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No. 92210-1

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SUPREME COURT  
OF THE STATE OF WASHINGTON

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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,

Petitioners,

vs.

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

Respondent.

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INTUITIVE SURGICAL'S ANSWER  
TO AMICI BRIEFS

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## A. INTRODUCTION

The Court accepted the amici briefs of the Product Liability Advisory Council, Inc. (“PLAC”), the Medical Device Manufacturers Association and the National Association of Manufacturers (“MDMA/NAM”), the Washington State Hospital Association (“WSHA”), and the Washington State Association for Justice Foundation (“WSAJF”) by its letter ruling of May 6, 2016. In accordance with that ruling, Intuitive Surgical, Inc. (“Intuitive”) provides this answer to the amici briefs.

At trial, Josette Taylor, as the personal representative of the Estate of Fred Taylor (“Taylor”), benefitted from extraordinarily favorable jury instructions that did not correctly state Washington law on the duty to warn under the Washington Product Liability Act, RCW 7.72 (“WPLA”).<sup>1</sup> Taylor also had the opportunity to present all relevant evidence on the duty to warn issue,<sup>2</sup> but the jury ruled against Taylor and exonerated

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<sup>1</sup> As noted in Intuitive’s supplemental brief at 6-8, Taylor’s proposed instructions 12 and 28 provide that Intuitive owed Harrison Medical Center (“Harrison”) a duty to train, a requirement *nowhere* supported by the plain language of the WPLA, RCW 7.72.030(1)(b), or by the case law of any other jurisdiction. It is noteworthy that Taylor declines to address this point in her supplemental brief, seemingly conceding that her instructions contained an erroneous statement of law, precluding their review by this Court. *Havens v. C&D Plastics, Inc.*, 124 Wn.2d 158, 167, 876 P.2d 435 (1994).

Even Taylor’s amicus ally, WSAJF, declines to argue anywhere in its brief that the WPLA mandates a duty to train product users.

<sup>2</sup> The only evidentiary issue raised on appeal by Taylor was the trial court’s

Intuitive from any liability for Dr. Scott Bildsten's negligent decision to perform robotic surgery on Fred Taylor even though he was an extremely poor candidate for such surgery.

Now, ignoring the critical fact that she settled any negligence claims against Harrison, she presented little, if any, evidence of Intuitive's involvement with Harrison,<sup>3</sup> and Dr. Bildsten's negligence in selecting Fred Taylor for robotic surgery and performing the non-robotic component of the surgery was the real cause of Fred Taylor's harm, Taylor asks this Court to distort Washington's WPLA on the duty to warn and actions under comment k to the *Restatement (Second) of Torts*. This Court should not permit Washington law to take such an extreme, outlier position; it should reject Taylor's request and affirm the Court of Appeals.

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decision to exclude Exhibit 304. Intuitive supp'l br. at 20-21; Intuitive br. at 38-46. The trial court did not abuse its discretion in excluding that exhibit where Taylor herself sought to exclude evidence of other robotic surgeries at Harrison in limine. CP 2723. Disregarding her own efforts in limine to preclude the admission of such evidence, Taylor then raised the subject of other robotic surgeries at Harrison with Intuitive's Sean O'Connor. RP 730-33. On cross, without objection, O'Connor indicated there were no problems with the quality of Harrison's robotic surgery program. RP 855. When Taylor sought to introduce Exhibit 304, a compilation of various robotic surgeries at the hospital, the trial court properly excluded it after an analysis under ER 403. RP 1429. The court gave the jury a curative instruction. CP 4693-94. The trial court did not abuse its discretion in addressing Exhibit 304 because Washington law disfavors the admission of other incidents as evidence of negligence because such evidence invites a resort to mini-trials on whether those incidents occurred under the same or similar circumstances. *Blood v. Allied Stores Corp.*, 62 Wn.2d 187, 189, 381 P.2d 742 (1963).

