

No. 45052-6-II

IN THE COURT OF APPEALS
OF THE STATE OF WASHINGTON
DIVISION II

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,

v.

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

Respondent.

ANSWER TO AMICUS BRIEF

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TABLE OF CONTENTS

INTRODUCTION	1
REPLY TO WSHA ARGUMENT	2
A. WSHA's argument that the learned intermediary doctrine applies only to doctors ignores Harrison Hospital's role in patient safety, and vital distinctions between the da Vinci robot and the medical products at issue in Washington precedent.	2
1. That prescribing doctors are learned intermediaries between the manufacturer and patient, does not suggest that they are the only learned intermediaries.	2
2. That doctors exercise "medical judgment" does not mean that only those exercising "medical judgment" can be learned intermediaries.....	6
3. The da Vinci robot only reached Fred Taylor because Harrison exercised its judgment to purchase it and to credential Bildsten to use it.....	8
4. This is a case of first impression – our courts have not yet resolved whether warning a prescribing doctor obviates the manufacturer's duty to warn the product purchaser.	10
B. WSHA's argument that the learned intermediary doctrine obviates any other duty to warn product purchasers misinterprets the WPLA and again ignores Harrison's role in patient safety.	12
CONCLUSION	16

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Koenig v. City of Des Moines</i> , 158 Wn.2d 173, 142 P.3d 162 (2006).....	15
<i>McKee v Am. Home Products Corp.</i> , 113 Wn.2d 701, 782 P.2d 1045 (1989).....	<i>passim</i>
<i>Pedroza v. Bryant</i> , 101 Wn.2d 226, 677 P.2d 166 (1984).....	7
<i>Ruiz-Guzman v. Amvac Chem. Corp.</i> , 141 Wn.2d 493, 7 P.3d 795 (2000).....	5, 12, 13
<i>Terhune v. A.H. Robins Co.</i> , 90 Wn.2d 9, 577 P.2d 975 (1978).....	<i>passim</i>
Statutes	
RCW 7.72.030	14
RCW 7.72.030(1)(a).....	15
RCW 7.72.030(1)(b).....	14
RCW 7.72.030(1)(c).....	14
RCW 7.72.030(3)	14, 15

INTRODUCTION

The fatal flaw in WSHA's brief is that it ignores the differences between the da Vinci robot and drugs or vaccines, the products typically associated with comment *k* and the learned intermediary doctrine. Comment *k* was first applied to a medical device, the Dalkon Shield, in ***Terhune v. A.H. Robins Co.***, 90 Wn.2d 9, 577 P.2d 975 (1978). In adopting the learned intermediary doctrine, ***Terhune*** plainly contemplated “drugs, vaccines and the like” which are “obtainable only through . . . a physician.” 90 Wn.2d at 13, 17.

Under ***Terhune***, a manufacturer satisfies its duty to warn patients, the consumers of drugs and personal-use medical products, by adequately warning their prescribing physicians. These cases do not address a manufacturer's duty to warn anyone else.

The da Vinci robot is nothing like a drug or the Dalkon Shield. Neither Fred nor his doctor “obtained” the da Vinci robot. Harrison obtained it, but directly from ISI, not “through a physician.” For these reasons too, the learned intermediary doctrine does not obviate ISI's WPLA duty to warn Harrison, the product purchaser.

But in any event, Harrison too was an “intermediary” between ISI and Fred. The dangerous robot reached Fred only through Harrison's purchase and credential.

REPLY TO WSHA ARGUMENT

A. **WSHA's argument that the learned intermediary doctrine applies only to doctors ignores Harrison Hospital's role in patient safety, and vital distinctions between the da Vinci robot and the medical products at issue in Washington precedent.**

1. That prescribing doctors are learned intermediaries between the manufacturer and patient, does not suggest that they are the only learned intermediaries.

WSHA begins with the uncontested assertion that prescribing physicians are learned intermediaries between drug and medical-product manufacturers and patients. Amicus at 4-5 (*Terhune*, 90 Wn.2d 9.) WSHA infers far too much from this obvious truth, and from *Terhune*.

Terhune holds that manufacturers of products like the Dalkon Shield satisfy their duty to warn the patient by warning her prescribing doctor, "a 'learned intermediary' between the manufacturer or seller and the patient." 90 Wn.2d at 14, 17. The rationale underlying the learned intermediary doctrine is threefold: (1) a prescribing doctor exercises independent judgment based on her knowledge of the patient and the product, and is better situated to act in the patient's best interest; (2) it is presumed that the patient will rely primarily on his prescribing doctor's judgment; and (3) it is

ordinarily difficult for manufacturers to communicate directly with patients. *Id.*

No Washington case, including ***Terhune***, addresses the issue here – whether a credentialing hospital can be a second learned intermediary. But the rationales underling the learned intermediary doctrine support its application here. Like a doctor, Harrison exercised “independent judgment” regarding the da Vinci when it decided to purchase, developed credentialing requirements, credentialed Bildsten and obtained Fred’s informed consent.¹ Patients certainly rely on hospitals to keep them safe, and one of a hospital’s principal mechanisms of doing so is adopting reasonable credentialing requirements. And while ISI may find it difficult to warn patients, it did “warn” Harrison, although not adequately.

