NO. 92210-1

SUPREME COURT
OF 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

vs.

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

Respondent

AMICI CURIAE BRIEF OF MEDICAL DEVICE MANUFACTURERS ASSOCIATION AND NATIONAL ASSOCIATION OF MANUFACTURERS IN SUPPORT OF RESPONDENT/DEFENDANT

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I. QUALFICATIONS AS *AMICI*

The Medical Device Manufacturers Association ("MDMA") is a national trade association in Washington, DC providing educational and advocacy assistance to about 300 innovative and entrepreneurial medical technology companies. Since 1992, MDMA has been the voice for smaller companies, playing a proactive role in helping shape policies that impact medical device innovators. MDMA promotes public health and improves patient care through the advocacy of innovative, research-driven medical device technology. This includes filing *amicus* briefs.

The National Association of Manufacturers ("NAM") is the largest manufacturing association in the United States. It is a not-for-profit trade association of small and large manufacturers in every sector and in all 50 states. Manufacturing employs nearly 12 million men and women, contributes more than $2.17 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for three-quarters of private-sector research and development. The NAM is the powerful voice of the manufacturing community and the leading advocate for policies that help manufacturers compete in the global economy.

Amici have an interest in this case because it could adversely impact liability over their members' prescription medical devices.

II. INTRODUCTION AND SUMMARY OF ARGUMENT

This case provides the Court with the opportunity to affirm that Washington follows mainstream, well-reasoned American jurisprudence for failure-to-warn liability for medical device manufacturers. The medical device at issue here is the da Vinci System, which provides physicians with a robotic option for conducting laparoscopic surgeries. Medical device innovations such as the da Vinci System have broad, positive impacts for many patients, particularly as medical services have become increasingly complex. As with all prescription medical products, a medical device is not appropriate for all people in all situations. With some, the risk of using a device will outweigh its potential benefits.

Washington liability law for managing manifestations of these risks has been considered settled for medical device manufacturers. The Washington Product Liability Act ("WPLA") serves as the "exclusive" source of remedies for patient claims against manufacturers for harms caused by their products. *See Macias v. Saberhagen Holdings, Inc.*, 175 Wn.2d 402, 282 P.3d 1069 (2012). A medical device manufacturer "fulfills its duty" to warn the patient when it informs his or her physician about the benefits and risks of a device. *See Terhune v. A.H. Robbins Co.*, 90 Wn.2d 9, 577 P.2d 975 (1978). The physician serves as the "learned

intermediary" who makes an individual and knowledgeable assessment as to whether the device is appropriate for each patient. *See McKee v. Am. Home Prods., Corp.*, 113 Wn.2d. 701, 709, 782 P.2d 1045, 1049 (1989) ("[I]t is the physician's duty to warn the ultimate consumer.").

Because medical devices, as with prescription drugs, have risks that may be unavoidable and cannot be made fully safe even with proper warnings, the Court has applied a fault-based approach to the adequacy of these warnings. *See Rogers v. Miles Labs., Inc.*, 116 Wn.2d 195, 207, 802 P.2d 1346, 1353 (1991) ("If the manufacturer of an unavoidably unsafe product fails to provide an adequate warning, it has been negligent-but it is liable in negligence and not strict liability."). The Court follows the legal principles enunciated in comment k of the Restatement (Second) of Torts § 402A (1965): the manufacturer must warn the physician of known or knowable risks associated with the medical device. *See id.*; *Ruiz-Guzman v. Amvac Chem. Corp.*, 141 Wn.2d 493, 7 P.3d 795 (2000).

These liability laws situate Washington within the mainstream of American jurisprudence and federal oversight of medical devices. The Food & Drug Administration ("FDA") and device manufacturers manage public risks associated with medical devices. The manufacturer develops devices useful to classes of patients, and uses warnings to physicians to

guide individual treatment decisions. A hospital, as here, may purchase a medical device for use by physicians who practice at the hospital. But, that does not change the fact that each physician is responsible for determining whether and how to use the medical device, taking into account whether the patient is a good candidate for a procedure, such as robotic-assisted surgery, and if the physician is the right person to provide that treatment.

