

RECEIVED
SUPREME COURT
STATE OF WASHINGTON
CLERK'S OFFICE

Apr 22, 2016, 4:16 pm

No. 92210-1

RECEIVED ELECTRONICALLY

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.

BRIEF OF AMICUS CURIAE

WASHINGTON STATE HOSPITAL ASSOCIATION

Barbara Allan Shickich, WSBA No. 8733
Brett S. Durbin, WSBA No. 35781
Sarah E. Joye, WSBA No. 44357
Riddell Williams P.S.
1001 Fourth Avenue, Suite 4500
Seattle, WA 98154
(206) 624-3600



ORIGINAL

FILED
MAY - 6 2016
WASHINGTON STATE
SUPREME COURT

g
h

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. IDENTITY AND INTEREST OF AMICUS CURIAE.....	2
III. STATEMENT OF THE CASE.....	2
IV. ARGUMENT.....	2
A. The WPLA Only Imposes A Duty On Manufacturers To Warn The Consumers Or Users Of The Product, Not Everyone In The Distribution Chain	2
B. Expanding A Manufacturer’s Duty To Warn To Include Hospitals That Make Prescription Medical Products Available To Physicians Would Undermine The Basis For The Learned Intermediary Doctrine.....	7
C. Hospitals Do Not Exercise Medical Judgment During The Credentialing And Informed Consent Process	9
1. Credentialing and privileging establish general competency requirements, not patient specific evaluations.....	10
2. Hospitals do not exercise medical judgment in confirming a patient’s informed consent has been obtained.....	15
D. Requiring Product Manufacturer Involvement In The Credentialing Process Would Impermissibly Intrude On Hospitals’ Independent Decision- Making	18
V. CONCLUSION.....	20

TABLE OF AUTHORITIES

FEDERAL COURT CASES

Adams v. Synthes Spine Co., LP.,
298 F.3d 1114, 1117 (9th Cir. 2002)3

STATE COURT CASES

Alexander v. Gonser,
42 Wn. App. 234, 711 P.2d 347 (1985),
rev. denied, 105 Wn.2d 1017 (1986)15

Howell v. Blood Bank,
114 Wn.2d 42, 785 P. 2d 815 (1990).....15, 16

Estate of LaMontagne v. Bristol-Myers Squibb,
127 Wn. App. 335, 111 P.3d 857 (2005)4

McKee v. American Home Products Corp.,
113 Wn.2d 701, 782 P.2d 1045 (1989)..... passim

Pedroza v. Bryant,
101 Wn.2d 226, 677 P.2d 166 (1984).....9

Rogers v. Miles Laboratory,
116 Wn.2d 195, 802 P.2d 1346 (1991).....4

Ruiz-Guzman v. Amvac Chem. Corp.,
141 Wn.2d 493, 508 7 P.3d 795 (2000).....4, 5

Silves v. King,
93 Wn. App. 873, 970 P.2d 790 (1999).....13, 14

Taylor v. Intuitive Surgical, Inc.,
188 Wn. App. 776, 355 P.3d 309 (2015)1, 6, 17

Terhune v. A.H. Robins Co.,
90 Wn.2d 9, 577 P.2d 975 (1978).....3, 4, 5, 8, 9

Washington State Physicians Ins. Exch. & Ass'n v. Fisons Corp.,
122 Wn.2d 299, 858 P.2d 1054 (1993).....4, 8

Young v. Key Pharmaceuticals,
130 Wn.2d 160, 922 P.2d 59 (1996).....4

STATE STATUTORY AUTHORITIES

RCW 4.24.81010

RCW 7.72.030(1).....3

RCW 7.72.030(1)(c)	3
RCW 7.72.030(3).....	3
RCW 70.41.200.	12
RCW 70.41.230	10, 11
WAC 246-320-161.....	10
WAC 246-320-161(2).....	11
WAC 246-320-166(4)(c)	16
WAC 246-863-095.....	6
WAC 246-869-220.....	6

FEDERAL RULES AND REGULATIONS

42 C.F.R. § 422.204.....	10, 11
42 C.F.R. § 422.204(b)(2)(ii)	12
42 C.F.R. § 482.12(a)(6).....	11
42 C.F.R. § 482.24(c).....	16
42 C.F.R. § 482.51(b)(2).....	16

