell under comment *k*'s narrow exception to the strict liability rule. 116 Wn.2d at 204. *Rogers* is not a WPLA case, however, where the WPLA excludes blood and blood products from coverage. RCW 7.72.010(3) – (5); *Rogers*, 116 Wn.2d at 197 (“The certified question must, then, be answered based on the common law”). Thus, this

Court relied heavily on *Howell v. Spokane & Inland Empire Blood Bank*, examining strict liability under the common law. 114 Wn.2d 42, 53, 785 P.2d 815 (1990).

At issue in *Rogers* was an alleged design defect, not inadequate warnings. 116 Wn.2d at 197. This Court deferred “any issues regarding defendants’ duty to warn” to the federal court. *Id.* The Court nonetheless stated that “it might be argued” that to determine whether strict liability applies under comment *k*, a court must also resolve whether the manufacturer met its duty to warn under comment *k*. 116 Wn.2d at 207. Rejecting that hypothetical, the Court adopted the reasoning articulated in *Brown v. Superior Court*, a California case purporting to hold that comment *k* “is based on negligence,” despite its plain language. *Id.* (citing 44 Cal.3d 1049 (1988)).⁶

That portion of *Rogers* is *dicta*, so is not binding. *Protect the Peninsula's Future v. City of Port Angeles*, 175 Wn. App. 201, 215, 304 P.3d 914, *rev. denied*, 178 Wn.2d 1022 (2013). This *dicta* is contrary to numerous Washington cases holding that strict liability is the standard applicable to inadequate-warning claims. *Little v.*

⁶ *Brown* and its progeny are addressed fully below, Argument § B 4.

PPG Industries, Inc., 92 Wn.2d 118, 594 P.2d 911 (1979). And this *dicta* is impossible to reconcile with this Court's subsequent warning that comment *k* must be sparingly applied, "lest we defeat the letter or policy of the WPLA." **Ruiz-Guzman**, 141 Wn.2d at 505.

Relying heavily on the **Rogers dicta** and **Brown**, this Court's 4-4 **Young** decision held, without a constitutional majority, that comment *k* applies a negligence standard to inadequate-warning claims. 130 Wn.2d at 168-71. Like **Rogers**, **Young** was not decided under the WPLA, where the claims arose before WPLA's adoption. *Id.* at 162.

Chief Justice Madsen's dissent, joined by three other Justices, disagreed with the plurality's refusal to apply strict liability. *Id.* at 204 (Madsen, J., dissenting). Faulting the plurality's reliance on **Rogers**, the dissent explains: (1) **Rogers** "departed from Washington precedent regarding failure to warn"; (2) **Rogers** is founded on **Brown**, "which the California Court subsequently explained did not hold that comment *k* alters the § 402A rule of strict liability when the claim is failure to adequately warn"; (3) **Rogers** did not involve inadequate-warning claims, so is easily distinguishable from **Young** (and this matter); and (4) the portion of **Rogers** applying

comment *k* to inadequate-warning claims is *dicta*, so “is simply not binding authority.” *Id.* at 203-04 (Madsen, J., dissenting).

PLAC says little about *Rogers*, failing to address any of the shortcomings raised in Chief Justice Madsen’s *Young* dissent and addressed at length on Taylor’s briefs. PLAC at 5-6; *see also* MDMA at 14. PLAC falsely asserts that “*Rogers* expressly applied negligence in comment *k* warning cases.” PLAC at 6. *Rogers* did not involve an inadequate-warning claim, so this Court did not “apply” a negligence standard. *Compare Id. with* 116 Wn.2d at 207.

PLAC also says remarkably little about *Young*, other than stating that the Court “reaffirmed . . . comment *k*’s . . . reliance on negligence principles.” PLAC at 6; *see also* MDMA at 14, 15-16. PLAC ignores that *Young*, a plurality decision, “has limited precedential value and is not binding.”⁷ *Young*, 130 Wn.2d 160; *Lauer v. Pierce Cnty.*, 173 Wn.2d 242, 258, 267 P.3d 988 (2011) (quoting *In re Pers. Restraint of Isadore*, 151 Wn.2d 294, 302, 88 P.3d 390 (2004)).