<sup>3</sup> As noted in Intuitive's supplemental brief at 13-14, Taylor did not make a record regarding Harrison's use of Intuitive's da Vinci robotic surgical system or how Intuitive's alleged failure to warn Harrison's staff caused Fred Taylor's injuries. Taylor called no witnesses from Harrison and offered no documentary evidence on Harrison's credentialing process for medical professionals or its use of robots.

## B. STATEMENT OF THE CASE

The facts and procedures in this case are appropriately set forth in the Court of Appeals opinion and in the parties' supplemental briefs. The amicus briefs rely on those recitations of facts and procedure. Two points bear emphasis, however. First, as noted above, left largely unaddressed either in Taylor's supplemental brief, the WSAJF brief, or the Court of Appeals dissent is the glaring fact that *Taylor settled any claims against Harrison*. Whatever claims Taylor might have had for Harrison's corporate negligence pertaining to anything having to do with staffing or equipment provided at the hospital for use by its staff under *Pedroza v. Bryant*, 101 Wn.2d 226, 677 P.2d 166 (1984) were *resolved*. It is difficult to discern precisely how *Taylor* has standing to assert what might essentially be a claim *by Harrison* against Intuitive for its alleged failure to provide information about the da Vinci system for purposes of credentialing at the hospital. Neither Taylor, nor WSAJF, address this point.

Second, Taylor has repeatedly asserted that Intuitive should have warned Harrison that Dr. Bildsten should have had further training before he could be credentialed to perform robotic surgery. Taylor supp'l br. at 3-6. Presumably, this factored into WSAJF's contention that a medical device manufacturer has a duty to warn hospitals purchasing a medical

device that is separate from the duty to warn professionals like Dr. Bildsten, who actually exercise medical judgment in utilizing the device under the learned intermediary principle. WSAJF br. at 13-17. But, as Intuitive has pointed out, the number of procedures necessary to train surgeons is an *individual* decision. Intuitive supp'l br. at 14 n.18. In fact, hospitals vary in the number of procedures necessary for a surgeon to be credentialed in the use of robotic surgery. WSHA br. at 12-13. Ultimately, Harrison's credentialing of Dr. Bildsten on the da Vinci system is not a basis for holding Intuitive liable to Taylor for Fred Taylor's surgery; only Dr. Bildsten exercised medical judgment in prescribing the use of robotic surgery for Fred Taylor.

Here, Dr. Bildsten was a board-certified urologist with extensive surgical experience. Intuitive supp'l br. at 3 n.3. He was trained in the use of the da Vinci system. *Id.* Most critically, and again largely ignored by Taylor and WSAJF, it is *undisputed* that Bildsten was *expressly* and *repeatedly* advised by Intuitive about the criteria for selection of patients for robotic laparoscopic surgery. Intuitive supp'l br. at 3-4. Fred Taylor was an extremely poor candidate for such surgery,<sup>4</sup> but Dr. Bildsten

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<sup>4</sup> Fred Taylor weighed 280 pounds at the time of his surgery, and had a BMI of approximately 39. CP 926. Dr. Bildsten admitted that "extremely obesity" was an "absolute contraindication" for the da Vinci surgery. RP 1138. Fred Taylor was "severely obese," CP 173-74; RP 1140, or "morbidly obese" in clinical terms. RP 1359. He had a history of multiple surgeries, including three abdominal surgeries

ignored Intuitive's instructions on patient selection and performed robotic surgery on Mr. Taylor anyway and, further, he performed both the robotic and non-robotic aspects of the surgery negligently, as Taylor's own experts readily acknowledge. RP 905-06, 977, 1134.

