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COURT OF APPEALS, DIVISION II,
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,

Appellants
STATE OF WASHINGTON
2014 NOV 12 PM 1:35
Respondent:

vs.

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

FILED
COURT OF APPEALS
DIVISION II

BRIEF OF AMICUS CURIAE
WASHINGTON STATE HOSPITAL ASSOCIATION

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I. INTRODUCTION

This case addresses the scope of the learned intermediary doctrine adopted in *Terhune v. A.H. Robins Co.*, 90 Wn.2d 9, 577 P.2d 975 (1978). The learned intermediary doctrine limits a manufacturer's duty to warn of the potential harms of using a medical product to the physician prescribing or using the product. *Id.* at 14. The doctrine is based on the rationale that the physician is in the best position to balance the risks and benefits of using the medical product through the application of professional medical judgment to the patient's particular circumstances. *Id.*

This rationale does not support the Appellants' position that the learned intermediary doctrine should be expanded to include anyone "responsible for patient safety." Reply Brief at 6. While hospitals play an important role in promoting patient safety, they do not share the physician's knowledge of an individual patient's medical conditions and generally are not in a position to question the physician's specific medical judgments regarding a particular patient. Expanding the learned intermediary doctrine to include hospitals would be contrary to the underlying rationale for the doctrine; hospitals do not exercise professional medical judgment and the hospital's provision of warnings would interfere with the physician-patient relationship. Therefore, the court should reject the Appellants' request to treat Harrison Hospital as a learned intermediary.

The Appellants' contention that ISI had a duty to provide warnings to Harrison Hospital as the purchaser of the da Vinci Surgical System ("da Vinci System") is not supported by the statute and is contrary to the learned intermediary doctrine. RCW 7.72.030(1) only states that a "manufacturer is liable 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.” It does not state to whom the warnings or instructions must be provided. The most logical reading is that the warnings must be communicated to the ultimate user of the product, 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 prescribing and using the devices, shifts the focus from providing highly detailed and technical warnings to a small group of sophisticated users, 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, i.e. to encourage the communication of sophisticated warnings to those in a position to understand them and exercise care and judgment in the use of the product. Accordingly, the 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 99 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 Brief of Respondent.

IV. ARGUMENT

A. **The Learned Intermediary Doctrine Limits A Manufacturer's Duty To Warn The Physician Prescribing Or Using A Medical Product.**

Under the Washington Products Liability Act ("WPLA"), RCW Ch. 7.72, manufacturers are typically strictly liable for harms caused by unsafe products. RCW 7.72.030. The Washington Supreme Court has recognized an exception to this strict liability where a prescription medical product is "unavoidably unsafe." *Ruiz-Guzman v. Amvac Chem. Corp.*, 141 Wn.2d 493, 506, 7 P.3d 795 (2000). In determining whether a manufacturer has met its duty to give adequate warnings for a prescription medical product,¹ Washington has adopted the "learned intermediary" doctrine. *See Terhune*, 90 Wn.2d at 13-14. Under this doctrine, the manufacturer satisfies its duty to "warn of the dangers involved in the use of a product ... if it gives adequate warning *to the physician who prescribes it.*" *Id.* at 13 (emphasis added). All of the Washington court

¹ The term "prescription medical products" in this brief refers to the products discussed in *Terhune* that are "available only on prescription or through the services of a physician." 90 Wn.2d at 14.

decisions addressing the learned intermediary doctrine clearly limit the manufacturer's duty to warn the physician who prescribes the product.² This case does not present a basis for expanding the learned intermediary doctrine in Washington to treat hospitals as learned intermediaries to which manufacturers owe a duty to warn.

1. A learned intermediary is a physician who exercises medical judgment with respect to the use of the product.

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 the Court in *Terhune* explained:

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).

The 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

² See *Terhune*, 90 Wn.2d at 13; *McKee v. American Home Products Corp.*, 113 Wn.2d 701, 709, 782 P.2d 1045 (1989); *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*, 141 Wn.2d at 506; *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).

intermediary doctrine. See FN. 1, supra. As the Court in *Terhune* notes, the doctrine is based upon principles that “have their basis in the character of the medical 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 learned intermediary.

Subsequent decisions have also reinforced the conclusion that the learned intermediary 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*, 141 Wn.2d at 508 (“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.”)