PLAC suggests that there is a long line of cases in this State “faithfully appl[ying] this Court’s precedent to prescription medical

⁷ MDMA does not address *Rogers* or *Young* on this point.

products.” PLAC at 8-9. But the only Washington State appellate court case applying a negligence standard in a comment *k* inadequate-warnings case is *Estate of LaMontagne v. Bristol Meyers Squibb*, 127 Wn. App. 335, 343, 111 P.3d 857 (2005). This Court should overrule *LaMontagne*, where it misplaces reliance on *Ruiz-Guzman* and fails to address *Young* and *Rogers*.

4. The foreign cases Amici rely on are unpersuasive.

PLAC and MDMA rely on foreign cases to support the assertion that comment *k* creates a negligence standard for inadequate-warning claims. PLAC 10-20, MDMA 10-11, 13, 15, 17-18. Yet many of those cases hold that comment *k* applies a negligence standard only when proper warnings are provided, maintaining § 402A strict liability for inadequate-warning claims. Many more cases PLAC and MDMA omit also hold that comment *k* does not abrogate strict liability for inadequate-warning claims. This Court should interpret comment *k* consistent with its plain language, and hold that a manufacturer must adequately warn before it is entitled to comment *k*'s exception to WPLA strict liability.

Much of PLAC's argument addresses a strawman Taylor never raised, claiming: "Plaintiff broadly challenges use of negligence principles in product-liability litigation involving

prescription medical products.” PLAC at 10. Taylor has never purported to address whether other states use “negligence principles” in this area. Washington does not. Taylor argues only that comment *k* does not abrogate § 402A strict liability for inadequate-warning claims. Her claim has nothing to do with “the use of negligence principles” in any other products-liability context. *Id.*

Focusing on Chief Justice Madsen’s *Young* dissent, PLAC and MDMA argue that the dissent misunderstood *Brown* (upon which the *Rogers dicta* is based) and California’s subsequent case law addressing *Brown*. PLAC at 7-8, 10 (addressing *Brown*, 44 Cal.3d at 1059; *Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal.3d 986 (1991); MDMA at 15-18 (same). PLAC argues that after this Court decided *Rogers*, California has “repeatedly held that strict products liability law ... may incorporate negligence concepts without undermining the principles fundamental to a strict liability claim.” PLAC at 10 (quoting *Johnson v. American Standard, Inc.*, 43 Cal.4th 56, 73 (2008). This shift, PLAC claims, “explains that state’s subsequent interpretation of *Brown*,” referenced in Chief Justice Madsen’s *Young* dissent. PLAC at 10. PLAC and MDMA misconstrue *Brown* and *Anderson*, as neither supports their

assertions that comment *k* abrogates strict liability for inadequate-warning claims under § 402A.

As the *Young* dissent explains, *Brown*'s procedural posture gave rise to the following passage from *Brown*, as quoted in the *Rogers dicta*:

[T]here is a general consensus that, although [comment *k*] purports to explain the strict liability doctrine, in fact the principle it states is based on negligence. That is, comment *k* would impose liability on a drug manufacturer only if it failed to warn of a defect of which it either knew or should have known.

Young, 130 Wn.2d at 185 ((Madsen, J., dissenting) (citing *Rogers*, 116 Wn.2d at 207, quoting *Brown*, 44 Cal. 3d at 1059). In *Brown*, the trial court ruled before trial that under comment *k*, a manufacturer could not be strictly liable for defective design, but could be strictly liable for failing to adequately warn about the drug's known or knowable side effects. *Young*, 130 Wn.2d at 185 (Madsen, J., dissenting); *Anderson* 53 Cal. 3d at 999 (explaining *Brown*). That ruling was not challenged on appeal. *Id.* Plaintiff asked the appellate court to extend the pre-trial ruling to unknown risks, but the appellate court affirmed the trial court. *Id.*

Revisiting *Brown* in *Anderson*, the court "reject[ed] the contention that every reference to a feature shared with theories of

negligence can serve to defeat limitations on the doctrine of strict liability." **Anderson**, 53 Cal. 3d at 1002. The court explained the marked difference in negligence and strict liability failure-to-warn:

Strict liability is not concerned with the standard of due care or the reasonableness of a manufacturer's conduct. The rules of strict liability require a plaintiff to prove only that the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution. Thus, in strict liability, as opposed to negligence, the reasonableness of the defendant's failure to warn is immaterial.