### C. ARGUMENT

(1) Taylor's Position on Intuitive's Duty to Warn Is Contrary to the Language of the WPLA and This Court's Decisions, and Would Make Washington an Extreme Outlier on Product Liability Law in the United States

Taylor and WSAJF contend that the WPLA obligates a medical device manufacturer like Intuitive to essentially warn anyone who might come into contact with the product regarding its possible hazards,<sup>5</sup> notwithstanding the fact that a licensed physician must prescribe its use. Alternatively, they contend that Harrison was a second learned intermediary as to the use of the da Vinci system entitled to a separate, and possibly different, warning from that given by Intuitive to Dr. Bildsten, the licensed professional who exercised medical judgment in actually

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(appendectomy, gall bladder removal, hernia surgery with mesh), which complicated his suitability for prostate surgery. CP 178. Taylor had been diagnosed with diabetes, coronary artery disease, hypertension, and high cholesterol. RP 1348-50, 1370. Fred Taylor's physicians prescribed blood pressure, cholesterol, and diabetes medications, which he did not regularly take. *Id.* Taylor's medical records disclosed that his diabetes and high blood pressure had been out of control for many years before his death. RP 1376.

<sup>5</sup> Moreover, again unaddressed by either Taylor or WSAJF, such warnings, in order to be effectual, could conceivably differ, depending upon who was receiving the warning. This further reinforces the impracticality of Taylor's position.

prescribing its use in Fred Taylor's case.

Taylor/WSAJF's interpretation of the duty to warn here is not only highly impractical, it is contrary to the explicit language of the WPLA and this Court's decisions, as PLAC, MDMA/NAM, and the WSHA readily point out. Taylor/WSAJF's argument, if adopted by this Court, would impose practical hardships on Washington manufacturers and would establish Washington product liability law as an extreme outlier in the United States. This Court should reject that position and affirm the well-reasoned decision of the Court of Appeals majority here.

Turning first to the second learned intermediary argument, Taylor gives it scant attention. Taylor supp'1 br. at 10-11. WSAJF argues that comment k is inapplicable, WSAJF br. at 16-17, and effectively concedes that Taylor's argument regarding Harrison as a second intermediary is a non-starter.<sup>6</sup> The Court of Appeals correctly rejected the notion that Harrison is a second learned intermediary. Op. at 12-14.

On the learned intermediary principle, both WSHA and MDMA/NAM make clear that only persons exercising medical judgment step into the patient's shoes for purposes of receiving a warning from a medical device or pharmaceutical manufacturer. WSHA br. at 2-17;

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<sup>6</sup> WSAJF declines to address the issue in its brief. WSAJF br. at 16.

MDMA/NAM br. at 6-9. This fully comports with this Court's decisions in *Terhune v. A.H. Robins Co.*, 90 Wn.2d 9, 577 P.2d 975 (1978) and *McKee v. Amer. Home Products Corp.*, 113 Wn.2d 701, 782 P.2d 1045 (1989). Such a position avoids the practical problems of potentially different "adequate" warnings for hospitals and physicians regarding the product, WSHA br. at 18, or the improper intrusion of the hospital into the patient-physician relationship. WSHA br. at 17-19; MDMA/NAM br. at 12-13.<sup>7</sup>

Harrison was not a second learned intermediary for purposes of RCW 7.72.030(1) or comment k.

Taylor and WSAJF also argue that manufacturers have an additional duty to warn unspecified numbers of others who come in contact with the product that is *separate* from the duty to warn learned intermediaries. Taylor supp'l br. at 6-10; WSAJF br. at 13-18.<sup>8</sup> The precise contours of such a duty are ill-defined in both briefs.

WSAJF requests that this Court reject the argument advanced by

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<sup>7</sup> Indeed, arguably, such an intrusion exposes hospitals to potential liability under RCW 7.72.

<sup>8</sup> MDMA/NAM cogently note that Taylor/WSAJF's effort to create a duty to warn distanced from the specific duty to warn in the WPLA's RCW 7.72.030(1) violates the directive in that statute that it was creating a single cause of action, preempting all other product liability theories. RCW 7.72.010(4); *Wash. Water Power Co. v. Graybar Elec. Co.*, 112 Wn.2d 847, 853-54, 774 P.2d 1199 (1989). MDMA/NAM br. at 9-12.