Accordingly, the learned intermediary doctrine clearly limits the manufacturer’s duty to warn to the physician prescribing or using a prescription medical product.

2. The risk-benefit analysis underlying the learned intermediary doctrine involves the application of medical judgment regarding a specific patient.

The origin of the learned intermediary doctrine further demonstrates the appropriateness of limiting the doctrine to the prescribing physician. The learned intermediary doctrine arises in the context of comment *k* to Section 402A of the Second Restatement 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 Fisons*, 122 Wn.2d at 313 (“In 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.

3. Hospitals do not exercise medical judgment with respect to the treatment of a patient.

Just as with the pharmacists in *McKee*, hospitals do not exercise medical judgment with respect to the treatment provided to patients and are not in a position to question the risk-benefit analyses performed by a physician in selecting the tool to treat a specific patient. Proper weighing of the risks and benefits of a proposed treatment “requires individualized medical judgment based on knowledge of the patient and his or her medical condition.” *Silves v. King*, 93 Wn. App. 873, 881, 970 P.2d 790 quoting *McKee*, 113 Wn.2d at 711-12 (citing *Smith v. Shannon*, 100 Wn.2d 26, 31, 66 P.2d 351 (1983)). Neither hospitals, nor non-physician hospital personnel are qualified to make the medical judgment necessary to weigh the risks and benefits of a particular medical treatment or

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).

product—that is the duty of the physician. *See, Silves*, 93 Wn. App. at 881. As such, concluding that a hospital is a learned intermediary would ignore the very reason that a physician is considered a “learned intermediary” in the first place, i.e., that they exercise informed medical judgment to weigh the potential benefits and risks associated with using a product to treat a specific patient.

In their reply brief, Appellants attempt to distinguish *McKee* by arguing that pharmacists do not play a role in patient safety. Reply Br. at 9. While this statement is not accurate, it does not matter as Appellants misread the holding in *McKee*.⁴ The 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 710-11. The court went on to conclude that, “[n]either the manufacturer nor the pharmacists has the medical education or knowledge of the medical history of the patient that would justify a judicial imposition of a duty to intrude into the physician-patient relationship.” *Id.* at 711. Thus, the court in *McKee* did not base its holding on whether the pharmacists played a role in patient safety, but rather on whether they exercised informed medical judgment regarding the treatment of a specific patient.

Appellants also assert that Harrison exercised medical judgment when it established credentialing requirements for performing robotic surgery and obtained Mr. Taylor’s informed consent to surgery. Reply Br.

⁴ *See* WAC 246-863-095 “[a] pharmacists 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).

at 9. While these statements are likewise incorrect for the reasons described below, they again miss the point. As discussed above, the key role of a learned intermediary is to exercise medical judgment regarding the use of the product to treat a specific patient. In this case, Harrison did not evaluate Mr. Taylor, did not review Mr. Taylor's treatment options, and did not prescribe or select the use of the da Vinci System to treat Mr. Taylor. Resp. Br. at 28. As such, Harrison did not exercise any medical judgment regarding the use of the da Vinci Surgical 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, 785 P. 2d 815 (1990) citing *Alexander v. Gonser*, 42 Wn. App. 234, 711 P.2d 347 (1985), review denied 105 Wn.2d 1017 (1986).

The consent form obtained by Harrison from Mr. Taylor served to confirm that Mr. Taylor had given informed consent to Dr. Bildsten to perform a specific type of surgery. Hospitals are subject to state and federal regulations which require them to obtain signed consent documents. See WAC 246-320-166(4)(c) (requiring hospitals to create medical records that among other things, "have signed consent documents"); 42 C.F.R. § 482.24.24(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.) The Centers for Medicare and Medicaid guidelines explain that "[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." CMS Guidelines, Tag A-0392 available at <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/scletter07-17.pdf>. Given this context, it is clear Harrison's consent form does not evidence the exercise of medical judgment by Harrison.⁵

A comparison of the consent form obtained by Harrison with the consent form obtained by Dr. Bildsten, underscores the fallacy of Appellants' argument that Harrison exercised judgment about the use of 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. ("The treatment(s) planned for my condition(s) *has (have) been explained to me by my physician* to be: agree w/above" ("radical robotic prostectomy"); "*My physician has informed me* of the above points to my satisfaction prior to my authorization of the proposed treatment.") CP 250 (emphasis added). In contrast, the consent form obtained by Dr. Bildsten is a lengthy form which describes in some detail the risk 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.