OTHER AUTHORITIES

Centers for Medicare and Medicaid Services, Medicare Managed Care Manual, CMS Pub, 100-16, Chap. 6, Sec. 60.3 (Rev. 24, June 6, 2003); available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c06.pdf	10, 11
Centers for Medicare and Medicaid Services, Revisions to the Hospital Interpretive Guidelines for Informed Consent (April 13, 2007); available at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/scletter07-17.pdf	16
Restatement (Second) of Torts § 402A.....	8
The Joint Commission Standards, MS.06.01.03, MS.06.01.05, MS.06.01.07.....	11
The Society of American Gastrointestinal and Endoscopic Surgeons, “A Consensus Document on Robotic Surgery,” November 2007; available at	

<http://www.sages.org/publications/guidelines/consensus-document-robotic-surgery/>.....12

I. INTRODUCTION

This case addresses the scope of the Washington Products Liability Act (“WPLA”), Chapter 7.72 RCW.

The Court of Appeals majority opinion correctly concluded that “under the learned intermediary doctrine, ISI only had a duty to warn the surgeon and not the hospital.” *Taylor v. Intuitive Surgical, Inc.*, 188 Wn. App. 776, 780, 355 P.3d 309 (2015). Its rejection of Petitioners’ contention that ISI had a duty to provide warnings to Harrison Hospital is consistent with the WPLA and with Washington cases applying the learned intermediary doctrine. It also is consistent with the separate and distinct relationships between a hospital and a patient, and between a physician and a patient. It is logical to conclude that the warnings must be communicated to the ultimate user of the product—the physician—not to every person in the supply chain.

Requiring manufacturers of complex medical products to provide warnings to everyone in the supply chain, instead of just the learned intermediaries responsible for weighing the risks and benefits and prescribing or using the devices, would shift the focus from providing highly detailed and technical warnings to a small group of sophisticated users who must apply that information to the use or application of the product for a specific patient, to providing general and simplified warnings to a large group of purchasers who typically have limited involvement in the actual use of the product. Such a result is contrary to the underlying basis for establishing the learned intermediary doctrine in the first place—to encourage the communication of sophisticated warnings to those in a position to understand them and exercise care and medical judgment in the *use* of the product. Petitioners’ assertion that

manufacturers have a duty to warn hospitals just like physicians, because hospitals credential physicians and obtain informed consent from patients, misconstrues both the credentialing process and the limited role hospitals play in obtaining informed consent. This Court should reject a reading of the WPLA that would hinder the communication of effective warnings to the medical professionals responsible for prescribing and using a manufacturer's products.

II. IDENTITY AND INTEREST OF AMICUS CURIAE

The Washington State Hospital Association ("WSHA") is a nonprofit membership organization representing Washington's 107 community hospitals. WSHA works to improve the health of the people of the State by advocating on matters affecting the delivery, quality, accessibility, affordability, and continuity of health care.

WSHA's members would be directly affected by an expansion of the learned intermediary doctrine to hospitals. Hospitals would be compelled to intrude in physician-patient relationships. Manufacturer's communication of warnings to physicians—not hospitals—provides the most effective mechanism for the delivery of quality and affordable health care to the communities served by WSHA's members.

III. STATEMENT OF THE CASE

WSHA relies on the statement of the case in the Revised Supplemental Brief of Respondent.

IV. ARGUMENT

A. The WPLA Only Imposes A Duty On Manufacturers To Warn The Consumers Or Users Of The Product, Not Everyone In The Distribution Chain.

The WPLA only states that a manufacturer is liable if the product was not reasonably safe because adequate warnings or instructions were

not provided. RCW 7.72.030(1). When read as a whole, the WPLA requires the warning to be given to the users of the product, not every person in the chain of distribution. In order to determine if a product is “not reasonably safe” the statute requires the trier of fact to determine whether the product was “unsafe to an extent beyond that which would be contemplated by the *ordinary consumer*.” RCW 7.72.030(3) (emphasis added). The statute also states that manufacturers satisfy their duty to warn of dangers learned after a product is manufactured so long as the manufacturer “exercises reasonable care to inform product *users*.” RCW 7.72.030(1)(c) (emphasis added). Both of these provisions show that the warning must be provided to the user or “consumer,” not everyone in the chain of distribution.

In the case of a prescription medical product, the user or “consumer” is the physician using or prescribing the product. *Adams v. Synthes Spine Co., LP.*, 298 F.3d 1114, 1117 (9th Cir. 2002) (citing *Terhune v. A.H. Robins Co.*, 90 Wn.2d 9, 14, 577 P.2d 975 (1978)). This is true, even if the device is kept in the hospital. *Id.* at 1116. Therefore, the plain language of the statute only imposes a duty to warn the physician using or prescribing the product.