WSHA in its Court of Appeals amicus brief that WPLA warnings were not required for every conceivable person in the supply chain of a product, other than its ultimate user. WSAJF br. at 14. Thus, WSAJF seemingly endorses the proposition that such a universal warning notion is *mandated* under RCW 7.72.030(1). Indeed, WSAJF goes so far as to contend that “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.” *Id.* WSAJF’s argument contemplates that a medical device manufacturer, like other product manufacturers, must give different warnings to different possible product “users.” Such an analysis is wildly impractical, creating unpredictability for product manufacturers who must seemingly guess as to who will “use” their product and what the nature of an “adequate” warning might be. WSAJF’s only answer to this predicament is that such a matter is universally a jury question, WSAJF br. at 16,<sup>9</sup> and it suggests in a footnote

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<sup>9</sup> WSAJF does not articulate precisely how in this case, had Harrison received a warning from Intuitive, presumably about credentialing surgeons on robotic surgery, that Harrison would have been “in a position to prevent harm to [Fred Taylor] if adequate warnings had been given.” WSAJF br. at 16. No evidence was adduced at trial by Taylor on this point. Intuitive supp’l br. at 13-14. Moreover, the jury here found Dr. Bildsten was adequately trained pursuant to Instruction Numbers 10 and 11; it was Dr. Bildsten who selected Fred Taylor for robotic surgery contrary to Intuitive’s express warnings. *Id.* at 12-13.

that this interpretation of a manufacturer's liability will not be "unduly expansive," without any real analysis of why that bald assertion is true. *Id.* at 16 n.12.

The better interpretation<sup>10</sup> of the duty to warn is found in the language of RCW 7.72.030 itself that makes the duty to warn one owed by manufacturers to product *users*. This mandate is found explicitly in RCW 7.27.030(1)(b)'s post-manufacture duty to warn, and only makes good sense.<sup>11</sup> Similarly, as WSHA notes in its brief at 3, that is consistent with the focus of the WPLA on the ordinary consumer. RCW 7.72.030(3). Taylor/WSAJF's interpretation of the statute providing for an amorphous, ever-changing warning will only lead to absurd consequences.

As noted in the WSHA and MDMA/NAM amicus briefs, the crucial issue is how best to make sure that the persons actually using the

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<sup>10</sup> The primary goal of statutory interpretation is to carry out legislative intent. *Cockle v. Dep't of Labor & Indus.*, 142 Wn.2d 801, 807, 16 P.3d 583 (2001). In Washington, this analysis begins by looking at the words of the statute. "If a statute is plain and unambiguous, its meaning must be primarily derived from the language itself." *Id.* Courts look to the statute as a whole, giving effect to all of its language. *Dot Foods, Inc. v. Wash., Dep't of Revenue*, 166 Wn.2d 912, 919, 215 P.3d 185 (2009). Courts must look to what the Legislature said in the statute and related statutes to determine if the Legislature's intent is plain. *Dep't of Ecology v. Campbell & Gwinn, L.L.C.*, 146 Wn.2d 1, 9-10, 43 P.3d 4 (2002). If the language of the statute is plain, that ends the courts' role. *Cerrillo v. Esparza*, 158 Wn.2d 194, 205-06, 142 P.3d 155 (2006).

<sup>11</sup> WSAJF, in particular, arrives at this interpretation of the WPLA by interpreting its provisions on a manufacturer's sales-related and post-manufacture duty to warn product users in a strained interpretation of the statutory language. WSAJF br. at 4, 14-15. The plain intent of the Model Uniform Product Liability Act ("MUPLA"), upon which the WPLA was based, was that warnings were to be provided to product users. 44 Fed. Register 62721. No other interpretation makes any real sense. This Court should reject such a strained approach to the plain language of the WPLA.

product will be effectively warned so as to avoid harm to patients in their use. That is the whole reason for the creation of the learned intermediary principle. The professional who exercises medical judgment about a pharmaceutical or a medical device is the better recipient of a manufacturer's product warnings. That professional can understand the medical ramifications of the product's use in the case of a particular patient. *Terhune*, 90 Wn.2d at 14; WSHA br. at 2-9; MDMA/NAM br. at 6-9.