The jury in this case concluded that Defendant Intuitive Surgical, Inc. ("Intuitive") provided proper warnings to Mr. Taylor's physician about the risks at issue with this surgery. It returned a defense verdict. Rather than accept this verdict, Plaintiffs are attempting to re-write Washington law in favor of new, unsound liability theories that circumvent the letter and purpose of the WPLA. The Legislature enacted the WPLA to be the exclusive source of remedies for harms caused by products in an effort to guard against such creative lawyering. *Amici* respectfully urge the Court to affirm the ruling below. The alternative to the current liability regime could have devastating impacts on patients. *See Rogers*, 116 Wn.2d at 204, 802 P.2d at 1351 (stating that changing liability rules would mean that products "essential to sustain the life of some individuals, would not be available").

III. STATEMENT OF THE CASE

Amici adopt Respondent/Defendant's statement of the case.

IV. ARGUMENT

In this action, Plaintiffs are seeking compensation from Intuitive for injuries they allege were sustained from the physician's decision to use the da Vinci System to remove Mr. Taylor's prostate gland. They already settled claims directly against the physician and the hospital. The jury concluded that Intuitive's warnings to the physician with respect to the risk factors at issue here, namely the level of experience a physician should have before performing this operation on someone of Mr. Taylor's size, were proper under the WPLA and comment k of the Restatement (Second) of Torts § 402A. Therefore, Plaintiffs had to make two changes to current Washington law in order to receive a new trial.

First, Plaintiffs allege that device manufacturers, in addition to warning physicians as learned intermediaries, have an independent duty to patients to warn or train hospitals as second learned intermediaries. Second, they assert that comment k's fault-based standards for the adequacy of medical device warnings should not be applied to all devices, as this Court has held. The Court should reject both changes because they

contradict Washington law, represent unsound public policy, and would push Washington out of the mainstream of American jurisprudence.

A. Medical Device Manufacturers' Duty of Care to Patients Is to Provide Their Physicians, Not Hospitals, with Proper Warnings for the Risks of Using a Device

1. Under the WPLA, There Is Only One Learned Intermediary: The Patient's Treating Physician

The WPLA provides the exclusive source of remedy for any claims that Plaintiffs have against Intuitive. Pursuant to the WPLA and this Court's case law, Intuitive did not have a direct duty to warn Mr. Taylor of risks associated with the da Vinci System. Rather, the manufacturer of a prescription-only medical device fully satisfies its duty to warn the patient when it properly warns the patient's learned intermediary, which is the treating physician. Allowing the communications between the manufacturer and the hospital to be the basis of a duty of care directly to the patient would require the Court to add the hospital as a second learned intermediary. The Court has been clear, though, that this duty "runs only to the physician." *McKee*, 113 Wn.2d at 709, 782 P.2d at 1049. The purpose of the learned intermediary doctrine is to assure that the manufacturer provides warnings, instructions, and other relevant guidance to the prescribing physician, not the staff of the hospital or other facility where the treatment physically takes place.

The term "learned intermediary" is purposefully singular; it focuses on the individual physician treating the patient. The physician is "learned" with respect to both the technology and the patient. He or she is specially trained and must "inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients." *Terhune*, 90 Wn.2d at 14, 577 P.2d at 978. Also, only the treating physician has knowledge of a patient's specific situation and can determine whether a medical device is worth using with each patient. *See* 90 Wn.2d at 15, 577 P.2d at 978 (explaining the physician is positioned to "tak[e] into account his knowledge of the patient as well as the product").