53 Cal. 3d at 1002-03. Thus, the **Young** dissent was correct: **Brown** does not support the **Rogers dicta** that comment *k* eliminates strict liability for inadequate-warning claims. **Young**, 130 Wn.2d at 185 ((Madsen, J., dissenting). PLAC's and MDMA's contrary assertion fails. PLAC at 10-13; MDMA at 17-18.

PLAC confuses the issue, stating "[u]nless and until this Court follows California's lead and allows consideration of reasonableness and foreseeability in all strict-liability warning cases, Plaintiffs' California analogy is inapt." PLAC at 12-13. But Taylor does not analogize to California law, which takes an entirely different approach to strict liability (particularly in warning claims), focusing not on the consumer and the product, but on the manufacturer. Compare, **Falk**, 113 Wn.2d at 654, **Tabert**, 82 Wn.2d at 154; and

Ryder, 91 Wn.2d at 117-18; with *Anderson*, 53 Cal.3d at 1001-02.

Even PLAC acknowledges, as it must, that Washington's approach is entirely different than California's:

Washington, unlike California, does not temper non-prescription medical-product-warning cases with "negligence" concepts like foreseeability. Instead, "foreseeability of harm is not an element of a strict liability warning claim."

PLAC at 12 (quoting *Simonetta v. Viac Corp.*, 165 Wn. 2d 341, 330, 197 P.3d 127 (2008)). California's distinct approach further illustrates that *Rogers'* reliance on California law was misplaced.

MDMA similarly relies on *Anderson* for the proposition that "Warning liability is a conduct-based tort, which is why courts are increasingly finding that it sounds in negligence." MDMA at 17. But Washington "warning liability" is not a "conduct-based tort," and Washington jurisprudence has not "gravitat[ed] to fault-based standards." *Id.*

Finally, PLAC's and MDMA's selective collection of foreign cases is unpersuasive. PLAC at 13-20; MDMA at 10, 13, 15, 17-18. PLAC in particular raises many foreign cases, broadly asserting that these "precedents . . . support affirmance." PLAC 13-20. Many of those cases do not address whether comment *k* abrogates strict liability for inadequate-warning claims. See PLAC at 13-14, 17-18.

Most of those cases address using “negligence concepts in § 402A warning cases.” *Id.* at 14-19. Only a few adopt a negligence standard. *Id.* Thus, those cases collectively do not suggest that comment *k* abrogates strict liability for inadequate-warning claims, but more broadly address the varying approaches different states take to applying strict liability.

Washington’s approach is well-settled: a manufacturer can be strictly liable for failing to adequately warn at the time of manufacture under *either* a risk/utility *or* a consumer-expectation analysis. Foundation at 10-11 (citing *Falk*, 113 Wn.2d at 654). This approach focuses on the consumer’s expectations and the inherent nature of the product, not on the manufacturer’s conduct. *Id.* ISI has not asked this Court to revisit this approach, and it should not do so.

Further, as the *Young* dissent noted, many other jurisdictions have held that comment *k* does not abrogate strict liability for inadequate-warning claims, but rather applies a negligence standard only when adequate warnings are provided:

- ◆ ***Borel v. Fiberboard Paper Prods. Corp.***, 493 F.2d 1076 (5th Cir. 1975) (“court correctly instructed on strict liability in failure to warn claim involving unavoidably unsafe product under comment *k*”), *cert. denied*, 419 U.S. 869, 42 L. Ed. 2d 107, 95 S. Ct. 127 (1974);