Simply put, as MDMA/NAM notes in its brief at 8, "Hospital personnel are also not 'learned intermediaries.'" This point is confirmed by WSHA in its brief at 9-17. Physicians like Dr. Bildsten, not hospitals like Harrison, decide if a particular pharmaceutical or surgical procedure is appropriate for a particular patient and they then secure the patient's informed consent to the treatment. Any suggestion that hospitals should second guess a physician's decision to use a particular drug, a particular scalpel, or a particular approach to a particular surgery for a particular patient improperly invades the physician-patient relationship as well as a hospital's credentialing decisionmaking. MDMA/NAM br. at 12-13; WSHA br. at 17-19.<sup>12</sup>

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<sup>12</sup> A hospital's independent duty to patients like Fred Taylor under *Pedroza* is non-delegable. 101 Wn.2d at 232-33. Taylor and WSAJF would have Harrison delegate

In sum, this Court should reject the Taylor/WSAJF formulation of the WPLA's duty to warn and adhere to the sensible analysis of the Court of Appeals.

(2) A Unanimous Court of Appeals Correctly Determined That a Negligence Standard Applies to Comment k Warnings

Taylor/WSAJF contend that the Court of Appeals erred in determining that the jury here was properly instructed, based upon WPI 110.02.01; they claim that a negligence standard applied with regard to Intuitive's duty to warn Dr. Bildsten as a learned intermediary. Taylor supp'l br. at 12-17; WSAJF br. at 18-20. They are wrong. The Court of Appeals correctly discerned that a negligence standard applies to a manufacturer's comment k liability. Op. at 14-15.<sup>13</sup>

WPI 110.02.01 specifically provides for a negligence standard in comment k cases; that position is fully supported by this Court's decisions in *Rogers v. Miles Labs, Inc.*, 116 Wn.2d 195, 802 P.2d 1346 (1991) and *Young v. Key Pharmaceuticals, Inc.*, 130 Wn.2d 160, 922 P.2d 59 (1996).

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its credentialing obligations to manufacturers like Intuitive.

<sup>13</sup> WSAJF notes that this Court imported the common law liability of a manufacturer under comment k to the *Restatement (Second) of Torts* § 402A into the WPLA in *Ruiz-Guzman v. AmVac Chem. Corp.*, 141 Wn.2d 493, 7 P.3d 795 (2005). WSAJF br. at 13. Intuitive concurs in that analysis. But WSAJF also baldly asserts in its brief at 18 that "Comment k does not expressly state whether such warnings are based on a negligence or strict liability standard." While true, the statement *ignores* the risk-utility calculus, the core of the negligence analysis, that is its basis. Moreover, WSAJF cites *no case* applying a strict liability standard to a comment k case.

It has been applied in numerous Court of Appeals and federal court decisions. *E.g.*, *Estate of La Montagne v. Bristol-Meyers Squibb*, 127 Wn. App. 335, 111 P.3d 857 (2005); *Payne v. Paugh*, 190 Wn. App. 383, 360 P.3d 39 (2015); *Laisure-Radke v. Par Pharmaceuticals, Inc.*, 894 F. Supp. 1324 (E.D. Wash. 2012), *aff'd*, 555 Fed. Appx. 710 (9th Cir. 2014).<sup>14</sup> Critically, the Legislature has never overridden that interpretation, despite the elapse of 20 years since *Young*, the promulgation of WPI 110.02.01, and the issuance of the Court of Appeals and federal decisions referenced above, thereby acquiescing in it, Intuitive supp'l br. at 17 n.25, a point left unaddressed by Taylor and WSAJF.

In arguing for a strict liability standard to somehow distinguish this overwhelmingly contrary authority, WSAJF contends that a strict liability standard is appropriate generally in product warning cases in Washington and should also apply in the context of a comment k case. WSAJF br. at 6-13. But in making this argument, WSAJF inaccurately relates the legislative intent on a WPLA duty to warn and the significance of *Ruiz-Guzman*, and fails to appreciate the national trend toward a negligence standard generally in duty to warn jurisprudence fully reflected in the *Restatement (Third) of Torts*. PLAC br. at 10-20; MDMA/NAM br. at 13-

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<sup>14</sup> WSAJF only addresses *La Montagne*, and argues in a footnote that it should be overruled. WSAJF br. at 20 n.16.