The physician is also the intermediary. He or she is solely responsible for "decid[ing] what facts should be told to the patient" and receiving the patient's informed consent before pursuing any treatment. 90 Wn.2d at 14, 577 P.2d at 978. "In any such situation which may come to mind, the patient is expected to look to the physician for guidance and not to the manufacturer of the products which he may use" or, for that matter, anyone else. 90 Wn.2d at 15, 577 P.2d at 978. "Prescription medical products are unique, involve highly technical properties and apply to each patient differently based on his or her physiological makeup and medical history." John A. Camp & Gary M. Pappas, *A Response to*

Plaintiffs' Call to Abolish the Learned Intermediary Doctrine, Prod. Liab. Litig., Vol. 21, No. 3 (2010). As the lower court appreciated, the patient-physician relationship must be protected to assure that patients can receive individualized care. *See* Op. at 11 (stating the law "should not interfere with the physician-patient relationship").

Consequently, the "learned intermediary" cannot be a multiplicity of individuals and institutions. This Court demonstrated a keen understanding of this point in rejecting an attempt to establish a pharmacist as a second learned intermediary. A pharmacist may be aware of the risks and benefits of a drug or medical device, but he or she does not treat the patient. *See McKee*, 113 Wn.2d at 701, 782 P.2d at 1045. "The relationship between the physician-patient-manufacturer applies equally to the relationship between the physician-patient and pharmacist. In both circumstances the patient must look to the physician, for it is only the physician who can relate the propensities of the [prescription medical product] to the physical idiosyncrasies of the patient." 113 Wn.2d at 711, 782 P.2d at 1050. Hospital personnel are also not "learned intermediaries." They do not have "the medical education or knowledge of the medical history of the patient which would justify a judicial imposition of a duty to intrude on the physician-patient relationship." 113

Wn.2d at 711, 782 P.2d at 1051. They should not be required to be an intermediary between patients and physicians.

2. Plaintiffs Cannot Create a Separate Duty of Care on the Manufacturer Outside of the WPLA

The dissent in the Court of Appeals suggests that even if a hospital is not a learned intermediary, the manufacturer can be subject to liability directly to the patient for failure to warn the hospital about risks and benefits of the da Vinci System. The WPLA does not permit such a conclusion. "It supplants all common law claims or actions based on harms caused by a product." *Macias*, 175 Wn.2d at 409, 282 P.3d at 1073. "Insofar as a negligence claim is product-based, the negligence theory is subsumed under the WPLA." 175 Wn.2d at 409, 282 P.3d at 1074. There can be no additional basis for liability between the patient and manufacturer, including statements to the hospital about the product, its risks, or the qualifications needed before a physician can use the device. As discussed above, pursuant to the WPLA and this Court's rulings, the manufacturer's duty to warn obligation to the patient is fully extinguished through warning the learned intermediary.

The WPLA's establishment of a single body of law for harms caused by products is consistent with laws in the more than twenty states

with similar product liability statutes.[1] The WPLA, along with many of these statutes, were enacted in the 1980s and 1990s based on the Model Uniform Product Liability Act ("UPLA"). *See* 44 Fed. Reg. 62714 (daily ed. Oct. 31, 1979).[2] These acts provide a single action for injuries stemming from products to provide manufacturers, product sellers, and consumers with clarity and predictability. *See id.* § 103(a), 44 Fed. Reg. at 62720 ("This Act is in lieu of and preempts all existing law governing matters within its coverage. . . . The Act consolidates all product liability recovery theories into one."); *see also Patton v. Hutchinson Wil-Rich Mfg. Co.*, 861 P.2d 1299, 1311 (Kan. 1993) (explaining that under its product liability act "all legal theories of negligence, strict liability, and failure to warn are to be merged into one theory called a 'product liability claim'").