In addition to the plain language of the statute, it would not make sense to impose a duty to warn individuals about the potential dangers in using a product if they do not use the product. This is especially true in the context of prescription medical products where adequate warnings must contain highly technical and detailed information that would only be meaningful to the prescribing physician. *See McKee v. American Home Products Corp.*, 113 Wn.2d 701, 718-19, 782 P.2d 1045 (1989) (holding that pharmacists did not have a duty to give prescription medication

inserts directed at physicians to the patients taking the drugs because the technical information could unnecessarily confuse patients).

The case law regarding the learned intermediary doctrine reinforces this reading in the context of prescription medical products. The learned intermediary doctrine is founded on the premise that the prescribing physician is the only person in a position to exercise the appropriate medical judgment regarding the use of an “unavoidably unsafe” product. As this Court explained in *Terhune*:

The reasons for this rule should be obvious. Where a product is available only on prescription or through the services of a physician, *the physician acts as a “learned intermediary” between the manufacturer or seller and the patient.* It is his duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and *to exercise an independent judgment, taking into account his knowledge of the patient as well as the product. . . .* Thus, if the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, *the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient.*

Terhune, 90 Wn.2d at 14 (emphasis added).

This Court’s explanation clearly states that the “learned intermediary” is the prescribing physician. This explanation has been quoted in almost all of the Washington cases addressing the learned intermediary doctrine.¹ As noted by this Court in *Terhune*, the doctrine is based upon principles that “have their basis in the character of the medical

¹ See *Terhune*, 90 Wn.2d at 13; *McKee*, 113 Wn.2d at 709; *Rogers v. Miles Laboratory*, 116 Wn.2d 195, 207, 802 P.2d 1346 (1991); *Young v. Key Pharmaceuticals*, 130 Wn.2d 160, 167-68, 922 P.2d 59 (1996); *Ruiz-Guzman v. Amvac Chem. Corp.*, 141 Wn.2d 493, 506, 7 P.3d 795 (2000); *Washington State Physicians Ins. Exch. & Ass’n v. Fisons Corp.*, 122 Wn.2d 299, 313, 858 P.2d 1054 (1993); *Estate of LaMontagne v. Bristol-Myers Squibb*, 127 Wn. App. 335, 345, 111 P.3d 857 (2005).

profession and the relationship which exists between the manufacturer, the physician and the patient.” *Terhune*, 90 Wn.2d at 16. The physician is in the best position to understand the manufacturer’s warnings and exercise informed medical judgment in weighing the risks and benefits to the patient associated with the use of the product. *Terhune*, 90 Wn.2d at 14. Moreover, the physician’s exercise of informed judgment entails knowledge of both the product and the patient’s circumstances. *Id.* These considerations ground the learned intermediary doctrine in Washington on the fundamental premise that the physician who exercises informed medical judgment regarding the use of the product to treat a specific patient is the only person that needs to receive and evaluate the manufacturer’s warnings.

Subsequent decisions have also reinforced the conclusion that the only party with the ability to evaluate and appropriately act on the manufacture’s warnings is the prescribing physician. *See, e.g., McKee*, 113 Wn.2d at 711 (“Neither manufacturer nor pharmacist has the medical education or knowledge of the medical history of the patient which would justify a judicial imposition of a duty to intrude into the physician-patient relationship.”). *See also Ruiz-Guzman v. Amvac Chem. Corp.*, 141 Wn.2d 493, 508, 7 P.3d 795 (2000) (“The exceptions for medical products recognize the unique protection provided to the consumers of such products by the prescribing physician...A physician possesses the medical training to assess adverse health effects of a medical product and to tailor that assessment to a particular patient.”)

Hospitals make decisions about the products they purchase and make available to physicians who practice at the hospital. And, as described below, hospitals are responsible for credentialing physicians and

for granting physicians privileges to perform specific types of procedures. However, these decisions by hospitals do not mean that hospitals are either users of the products or learned intermediaries. As the Court of Appeals majority opinion correctly observed, “a party that simply *enables* a medical product to get to a patient does not share the special type of relationship with the patient as does the prescribing physician.” *Taylor*, 188 Wn. App. at 791 (emphasis in original).