18.

The actual language of the duty to warn provision in the WPLA, RCW 7.72.030(1), established a *negligence* standard for duty to warn cases generally: “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 because adequate warnings or instructions were not provided.” (emphasis added).

Three specific sources of legislative history document that the Legislature intended to create a negligence standard generally for warning cases. The WPLA was strongly influenced by the United States Commerce Department’s MUPLA. 44 Fed. Register 62714 (1979).<sup>15</sup> In discussing warnings and instructions, the MUPLA expressed the intent to establish a negligence standard in such cases, asserting that the “application of uncertain strict liability principles in the areas of design and duty to warn places a whole product line at risk; therefore a firmer

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<sup>15</sup> The Senate incorporated the section-by-section analysis of the WPLA by the Senate Select Committee on Tort Reform and Product Liability into its Journal; this analysis has been cited as authoritative by Washington courts. *See, e.g., Tegman v. Accident & Med. Investigations, Inc.*, 150 Wn.2d 102, 110, 75 P.3d 497 (2003); *Kottler v. State*, 136 Wn.2d 437, 452, 963 P.2d 834 (1998); *Scott v. Cascade Structures*, 100 Wn.2d 537, 547, 673 P.2d 179, 184 (1983). The Committee stated: “The Committee has utilized the UPLA as a focal point for its consideration of product liability tort reform, and, to a great extent, the final proposal of the Committee closely adheres to its substance, if not its precise language, in four key areas [including manufacturer’s standard of liability].” 1981 Sen. Journal at 624.

liability foundation is needed.” *Id.* at 62722.<sup>16</sup> The 1981 Senate Journal at 625 also indicated that a negligence standard was intended for duty to warn actions. Finally, the contemporaneous law review article of the chair of the Senate Committee from which the WPLA originated stated: “a negligence standard is imposed for those cases involving a defective product design or inadequate warnings.”<sup>17</sup>

While this Court determined that a strict liability standard applied generally to WPLA duty to warn actions in *Ayers v. Johnson & Johnson Baby Products Co.*, 117 Wn.2d 747, 762, 818 P.2d 1337 (1991)<sup>18</sup> to say that Washington law has *unambiguously* determined that strict liability applies generally in WPLA duty to warn is not entirely accurate.<sup>19</sup> Rather,

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<sup>16</sup> One of the MUPLA’s authors, Professor Victor Schwartz, authored the MDMA/NAM brief here. This Court can take note of the origins of the statutory language under *Campbell & Gwinn*, as “related” statutory language. 146 Wn.2d at 11.

<sup>17</sup> Philip A. Talmadge, *Washington’s Product Liability Act*, 5 U. Puget Sd. L. Rev. 1, 8 (1981). This article has been cited as authoritative source of WPLA legislative history by Washington courts. *See, e.g., Stanton v. Bayliner Marine Corp.*, 123 Wn.2d 64, 84, 866 P.2d 15, 26 (1993); *Washington Water Power Co. v. Graybar Elec. Co.*, 112 Wn.2d 847, 858, 774 P.2d 1199 *amended sub nom., Washington Water Power Co. v. Graybar Elec. Co.*, 779 P.2d 697 (1989); *Staton Hills Winery Co., Ltd. v. Collons*, 96 Wn. App. 590, 595, 980 P.2d 784, 787 (1999).

<sup>18</sup> *See Falk v. Keene Corp.*, 113 Wn.2d 645, 782 P.2d 974 (1989) (design case under WPLA).