- ◆ ***Alman Bros. Farms & Feed Mill, Inc. v. Diamond Lab., Inc.***, 437 F.2d 1295 (5th Cir. 1971) (“failure to give complete disclosure of the existence and extent of risk involved in use of product deprived product of comment *k* exemption”);
- ◆ ***Filler v. Rayex Corp.***, 435 F.2d 336 (7th Cir. 1970) (“exception to strict liability under comment *k* applies only when product accompanied by proper warning”);
- ◆ ***Davis v. Wyeth Lab., Inc.***, 399 F.2d 121 (9th Cir. 1968) (“failure to warn of risk that reasonable consumer would want to know rendered warning defective under comment *k* and product subject to strict liability”);
- ◆ ***Jackson v. Nestle-Beich, Inc.***, 147 Ill. 2d 408 (1992) (“unavoidably unsafe product subject to strict liability due to absence of warning of the unavoidable risk of injury posed by product”); and
- ◆ ***Niemiera v. Schneider***, 114 N.J. 550 (1989) (“comment *k* immunity does not eliminate strict liability for failure to provide a proper warning”).

Young, 130 Wn.2d at 185-86 (Madsen, J., dissenting).⁸ In holding that “comment *k* is not intended to apply a negligence standard to manufacturing defect claims,” the Ninth Circuit collected cases holding that comment *k* does not apply a negligence standard to manufacturing-defect claims *or* warning-defect claims:

- ◆ ***Pattern v. Lederle Labs.***, 676 F.Supp. 233, 236 (D Utah 1987) (holding that “comment *k*’s immunity from strict liability does not extend to strict liability claims based on some manufacturing flaw or on inadequacy of warning”);

⁸ The parentheticals are direct quotes from the ***Young*** dissent.

- ◆ ***Adams v. G.D. Searle & Co., Inc.***, 576 Sp. 2d 728, 732 n. 4 (Fla. App. 1991) (holding that “[a]n injured party may seek strict liability for manufacturing defects or inadequate warnings even though comment *k* applies”);
- ◆ ***Tansy v. Dacomed Corp.***, 890 P.2d 881, 886 (Okla. 1994) (holding that “[t]he comment *k* defense does not apply when the product is defective due to faulty manufacturing or inadequate warnings”);
- ◆ ***Catrignano v. E.R. Squibb & Sons, Inc.***, 546 A.2d 775, 780 (R.I. 1988) (holding that the comment *k* “exemption applies only to allegations of a defective design”); and
- ◆ ***Toner v. Lederle Labs., a Div. of Am. Cyanamid Co.***, 732 P.2d 297, 305 (Idaho 1987) (holding that “By its terms, comment *k* excepts unavoidably unsafe products from strict liability only where the plaintiff alleges a design defect, and not where the plaintiff alleges a manufacturing flaw or an inadequate warning”).

Transue v. Aesthetech Corp., 341 F.3d 911, 918-19 (2003).⁹

In sum, this Court would join good company in holding that comment *k* means what it says: negligence applies if, and only if, the product is accompanied by proper directions and warning.

5. Alternatively, this Court should adopt a product-specific approach

This Court should hold in the alternative that comment *k* does not apply unless a jury first finds that the da Vinci robot’s social utility greatly outweighed its inherent risk at the time of Fred’s procedure.

⁹ Taylor omits citations to California cases, as California law is addressed at length above.

This Court most recently addressed a product-specific approach in *Ruiz-Guzman*, holding (regarding pesticides) that comment *k* applies only where the manufacturer proves: (1) that the product's utility greatly outweighs its risk; (2) that the risk is known; (3) that there is no other way to achieve the product's benefit; and (4) that there is no known way to avoid the risk. 141 Wn.2d at 509-10. This Court declined to address whether the product-specific approach should also apply to prescription drugs, where the question was not properly before the Court on certification from the Ninth Circuit.¹⁰ 141 Wn. 2d at 508. The Court noted, however, that a blanket exemption is "arguably incongruent with the social utility reasoning in *Terhune* and *Rogers*." *Id.*; *Rogers*, 116 Wn.2d at 204 ("Comment *k* justifies an exception from strict liability by focusing on the product and its relative value to society, rather than on the manufacturer's position in the stream of commerce").

PLAC claims that in *Terhune*, "[t]his Court rejected any product specific exception to comment *k*," later arguing that "following *Terhune*," this Court placed the blood products at issue in

¹⁰ PLAC overlooks this point, misleadingly claiming that the Court "flatly refused to retreat from its comment *k* precedent with respect to prescription medical products" PLAC at 8.