In their supplemental brief, Petitioners attempt to avoid the application of *McKee* here by arguing that pharmacists, unlike hospitals, do not play a role in patient safety. Pet. Supp. Br. at 12. While this statement is not accurate, it does not matter as Petitioners continue to misread the holding in *McKee*.² This Court in *McKee* based its holding on the fact that pharmacists do not have medical training in the treatment of patients, and that “it is only the physician who can relate the propensities of the drug to the idiosyncrasies of the patient.” *McKee*, 113 Wn.2d at 711. This Court went on to conclude that, “[n]either manufacturer nor pharmacist has the medical education or knowledge of the medical history of the patient which would justify a judicial imposition of a duty to intrude into the physician-patient relationship.” *Id.* Thus, the holding in *McKee* is not based on whether the pharmacists played a role in patient safety, but rather on whether they exercise informed medical judgment regarding the treatment of a specific patient.

² See WAC 246-863-095 (“[a] pharmacist’s primary responsibility is to ensure patients receive safe and appropriate medication therapy.”). See also WAC 246-869-220 (“The pharmacist shall directly counsel the patient or patient’s agent on the use of drugs or devices. ... For each patient, the pharmacist shall determine the amount of counseling that is reasonable and necessary under the circumstance to *promote safe and effective administration of the medication* and to facilitate an appropriate therapeutic outcome for that patient from the prescription.”) (Emphasis added).

The learned intermediary doctrine clearly limits the manufacturer's duty to warn to the physician prescribing or using a prescription medical product for the treatment of a specific patient. As such, manufacturers do not have a duty under WPLA to warn anyone besides the prescribing physician of the dangers of a prescription medical product.

B. Expanding A Manufacturer's Duty To Warn To Include Hospitals That Make Prescription Medical Products Available To Physicians Would Undermine The Basis For The Learned Intermediary Doctrine.

Petitioners argue that expanding the manufacturer's duty to warn to hospitals would increase patient safety. Pet. Supp. Br. at 10. While the idea that providing warnings to more parties will result in better patient care is an alluring one, it is fundamentally flawed in the case of prescription medical products. The learned intermediary doctrine was created precisely because providing warnings to all of the parties involved in the use of prescription medical products can be contrary to the best interests of the patient. *McKee*, 113 Wn.2d at 719-20. In the case of an "unavoidably unsafe" product, the appropriate use of the product involves the application of medical judgment to the potential risks and benefits of each use of the product with regard to each patient.

With respect to prescription medical products, the prescribing physician is the only party in a position to exercise that judgment. As explained more fully below, a hospital credentialing process does not involve the application of medical judgment. And because, unlike a physician, a hospital cannot weigh the potential risks and benefits of the use of the product with respect to a particular patient, a hospital is in no better position than a patient to act on the manufacturer's warnings.

Physicians are licensed professionals that are charged with and trusted to exercise medical judgment, including understanding their abilities and the limitations of those abilities. While there may be instances where a physician does not appropriately exercise his or her medical judgment, such as in this case, hospitals are not in the position to second-guess physicians' medical judgments regarding the use of prescription medical products, and requiring them to do so will not be in the best interests of patients.

The learned intermediary doctrine arises in the context of comment *k* to Section 402A of the Restatement (Second) of Torts, which addresses the scope of liability for products that are “unavoidably unsafe.” *Terhune*, 90 Wn.2d at 12-14. Comment *k* discusses the need to allow the production and distribution of medical products whose use involves a high degree of unavoidable risk, but at the same time play an important role in treating illnesses and saving lives. *Id.* Because prescription medical products are “unavoidably unsafe,” weighing the risks and benefits associated with the use of the product is a key function performed by the learned intermediary.

This function can only be performed by the prescribing physician, who has knowledge of the potential risks and benefits posed by the product to a specific patient and can perform the risk-benefit analysis in light of the alternatives available to treat the patient. *See Washington State Physicians Ins. Exch. & Ass'n v. Fisons Corp.*, 122 Wn.2d 299, 313, 858 P.2d 1054 (1993) (“[I]n examining the nature of the relationship between a drug manufacturer, a prescribing physician and a patient, *it is the physician who compares different products, selects the particular drug for the ultimate consumer and uses it as a tool of his or her professional*

trade. Under the learned intermediary doctrine, a drug company fulfills its duty by giving warnings regarding prescription drugs to the physician rather than to the patient.” (emphasis added)) .