⁵ Similarly, the fact Harrison credentialed Dr. Bildsten to use the da Vinci Surgical System does not demonstrate Harrison exercised medical judgment in balancing the characteristics and needs of Mr. Taylor with the risks and benefits of using the da Vinci Surgical System to perform his surgery.

Because a hospital does not exercise medical judgment, it cannot be considered a learned intermediary under Washington law.

4. Under the learned intermediary doctrine, a manufacturer only has a duty to warn the learned intermediary.

All of the Washington case law applying the learned intermediary doctrine clearly states that the manufacturer satisfies its duty to warn by providing the warning to the prescribing physician.⁶ There is no holding or statement that the manufacturer is under a duty to warn any other person, including the patient. *Id.* Limiting the manufacturer's duty to warn to the physician prescribing or using the product, is consistent with the underlying rationale for the learned intermediary doctrine.⁷

Because these products are only available for use through a physician, physicians are in the best position to understand the manufacturer's warnings and ensure that the products are used appropriately to treat patients. As discussed above, no one else can exercise the required medical judgment regarding the appropriate use of "unavoidably unsafe" medical products. There is no reason to issue warnings to individuals who are not able to understand the warnings or who do not exercise the necessary judgment regarding the use of the product.

⁶ *Terhune*, 90 Wn.2d at 13; *McKee*, 113 Wn.2d at 709; *Rogers*, 116 Wn.2d at 207; *Young v. Key Pharmaceuticals*, 130 Wn.2d 167-68; *Ruiz-Guzman*, 141 Wn.2d at 506; *Fisons*, 122 Wn.2d at 313; *LaMontagne*, 127 Wn. App. at 345.

⁷ Appellants cite cases from foreign jurisdictions purportedly supporting expansion of the learned intermediary doctrine to Harrison. WSHA concurs with Respondent's arguments in distinguishing these cases. Resp. Br. at 30-32. In addition, with respect to the holding in *McEwen v. Ortho Pharm. Corp.* 270 Or. 375, 388, 528 P.2d 522, 529 (1974) cited by Appellants (Reply Br. at 11), the Court there extended the doctrine to "all members of the medical profession who come into contact *with the patient* in a decision-making capacity." (Emphasis added.) A hospital is not a "member of the medical profession" and, as discussed above, Harrison did not exercise the medical judgment or make the decision to use the da Vinci Surgical System in Mr. Taylor's surgery.

Limiting the manufacturer's duty to warn to the physician acting as the learned intermediary also ensures that the manufacturer can focus on providing highly detailed and technical warnings that would only be meaningful to the physician. Expanding the duty to warn other parties would dilute this focus and result in warnings that are more general and less useful to the physicians prescribing or using the products, thereby undermining one of the reasons for establishing the learned intermediary doctrine in the first place. As such, the case law does not support the assertion that the manufacturer has a duty to warn anyone other than the physician prescribing or using the product.

B. The Case Law Regarding The Learned Intermediary Doctrine Is Consistent With The Statutory Language In The WPLA.

The Appellants contend that the WPLA imposes a duty, outside of the learned intermediary doctrine, to warn the purchaser of prescription medical products in addition to the physician prescribing or using the product. Reply Br. at 3-4. This is incorrect. The cases applying the learned intermediary doctrine clearly recognize that the learned intermediary doctrine is a special application of the WPLA to "unavoidably unsafe" products. See *Ruiz-Guzman*, 114 Wn.2d at 506 (noting that application of comment *k* is made within context of the WPLA). As noted above, the cases applying the learned intermediary doctrine clearly hold that the manufacturer satisfies its duty to warn by communicating the warning to the physician. Accordingly, there is no duty to warn parties that merely purchase the product.

Moreover, these holdings are entirely consistent with the statutory language. 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). 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*, 90 Wn.2d at 14). 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*, 113 Wn.2d at 718-19 (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).

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.

V. CONCLUSION

For these reasons, the Washington State Hospital Association urges this court to reject the Appellants' arguments that hospitals are learned intermediaries and that the WPLA imposes a duty on manufactures to warn parties other than the prescribing physician.

RESPECTFULLY SUBMITTED this 7th day of November, 2014.

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