Indeed, this is a crucial feature of this case WSHA ignores. ISI sold itself as a partner with doctors and hospitals. BA 16-17. Three ISI employees sat on the Harrison committee that develops credentialing requirements. RP 720. ISI recommended that only two proctored procedures was sufficient to “ensure success.” BA 25-26; Ex 511; RP 573, 716, 840, 1036. But ISI admits that no clinical

¹ As addressed below, WSHA largely ignores these points in arguing that Harrison did not exercise “medical judgment.” *Infra*, § A2 & 3.

data supports its two-proctored-procedures recommendation. BA 25-26; RP 573, 711-12.

ISI did not tell Harrison that the learning curve is so high that many if not most surgeons lack the patient volume to succeed – a consideration that would obviously weigh heavily on any prospective purchaser. RP 805-06, 1949. And while telling Harrison that the robot “improve[s] cancer control,” ISI omitted that no clinical data supports that claim and that studies show that “positive margin rate[s]” – the amount of cancer left behind – may be 16-to-19 times higher in a robotic prostatectomy than in an open procedure. RP 1720, 1952, 1955-56, 2054-55; Exs 177, 509 p.4. Again, a relevant consideration for any purchaser. It is disingenuous at best to argue that ISI owed Harrison no duty to warn, when it in fact “warned” Harrison inadequately, creating false impressions about the da Vinci.

In short, ***Terhune*** is not controlling, where it involves a doctor/patient relationship not, as here, a relationship involving a third-party hospital whose decisions regarding the medical device at issue directly impact patient safety.

WSHA next incorrectly argues that subsequent decisions “reinforce” that the learned-intermediary doctrine applies only to doctors. Amicus at 5 (citing ***McKee v Am. Home Products Corp.***,

113 Wn.2d 701, 782 P.2d 1045 (1989) and ***Ruiz-Guzman v. Amvac Chem. Corp.***, 141 Wn.2d 493, 7 P.3d 795 (2000)). ***Ruiz-Guzman*** is inapposite – it addresses whether comment *k* applies to pesticides. 141 Wn.2d at 508. More importantly, WSHA misquotes ***Ruiz-Guzman***, omitting the portion providing that both physicians and pharmacists can be the “intermediary” between the manufacturer and patient: “The [comment *k*] exceptions for medical products recognize the unique protection provided to the consumers of such products by the prescribing physician (and/or pharmacist) intermediary.” Amicus at 5 (quoting ***Ruiz-Guzman***, 141 Wn.2d at 508, omitting underlined portion). This language plainly does not support WSHA’s claim that only prescribing physicians can be learned intermediaries.

In ***McKee***, our Supreme Court upheld summary judgment dismissing inadequate-warning claims against a pharmacist, holding that pharmacists have no duty to warn patients regarding drugs prescribed by a doctor. 113 Wn.2d at 720-21. In so holding, the Court discussed the learned intermediary doctrine, explaining that unlike prescribing doctors, pharmacists lack the education and patient knowledge to “justify a judicial imposition of a duty to intrude into the physician-patient relationship.” *Id.* at 711.

McKee is plainly inapposite, where the plaintiff's argument was that the pharmacists had a duty to second-guess her doctor's orders. *Id.* at 716-17. Taylor is not suggesting that Harrison had to second-guess Bildsten's decision to use the da Vinci robot on Fred Taylor. The point is that Harrison was required to and did make decisions about purchasing the robot, establishing credentialing requirements and credentialing Bildsten. These decisions did not "intrude" on the physician-patient relationship, but rather permitted Bildsten to use the robot on Fred.

2. That doctors exercise "medical judgment" does not mean that only those exercising "medical judgment" can be learned intermediaries.

WSHA next argues that doctors are the best learned intermediaries because they are the best suited to protect patients. Amicus at 6-7. Taylor does not disagree, and has consistently maintained that ISI has a duty to warn Harrison under the WPLA. BA 40-42; Reply at 3-4. Requiring ISI to warn Harrison would not eliminate its duty to warn doctors, as WSHA seems to suggest. Amicus at 6-7.

WSHA acknowledges that "hospitals play important roles in caring for patients and have an independent duty of care for hospital patients" but argues that they do not have "the same" role as doctors.

Amicus at 7 (citing *Pedroza v. Bryant*, 101 Wn.2d 226, 677 P.2d 166 (1984)). While undoubtedly true, this is beside the point. WSHA again ignores that Harrison purchased the robot, developed credentialing requirements and credentialed Bildsten. The da Vinci robot is not a drug or device the doctor administers without a hospital's involvement. Without Harrison's credential, Bildsten never could have used the da Vinci to operate on Fred Taylor.