Under *Terhune* and similar cases, the manufacturer is required to provide a warning to the person making the decision whether or not to use the product for a specific patient based on the “knowledge of the patient as well as the product.” *Terhune*, 90 Wn.2d at 14. While hospitals play important roles in caring for patients and have an independent duty of care for hospital patients³, they do not share the same role as physicians in treating patients. Hospitals have no particularized knowledge about whether surgery is appropriate or inappropriate for an individual patient, much less whether a specific type or method of surgery will be the most efficacious under the circumstances. Given the unique knowledge and experience physicians have in treating their patients, it is the physician prescribing or using the product, not the hospital that simply makes the product available to the physician, who is in a position to perform the role of a learned intermediary and act on the manufacture’s warnings.

C. Hospitals Do Not Exercise Medical Judgment During The Credentialing And Informed Consent Process.

Petitioners contend that Harrison exercised medical judgment when it established credentialing requirements for Dr. Bildsten and obtained a consent form from Mr. Taylor. Pet. Supp. Br. at 10, 12. This is an inaccurate characterization of the credentialing and informed consent process. Hospitals do not exercise medical judgment when credentialing

³ *Pedroza v. Bryant*, 101 Wn.2d 226, 677 P.2d 166 (1984) (Hospitals have a duty to exercise reasonable care in selecting, retaining and supervising the performance of their medical staff).

physicians for professional privileges. Rather, credentialing is the process by which hospitals collect, verify, and assess the overall qualifications of a physician to provide care at a hospital. Nor is the informed consent that hospitals obtain from patients, consent which requires the exercise of medical judgment.

1. Credentialing and privileging establish general competency requirements, not patient specific evaluations.

Hospitals are required to adopt credentialing guidelines in order to be accredited. 5/9/13 RP 2826. Credentialing of medical staff is also required to meet hospital licensing requirements and Medicare Conditions of Participation. RCW 70.41.230; WAC 246-320-161; 42 C.F.R. § 422.204. Credentialing requirements are set forth in the hospital's medical staff bylaws, rules and regulation, and policies and procedures. To begin the credentialing process, the physician submits an initial application with background information, including information regarding the physician's licensing, education, and training.⁴ *See, e.g.,* RCW 4.24.810 (Credentialing is "the collection, verification, and assessment of whether a health care provider meets relevant licensing, education, and training requirements.""). If the applicant meets threshold criteria, the hospital will verify the physician's licensure or certification, education, training, and board certification, as well as the physician's disciplinary status,

⁴ *See* Centers for Medicare and Medicaid Services, Medicare Managed Care Manual, CMS Pub. 100-16, Chap. 6, Sec. 60.3 (Rev. 24, June 6, 2003); available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c06.pdf>.

malpractice coverage, Drug Enforcement Agency status, history of professional liability claims and other information from the National Practitioner Data Bank, eligibility for participation in federal health care programs, and site visits as appropriate.⁵

RCW 70.41.230 requires hospitals to gather information from a physician applicant that includes information about facilities at which the physician has or had an association, medical misconduct proceedings or medical malpractice actions, and any limitations of or actions taken against the physician's license to practice, board certifications, professional memberships, clinical privileges, participation in federally funded programs, membership in health organizations, academic appointments, or authority to prescribe controlled substances.

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.⁶ 5/9/13 RP 2855-56; 42 C.F.R. § 482.12 (a)(6). The hospital then evaluates the information and makes a recommendation for membership and clinical privileges to the hospital's governing body for action.⁷ WAC 246-320-161(2). Once a member of the hospital medical staff, the physician

⁵ See 42 C.F.R. § 422.204; Centers for Medicare and Medicaid Services, Medicare Managed Care Manual, CMS Pub. 100-16, Chap. 6, Sec. 60.3 (Rev. 24, June 6, 2003); available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c06.pdf>. See also The Joint Commission Standards, MS.06.01.05.

⁶ See The Joint Commission Standards, MS.06.01.03, MS.06.01.07.

⁷ See also The Joint Commission Standards, MS.06.01.07.

remains subject to the hospital's ongoing review requirements. *See, e.g.*, RCW 70.41.200; 42 C.F.R. § 422.204(b)(2)(ii). In compliance with the statutory and regulatory requirements, the credentialing process involves an analysis of whether the physician meets certain qualifications; it does not involve a medical determination of whether the physician is able to perform a particular procedure on a specific patient.