<sup>19</sup> A concurrence in *Soproni v. Polygon Apartment Partners*, 137 Wn.2d 319, 971 P.2d 500 (1999) supported by four justices disputed whether strict liability was the proper standard in design defect or warning cases, given the legislative history of the WPLA. This Court there concluded that the Legislature had acquiesced in this interpretation, *id.* at 327 n.3, just as Intuitive asks this Court to conclude regarding a negligence standard in comment k cases.

the intent of the 1981 Legislature was to adopt a negligence standard in duty to warn cases where a risk-utility analysis is appropriate. This is consistent with the trend nationally, as was noted in the PLAC and MDMA/NAM briefs.

More fundamentally, WSAJF seems to ignore this Court's express determination in *Ruiz-Guzman* that a case-by-case assessment of whether to apply comment k at all is *unnecessary*. WSAFJ br. at 18-20. As PLAC appropriately noted in its brief at 8, *Ruiz-Guzman* eschewed a case-by-case analysis of particular pharmaceuticals or medical devices and applied comment k universally to prescription drugs and medical devices. 141 Wn.2d at 508. Moreover, by its very nature, comment k requires a court to look to the product itself, balancing its attendant risks and utility, a negligence-type of analysis. *Rogers*, 116 Wn.2d at 204. Contrary to WSAJF's position, it simply makes *no sense* to recognize comment k as a distinct theory in Washington product liability law, and then turn around and apply a strict liability standard to it, defeating its essential policy rationale.

Critically, a negligence standard in comment k cases is universally supported in product liability case in Washington and nationally, and comports with the rationale for comment k. PLAC br. at 10-20; MDMA/NAM br. at 13-18. The *Restatement (Third) of Torts* confirms

that liability for the failure to warn as to medical devices or pharmaceuticals is entirely fault-based. Its § 6 states in pertinent part:

(d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

(1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or

(2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

ALI, *Restatement (Third) of Torts* § 6 (1998).<sup>20</sup> This is entirely consistent with WPI 110.02.01 and *Rogers/Young*.

The focus for manufacturer liability under § 6(d) is classically under risk-utility balancing principles associated with negligence when speaking to the reasonableness of any warnings. This Court need not revisit the risk-utility principles inherent in the standard set by the Legislature in 1981 in RCW 7.72.030. Rather, it should continue to adhere to a negligence standard in comment k cases specifically where a

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<sup>20</sup> Indeed, just as the 1981 Legislature concluded that a negligence standard should apply to WPLA duty to warn cases generally, the *Restatement* concurs that such a standard should apply to duty to warn cases generally. *Restatement (Third) of Torts* § 2(c). As noted in comment a to § 2, a “risk-utility balancing” is necessary in duty to warn cases. “In general, the rationale for imposing strict liability on manufacturers for harm caused by manufacturing defects does not apply in the context of imposing liability for defective design and defects based on inadequate instruction or warning.”

risk-utility balance is fully appropriate to determine if the manufacturer of a pharmaceutical or medical device should be liable.

D. CONCLUSION

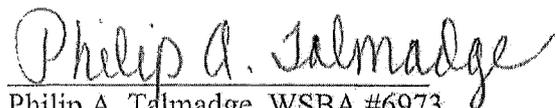
The amici briefs here confirm that Taylor received a fair trial based on exceedingly favorable jury instructions and still did not prevail; Taylor failed to persuade the jury that Intuitive was culpable for Fred Taylor's injuries given Dr. Bildsten's negligent patient selection despite adequate warnings, and the injury he caused to Fred Taylor during his surgery was unrelated to any action by Intuitive.

The amici briefs also demonstrate that this Court should not adopt Taylor's request to distort Washington product liability law and render our state an outlier on the duty to warn and comment k.

This Court should affirm the Court of Appeals and the judgment on the jury's verdict. Costs on appeal should be awarded to Intuitive.

DATED this 25<sup>th</sup> day of May, 2016.

Respectfully submitted,



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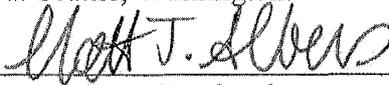
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I declare under penalty of perjury under the laws of the State of Washington and the United States that the foregoing is true and correct.

DATED: May 25, 2016, at Seattle, Washington.

  
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