The public policy rationale for these laws is that "a 'product liability action' is defined not by the substantive legal theory under which the plaintiff proceeds, but rather by the factual scenario that gives rise to the plaintiff's claim and injury that results from the conduct of the defendant. The term encompasses 'all' actions that otherwise meet the

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[1] *See, e.g.*, Ala. Code § 6-5-521; Ariz. Rev. Stat. § 12-681(5); Ark. Code Ann. § 16-116-102(5); Colo. Rev. Stat. § 13-21-401(2); Conn. Gen. Stat. § 52-572m(b); Ind. Code Ann. § 34-20-1-1; Kan. Stat. Ann. § 60-3302(c); Ky. Rev. Stat. § 411.300(1); La. Rev. Stat. Ann. § 9:2800.52; Miss. Code Ann. § 11-163(c)(1); N.J. Stat. Ann. § 2A:58C-8.

[2] A co-author of this brief, Victor Schwartz, drafted UPLA.

strictures of its definition." *Fields v. Wyeth, Inc.*, 613 F. Supp. 2d 1056, 1059 (W.D. Ark. 2009). Thus, an individual alleging injury from a medical device can sue successfully only when she can establish the elements of a product liability action against that defendant. In Washington, the source of that liability law is solely the WPLA. The law does not allow Plaintiffs to circumvent the WPLA to create new common law theories of liability directly against manufacturers, including of medical devices. The Court must dismiss Plaintiffs' claims because there is no valid liability theory through which Intuitive could be subject to liability directly to Plaintiffs for warnings it provided the hospital.

The question of what the hospital knew or should have known about the da Vinci System is solely relevant to Plaintiffs' corporate negligence claims against the hospital. Those claims were settled. Thus, Plaintiffs' attempt to invoke the hospital's credentialing methods and purchase of the device have no relevance to the current action against the manufacturer. Further, credentialing is 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 specified training sessions. *See* The Medical Staff Handbook, A Guide to Joint Commission Standards 88, 99 (3d ed. 2011).

It would be unsound public policy to deduct from the credentialing and procurement processes any obligation for manufacturers to instruct hospitals to second-guess decisions that physicians and patients make, including the one here to start the surgery using the da Vinci System.

It is this patient-physician decision alone that should be the focal point of any liability inquiry. *See Terhune*, 90 Wn.2d at 16, 577 P.2d at 979 (concluding that the treating physician is "who finally controls the dispensing of the product"). Again, all claims available to Plaintiffs relating to that decision have been settled or fully resolved at trial.

3. It Is Not In the Best Interest of Patients Generally for Hospitals to Interfere With the Patient-Physician Relationship

Ruling in favor of Plaintiffs would turn device manufacturers and hospitals into guarantors that medical devices will be used properly. If such a duty were recognized, manufacturers and hospitals would be required to intrude on the patient-physician relationship in order to manage their own liability exposures. As discussed, device manufacturers and hospital administrators are not necessarily medically educated or trained in each highly specialized practice in which physicians use medical devices. They are not better situated than physicians to weigh factors in an objective, thorough manner based on a patient's individualized needs.

They also are not positioned to discuss those factors with patients and receive the patient's informed consent. They should not be responsible for exercising medical judgment with respect to individual patient care.

Here, Intuitive properly warned physicians of the da Vinci System's risks, including the risks at issue in this case, and provided the hospital with sufficient information to properly credential physicians to use the medical device. The physician met the credentialing requirements, including having statements from other physicians that he was capable of using the da Vinci System. Whether Mr. Taylor's physician disregarded these warnings is not a liability-creating event for the manufacturer based on information provided to the hospital. Creating such new liability theories to find pockets for paying claims regardless of the consequences has been discredited as "deep pocket jurisprudence [which] is law without principle." *Huck v. Wyeth Inc.*, 850 N.W.2d 353, 380 (Iowa 2014) (rejecting a theory for subjecting brand-name drug manufacturers to liability for harms caused solely by their generic counterparts).