Further, although hospitals generally use uniform standards for credentialing applications, specific privileging criteria, including for robotic surgeries, vary among hospitals. The Society of American Gastrointestinal and Endoscopic Surgeons published "A Consensus Document on Robotic Surgery" in November, 2007, which outlined credentialing guidelines for hospitals regarding robotic surgery.⁸ The guidelines provide that "[t]he privileging structure and process remain the responsibility of the institution at which privileges are being sought" and recommend that privileging requirements include that a surgeon have: 1) satisfactorily completed a surgical residency with certification by the applicable specialty board; 2) completed either formal training in residency or fellowship programs or a structured training curriculum; and 3) documentation of either an appropriate number of cases or clinical experience undertaken under the review of an expert. *Id.* The guidelines, developed by medical experts, did not identify a particular number of

⁸ The Society of American Gastrointestinal and Endoscopic Surgeons, "A Consensus Document on Robotic Surgery," November 2007; available at <http://www.sages.org/publications/guidelines/consensus-document-robotic-surgery/>. *See also* 5/9/13 RP 2960.

cases or clinical experience recommended for privileging, leaving the decision to individual hospitals to develop their own criteria.

As with other privileging, and consistent with the above consensus guidelines, hospitals have established varying criteria for privileging physicians to perform robotic surgery. For example, one Washington hospital's robotic surgery privileging requirements required surgeons to have three proctored surgeries, with "[f]ull privilege [] not advanced until review of proctoring reports by surgical services committee with recommendations from proctor for privileges to be advanced." 4/22/13 RP 774-75. Another Washington hospital required four proctored surgeries. 5/7/13 RP 2408, 2446. A major teaching hospital in New York required one observed proctored surgery for those with previous training. 5/2/13 RP 2074-75.

The credentialing process does not require hospitals to evaluate whether a physician is able to perform a specific procedure on a particular patient. Neither hospitals, nor non-physician hospital personnel, are qualified to make the individualized medical judgment necessary to weigh the risks and benefits of a particular medical treatment or the use of a prescription medical product—that is the duty of the physician. *See Silves v. King*, 93 Wn. App. 873, 881, 970 P.2d 790 (1999) (nurse does not have an independent duty to warn a patient about the risks of a drug). The treating physician is in the best position to utilize his or her medical judgment to determine whether a specific type or method of surgery will

be the most efficacious under the circumstances, because proper weighing of the risks and benefits of a proposed treatment “requires an individualized medical judgment based on knowledge of the patient and his or her medical condition.” *Id.* (quoting *McKee*, 113 Wn.2d at 711-12). *See also* 5/7/13 RP 2409-10. Given the unique knowledge and experience physicians have in treating their patients, it is the physician prescribing or using the product, not a hospital that simply makes the product available for the physician’s use, who acts as the exclusive learned intermediary and determines whether a product should in fact be used for a particular patient.

Petitioners attempt to distinguish *McKee* by arguing that, unlike pharmacists, Harrison exercised independent medical judgment by “decid[ing] who qualifies to safely operate the robot...” Pet. Supp. Br. at 12. Hospitals can determine through the initial credentialing process who meets fundamental requirements to perform robotic surgery. However, they do not determine whether a robotic procedure is indicated for a particular patient. Nor is a hospital, regardless of the information it receives about a medical device or product from the manufacturer, able to second-guess in advance whether a physician has appropriately weighed the risks and benefits of using a prescription medical device for a particular patient or whether the treatment option selected by the patient and the physician is beyond the physician’s abilities for that patient.

By credentialing physicians, a hospital does not “dispense” or “administer” the product to the patient. *See* Pet. Supp. Br. at 12. While a hospital makes products available to physicians, the physician in his or her own medical judgment must determine whether a product should be used. For example, while a pharmacy may purchase prescription medications, store the medications, and physically provide the medications to patients, a physician still stands as the learned intermediary and determines whether the medication should be prescribed. In this case, although Harrison purchased the da Vinci System and maintained it in the hospital, it did not evaluate Mr. Taylor, review Mr. Taylor’s treatment options, or prescribe or select the use of the da Vinci System on him. As such, Harrison did not exercise any medical judgment regarding the use of the da Vinci System to treat Mr. Taylor. Moreover, just like the pharmacist in *McKee*, Harrison did not have the training or knowledge of Mr. Taylor’s medical history that would allow it to second-guess Dr. Bildsten’s decision to use the da Vinci System in the treatment of Mr. Taylor. Nor would it have been appropriate for Harrison to do so. Hospitals do not have a duty to intervene in the independent physician/patient relationship. *See Howell v. Blood Bank*, 114 Wn.2d 42, 55, 785 P.2d 815 (1990) (quoting *Alexander v. Gonser*, 42 Wn. App. 234, 239, 711 P.2d 347 (1985), *rev. denied*, 105 Wn.2d 1017 (1986)).