Rogers in the “category” of unavoidably unsafe products absent a product-specific analysis. PLAC at 4, 6; see *also* MDMA at 14-15. Those claims are misleading at best, where this Court was not asked to adopt a product-specific approach in either **Terhune** or **Rogers**. And again, reliance on **Terhune** and **Rogers** for that proposition is misplaced in light of this Court’s subsequent acknowledgment that exempting entire classes of products regardless of their social utility is “arguably incongruent with the social utility reasoning in **Terhune** and **Rogers**.” **Ruiz-Guzman**, 141 Wn.2d at 509-10. That is no less true for medical devices than it is for pesticides.

No more persuasive is MDMA’s argument for a blanket exemption to protect socially beneficial products. MDMA at 16. The product-specific approach takes social utility – and inherent risks – into account. **Ruiz-Guzman**, 141 Wn.2d at 509-10.

MDMA’s “horribles” are equally unpersuasive. MDMA at 19-20. MDMA concludes by touting the robot’s benefits, while speculating that if this Court adopts Taylor’s arguments, manufacturers might find it too risky to place unavoidably unsafe products into the market. *Id.* MDMA would plainly like to limit manufacturer liability as much as possible, but that should not be accomplished at the expense of patient safety. Comment *k* struck the

proper balance by reducing the standard of liability only where proper warnings are given. This Court should follow that wise compromise.

CONCLUSION

ISI has a WPLA duty to adequately warn Harrison, and is strictly liable for its failure to do so. This Court should reverse and remand for trial under proper instructions.

RESPECTFULLY SUBMITTED this 25th day of May, 2016.

MASTERS LAW GROUP, P.L.L.C.

A handwritten signature in black ink, appearing to read "Kenneth W. Masters", is written over a horizontal line.

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CERTIFICATE OF SERVICE

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RCW 7.72.010

Definitions.

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.

[1991 c 189 § 3; 1981 c 27 § 2.]

NOTES:

Preamble—1981 c 27: "Tort reform in this state has for the most part been accomplished in the courts on a case-by-case basis. While this process has resulted in significant progress and the harshness of many common law doctrines has to some extent been ameliorated by decisional law, the legislature has from time to time felt it necessary to intervene to bring about needed reforms such as those contained in the 1973 comparative negligence act.

The purpose of this amendatory act is to enact further reforms in the tort law to create a fairer and more equitable distribution of liability among parties at fault.

Of particular concern is the area of tort law known as product liability law. Sharply rising premiums for product liability insurance have increased the cost of consumer and industrial goods. These increases in premiums have resulted in disincentives to industrial innovation and the development of new products. High product liability premiums may encourage product sellers and manufacturers to go without liability insurance or pass the high cost of insurance on to the consuming public in general.

It is the intent of the legislature to treat the consuming public, the product seller, the product manufacturer, and the product liability insurer in a balanced fashion in order to deal with these problems.

It is the intent of the legislature that the right of the consumer to recover for injuries sustained as a result of an unsafe product not be unduly impaired. It is further the intent of the legislature that retail businesses located primarily in the state of Washington be protected from the substantially increasing product liability insurance costs and unwarranted exposure to product liability litigation." [1981 c 27 § 1.]

RCW 7.72.030

Liability of manufacturer.

(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.

[1988 c 94 § 1; 1981 c 27 § 4.]

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Subject: RE: In re the Estate of Taylor v. Intuitive Surgical, Inc. / WA Supreme Court No. 92210-1 - Petitioners' Response to Amici

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Subject: In re the Estate of Taylor v. Intuitive Surgical, Inc. / WA Supreme Court No. 92210-1 - Petitioners' Response to Amici

Attached please find the following documents filed on behalf of Petitioners, Estate of Fred E. Taylor:

1. Motion to File One Over-Length Brief in Answer to Four Amici Briefs; and
2. Petitioners' Response to Four Amici

Case Name: In re the Estate of Fred E. Taylor v. Intuitive Surgical, Inc.

Case No. 92210-1

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*Thank you,
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