B. The Adequacy of Warnings for Medical Devices Should Continue to Be Adjudged By a Fault-Based Standard

Plaintiffs also seek to change the liability standard used to assess the adequacy of a medical device manufacturer's warnings to a physician from fault to strict liability. Washington has applied principles set forth in

comment k of Restatement (Second) of Torts § 402A, which establish that the failure-to-warn standard for all prescription medical products is fault-based. *See Rogers*, 116 Wn.2d at 207, 802 P.2d at 1353 ("If the manufacturer of an unavoidably unsafe product fails to provide an adequate warning, it has been negligent-but it is liable in negligence and not in strict liability."); *Young v. Key Pharmaceuticals, Inc.*, 130 Wn.2d 160, 170, 922 P.2d 59, 64 (1996) ("[A] separate determination of whether a product is unavoidably unsafe need not be made on a case by case basis."). Plaintiffs argue that the Court should impose strict liability on these warnings, or remove the "blanket" approach that classifies all prescription medical devices under comment k.

Dean Prosser, Reporter for the Restatement (Second) of Torts, developed comment k for prescription medical products, including medical devices, as a class because these products provide important benefits despite their unavoidable risks. *See* Restatement (Second) of Torts § 402A cmt. k (stating these products are "fully justified, notwithstanding the unavoidable high degree of risk"). This Court has adopted this reasoning. *See Rogers*, 116 Wn.2at 204, 802 P.2d at 1351 (Prescription medical products are among a class of products that are "necessary regardless of the risk involved to the user"). 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. *See* Restatement (Second) of Torts § 402A cmt. k ("Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous.") (emphasis in original). Thus, notwithstanding their medically recognized risks, these beneficial medical devices can be made available to treat patients so long as they are accompanied with adequate warnings.

Courts around the country, including this Court, have recognized that subjecting manufacturers of prescription medical products to strict liability, or potential strict liability, undermines the public policy purpose of comment k, which is to encourage manufacturers to bring innovative medical products to market. *See, e.g., Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988). For these products, whether the risk "was knowable and whether defendants satisfied their duty to warn are negligence issues" based on the state of scientific knowledge at the time of marketing. *Rogers*, 116 Wn.2d at 197-98, 802 P.2d at 1347. "[I]t would have been irresponsible for the [medical product] company to warn of risks that were not proven to be legitimate risks." *Young*, 130 Wn.2d at 188, 922 P.2d at 73. If a medical device manufacturer meets this standard of care, the

device is not defective and the manufacturer has not committed a tort, even if the patient is injured from a physician's use of the device. *See* Victor Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment K*, 42 Wash. & Lee L. Rev. 1139 (1985).

The Restatement of Torts, Third: Products Liability sought to provide clarity for prescription medical products by offering a distinct section solely on the liability framework for product defects in prescription drugs and medical devices. *See* Restatement of Torts, Third: Prods. Liab. § 6 (1997); *see also* Victor E. Schwartz & Phil Goldberg, *A Prescription for Drug Liability and Regulation,* 58 Okla. L. Rev. 135 (2005). Under § 6, a medical device is defective for failure to warn only when the device is not accompanied by "reasonable instructions or warnings regarding foreseeable risks of harm." *See id*. Thus, the Third Restatement made clear that principles of comment k are applied to all prescription medical products are fault-based. *See id.*; *Ruiz-Guzman*, 141 Wn.2d at 511, 7 P.3d at 804 (comment k provides "a blanket" approach for all such products). Otherwise, there would be "a likelihood of erroneous and inconsistent risk-benefit decisions, uncertainty, and a threat of overdeterrence of socially beneficial products." Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual Track System*, 88 Geo. L.J.

2167, 2169 (2000). "The majority of States, either by case law or by statute, follow" these core principles. *Vasallo v. Baxter Healthcare Corp.*, 696 N.E.2d 909, 922 (Mass. 1998).