2. Hospitals do not exercise medical judgment in confirming a patient's informed consent has been obtained.

Petitioners incorrectly contend that the consent form obtained by Harrison from Mr. Taylor evidences that Harrison exercised medical judgment. While hospitals are subject to state and federal regulations that require them to obtain signed consent documents, hospitals do not have a duty to obtain a patient's informed consent. *See* WAC 246-320-166(4)(c) (requiring hospitals to create medical records that among other things, “[h]ave signed consent documents”); 42 C.F.R. § 482.24(c) and 42 C.F.R. § 482.51(b)(2) (Medicare Conditions of Participation for hospitals requiring hospital medical records include consent forms and that there be properly executed consent forms for surgery in the patient's chart before surgery); *Howell*, 114 Wn.2d at 55 (quoting *Alexander*, 42 Wn. App. at 239) (“To hold [that] a hospital or its employees have a duty to intervene in the independent physician/patient relationship [regarding the duty to inform]...would be far more disruptive than beneficial to a patient.”). Instead, “[h]ospitals must assure that *the practitioner(s) responsible for the surgery* obtain informed consent from patients in a manner consistent with the hospital's policies governing the informed consent process.”⁹ Given this context, it is clear Harrison's consent form does not evidence the exercise of medical judgment by Harrison or involvement in Mr. Taylor's specific procedure.

A comparison of the consent form obtained by Harrison with the consent form obtained by Dr. Bildsten, underscores the fallacy of Petitioners' argument that Harrison exercised judgment about the use of

⁹ *See* Centers for Medicare and Medicaid Services, Revisions to the Hospital Interpretive Guidelines for Informed Consent (April 13, 2007); available at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/scletter07-17.pdf> (emphasis added).

the da Vinci System for Mr. Taylor's surgery. The consent form obtained by Harrison is a single page document which enables Harrison to confirm Dr. Bildsten obtained informed consent from Mr. Taylor. *See* CP 250 ("The treatment(s) planned for my condition(s) *has (have) been explained to me by my physician*. I understand them to be: agree w/above [referencing "Radical Robotic Prostatectomy"]"; "*My physician has informed me* of the above points to my satisfaction prior to my authorization of the proposed treatment.") (emphasis added). In contrast, the consent form obtained by Dr. Bildsten is a six-page form that describes in detail the risks and benefits of the treatment/procedure and its alternatives. CP 243-48. Only Dr. Bildsten exercised medical judgment in describing the risks, benefits, and alternative forms of treatment for Mr. Taylor and determining whether to use the da Vinci System in performing his surgery—not Harrison.

Dr. Bildsten bore the medical decision-making responsibility for the use of the da Vinci System to perform surgery on Mr. Taylor and for providing information to and obtaining informed consent from Mr. Taylor. *See Taylor*, 188 Wn. App. at 791. Dr. Bildsten alone exercised patient-specific medical judgment, making him the exclusive learned intermediary between the manufacturer and the patient.

D. Requiring Product Manufacturer Involvement In The Credentialing Process Would Impermissibly Intrude On Hospitals' Independent Decision-Making.

Requiring product manufacturers to "warn and instruct" hospitals for purposes of developing credentialing criteria would allow product manufacturers to impermissibly intrude on hospitals' independent determination of appropriate credentialing and privileging criteria.

Hospitals already invest significant resources in developing credentialing criteria, and Petitioners' proposed requirement would oblige hospitals to rely on product manufacturers to develop such criteria. Product manufacturers would be required to provide hospitals with a breadth of information, including all medical literature, articles, and studies regarding a product and the particulars of the product's FDA approval process, whether or not the information is helpful or relevant. The hospital and manufacturer would then be required to develop credentialing criteria together.

Under the Petitioner's argument, if a cardiologist applied for privileges in clinical cardiac electrophysiology, the hospital would have a duty to develop specific credentialing criteria for each implantable pacemaker and defibrillator used in the hospital, based on "warnings and instructions" provided by each product manufacturer. Each product manufacturer would have a duty to provide the hospital with all FDA application materials and any study, literature, or article related to the product, which the hospital would be required to review. Each product manufacturer would then help develop specific credentialing criteria for the use of its implantable pacemaker or defibrillator. Finally, each manufacturer would have to instruct the hospital on how to use its product. All this would be in addition to the warnings the product manufacturer is already required to provide physicians. And still, the only way the pacemaker or defibrillator could ever be used on a specific patient is through a prescription from a treating physician, not directly from the hospital.

Creating such a duty would result in significantly *more* influence by product manufacturers on hospital credentialing processes. Hospitals

must make informed decisions about credentialing criteria. They rely on various resources to develop criteria, including relying on past experiences, literature, medical societies, and the practice of other hospitals. 5/9/13 RP 2969. Rather than conducting their own independent analysis of what criteria should be used to evaluate a physician's ability to operate safely, hospitals would be required to rely on information and instructions from product manufacturers. While evaluations of emerging medical devices such as the da Vinci system must be incorporated into hospital credentialing processes, credentialing criteria should be set according to hospitals' independent evaluation of appropriate qualifications for use of those devices, not as a result of undue influence by product manufacturers.

V. CONCLUSION

For these reasons, the Washington State Hospital Association urges this Court to uphold the Court of Appeals decision that ISI had no duty to provide warnings to Harrison Hospital.

RESPECTFULLY SUBMITTED this 22nd day of April, 2016.

RIDDELL WILLIAMS P.S.

By: Barbara Allan Shickich
Barbara Allan Shickich, WSBA No. 8733
Brett S. Durbin, WSBA No. 35781
Sarah E. Joye, WSBA No. 44357
1001 Fourth Avenue, Suite 4500
Seattle, WA 98154
(206) 624-3600

OFFICE RECEPTIONIST, CLERK

To: Magda, Veronica I.
Cc: valeriemcomie@gmail.com; amicuswsajf@wsajf.org; bryanpharnetiauxwsba@gmail.com; ken@appeal-law.com; gahrend@ahrendlaw.com; ctompkins@bpmlaw.com; JMBeck@ReedSmith.com; phil@tal-fitzlaw.com; hyoung@plac.net; Shickich, Barbara; Joye, Sarah; Durbin, Brett S.
Subject: RE: Taylor et al. v. Intuitive Surgical, Inc., No. 92210-1 - Efiling Amicus Brief

Received 4-22-16

Supreme Court Clerk's Office

Please note that any pleading filed as an attachment to e-mail will be treated as the original. Therefore, if a filing is by e-mail attachment, it is not necessary to mail to the court the original of the document.

From: Magda, Veronica I. [mailto:vmagda@Riddellwilliams.com]
Sent: Friday, April 22, 2016 4:02 PM
To: OFFICE RECEPTIONIST, CLERK <SUPREME@COURTS.WA.GOV>
Cc: valeriemcomie@gmail.com; amicuswsajf@wsajf.org; bryanpharnetiauxwsba@gmail.com; ken@appeal-law.com; gahrend@ahrendlaw.com; ctompkins@bpmlaw.com; JMBeck@ReedSmith.com; phil@tal-fitzlaw.com; hyoung@plac.net; Shickich, Barbara <bshickich@Riddellwilliams.com>; Joye, Sarah <sjoye@Riddellwilliams.com>; Durbin, Brett S. <bdurbin@Riddellwilliams.com>
Subject: Taylor et al. v. Intuitive Surgical, Inc., No. 92210-1 - Efiling Amicus Brief

Dear Clerk,

Attached, for filing, please find the following documents:

- Motion for Leave to File Brief of Amicus Curiae; and
- Brief of Amicus Curiae – Washington State Hospital Association.

Case name: *Taylor, et al. v. Intuitive Surgical, Inc.*
Case number: 92210-1
Filed by: Barbara Allan Shickich, WSBA No. 8733
(206) 624-3600
bshickich@riddellwilliams.com

Regards,

Veronica I. Magda | Riddell Williams P.S.
Executive Assistant D 206.389.1522
vmagda@riddellwilliams.com

T 206.624.3600 1001 Fourth Avenue, Suite 4500
F 206.389.1708 Seattle, Washington 98154-1192

CONFIDENTIALITY AND CIRCULAR 230 NOTICE: This communication is intended for the sole use of the individual and entity to whom it is addressed, and may contain information that is privileged, confidential and exempt from disclosure under applicable law. You are hereby notified that any dissemination, distribution or duplication of this communication by someone other than the intended addressee or its designated agent is strictly prohibited. As required by the Internal Revenue Service, anything contained in this communication pertaining to any U.S. federal tax matter is not to be used for the purpose of avoiding federal tax penalties under the Internal Revenue Code or for promoting, marketing or recommending to any third party the tax implications of any partnership or other entity, investment plan or arrangement discussed in this communication. If you have received this communication in error, please notify this firm immediately by collect call (206)-624-3600, or by reply to this communication.