This fault-based approach to warning defect claims for prescription medical products is consistent with jurisprudence on warning-based claims generally, which is gravitating to fault-based standards. In the 1960s, strict product liability was initially developed for manufacturing defects. *See Greenman v. Yuba Power Products, Inc.*, 377 P.2d 897, 900 (1963) ("A manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being."). Strict liability was gradually extended to claims brought on the basis of failure to warn or defective design. *See Cronin v. J.B.E. Olson Corp.*, 501 P.2d 1153 (Cal. 1972). Courts, though, struggled with applying strict liability in these cases. *See* John W. Wade, *On Product "Design Defects" and Their Actionability*, 33 Vand. L. Rev. 551 (1980).[3]

The California Supreme Court has explained that this is because

[3] Around this time, the Court held in *Ayers v. Johnson & Johnson Baby Prods. Co.*, 117 Wn.2d 747, 818 P.2d 1337 (1991) that WPLA applies a strict liability standard to warning claims even though the WPLA states that warning defect is based on "negligence." R.C.W. § 7.72.030(1)(b).

"the 'warning defect' theory is 'rooted in negligence' to a greater extent than are the manufacturing – or design-defect – theories. The 'warning defect' relates to a failure extraneous to the product itself. Thus, while a manufacturing or design defect can be evaluated without reference to the conduct of the manufacturer, the giving of a warning cannot." *Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549, 558 (Cal. 1991). Warning liability is a conduct-based tort, which is why courts are increasingly finding that it sounds in negligence. *See* UPLA, 44 Fed. Reg. 62714, 62722 (explaining why duty to warn should be based on fault).

C. Washington's Liability Regime for Medical Devices Advances Proper Liability and Health Care Policy

The liability regime Washington and other states follow complements the federal regulations and supports medical innovations.

The FDA provides the rules manufacturers must follow to develop medical devices. *See* 21 U.S.C. §360c. It approves their designs and warnings to assure the devices can be reasonably safe when used as intended based on risks that are known or knowable through proper due diligence and medical science. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001). Because the devices are available only by prescription, the treating physician must assess the safety profile of the device and the patient's risk factors before the device can be used. *See*

Ruiz-Guzman, 141 Wn.2d at 508, 7 P.3d at 803.

The importance of this case is underscored by the fact that the medical device industry is going through a very promising era of medical breakthroughs. *See, e.g.*, Michael R. Neuman, et al., *Advances in Medical Devices and Medical Electronics*, Proceedings of the IEEE, Vol. 100 (2012). The da Vinci System was a major advancement for reducing complications of surgery. This technology is being built upon to create wireless, intelligent surgical devices, as well as small-scale robotics. *See* Elizabeth Modic, *The Future of Medical Devices*, Today's Medical Developments, Mar. 15, 2013, *at* http://www.onlinetmd.com/rticle/tmd0313-medical-device-sector (last visited Apr. 20, 2016).

The next wave of high-tech medical products promises to similarly enhance patient outcomes. *See, e.g.*, Mark Baard, *Bionic Boomers: New Advances in High-Tech Medical Devices*, Next Avenue, June 26, 2012, *at* http://www.nextavenue.org/bionic-boomers-new-advances-high-tech-medical-devices (last visited Apr. 20, 2016) (discussing implantable devices, such as microchips to monitor artificial joints, and mechanisms to deliver drugs and alert physicians of internal infections).

The novel liability theories Plaintiffs offer would likely make it too risky for device manufacturers to introduce many new products when

otherwise ready for market. Even when physicians exercise all due care, the devices' unavoidable risks will manifest themselves in some patients. If this occurs, many other patients will be denied important benefits, and the development of other, related technologies will be slowed. *See* Ed Edelson, *Implantable Defibrillators are Getting Better*, ABC News, May 11, 2012, *at* http://abcnews.go.com/Health/Healthday (explaining that real life use is critical for improving devices) (last visited Apr. 20, 2016). If this Court were to adopt Plaintiffs' theories, Washington law would be inconsistent with mainstream American jurisprudence, sound legal policy, and the way medical devices are regulated and brought to market.

V. CONCLUSION

For the foregoing reasons, *Amici* respectfully request that this Court affirm the Court of Appeals and the judgment on the jury's verdict.

RESPECTFULLY SUBMITTED this 22nd day of April, 2016.

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