And as WSHA recognizes, hospitals owe an "independent duty of care to its patients directly." *Pedroza*, 101 Wn.2d at 232. Hospitals can be negligent under a theory of corporate negligence. *Id.* at 234-35. Their liability flows from the failure to exercise "reasonable care in the granting, renewal, and delineation of staff privileges." *Id.* at 235.

WSHA fails to answer a very basic, yet crucial question: why would a hospital not want the information necessary to make an informed decision about purchasing the robot and determining credentialing requirements? Again, ISI neglected to warn Harrison that the learning curve is so high that many surgeons will never become proficient robotic surgeons, or that cancer removal is often worse in robot prostatectomy. *Supra* § A1. This information is so plainly crucial to a hospital's decisions about purchasing and

credentialing, that the only reason to avoid adequate warnings must be to avoid potential liability. That is, without a warning, a hospital cannot be liable for failing to follow a warning. This self-interested motive cannot dictate whether a warning is owed.

3. The da Vinci robot only reached Fred Taylor because Harrison exercised its judgment to purchase it and to credential Bildsten to use it.

WSHA argues that hospitals do not exercise “medical judgment” so cannot be learned intermediaries. Amicus at 8-11. WSHA defines a learned intermediary is one who “exercise[s] medical judgment regarding the use of the product to treat a specific patient.” Amicus at 9. This argument is circular. WSHA really describes a prescribing doctor’s role vis-à-vis a patient. *Id.* All parties agree that prescribing doctors are learned intermediaries, but that does not answer whether there can be other learned intermediaries.

WSHA misunderstands Taylor’s argument to be that “Harrison exercised medical judgment.” Amicus at 8, 9. Taylor does not argue that Harrison’s judgments were “medical,” or that Harrison “exercised judgment about the use of the da Vinci System for Mr. Taylor’s surgery.” Amicus at 10. Again, Harrison’s judgment was: (1) determining whether to purchase a da Vinci robot; (2) adopting

credentialing requirements sufficient to ensure that doctors are ready to safety operate using the da Vinci (3) obtaining Fred's informed consent; and (4) credentialing Bildsten. Reply at 3-4, 8-10.

WSHA here too relies on **McKee**. Amicus at 8, 9. But again, a pharmacist filling a doctor's prescription is not comparable to Harrison, who purchased the robot, established credentialing requirements, obtained informed consent and credentialed Bildsten. Reply 9. The process of credentialing a surgeon does not "intrude" on the doctor patient relationship, but facilitates it. Amicus at 8. Credentialing, a gate-keeping mechanism, is the necessary prerequisite to allowing a doctor to perform a certain surgery, in this case using a certain medical device to perform invasive surgery at a hospital. Credentialing has nothing to do with a particular patient. It is a measure of the doctor's skills, experience, and readiness – not of his diagnosis, prescription, or plan for a patient.

No one denies that a hospital does not have the same relationship to a patient that a doctor has, nor that a hospital does not make the same type of patient-centric decisions a prescribing doctor makes. Amicus 9-11. But again, WSHA ignores that Harrison made very important judgments directly impacting patient safety. These decisions were hampered by ISI's inadequate warnings.

Finally on this point. WSHA carries on at length about the informed consent Harrison obtained from Fred, arguing that Bildsten's informed consent is far more detailed. Amicus 9-11. This too misses the point. Taylor raised Harrison's informed consent in response to ISI's mistaken assertion that Harrison never "met with" Fred or obtained his informed consent "separate from that obtained by Bildsten." Reply at 8 (quoting BR 15, 28). While the requirement that Harrison obtain its own informed consent certainly supports Taylor's argument that Harrison is entitled to proper warnings, the real thrust of Taylor's argument is that ISI had a duty to warn Harrison because it purchased the da Vinci, established credentialing requirements and credentialed Bildsten and others to use the robot. Reply 5-12.

4. This is a case of first impression – our courts have not yet resolved whether warning a prescribing doctor obviates the manufacturer's duty to warn the product purchaser.

WSHA argues that under Washington's learned intermediary doctrine, warning the doctor obviates any duty to warn any other entity. Amicus at 11-12. WSHA overstates Washington precedent. ***Terhune*** and its progeny hold that a manufacturer satisfies its duty to warn a patient, the "consumer," by properly warning the primary

doctor. With the exception of *McKee supra*, which is inapposite, these cases do not address the manufacturer's duty to warn anyone other than the doctor or patient. Our courts have not yet addressed whether a hospital is entitled to a warning under the WPLA or can be a second learned intermediary, where it purchases a dangerous medical device and makes it available to doctors – and patients – through the credentialing process.

WSHA suggests that Harrison is incapable of understanding warnings accompanying the robot. Amicus at 11. Harrison's committee in charge of credentialing requirements was no doubt comprised of expert surgeons, and included three ISI salespeople. 720, 1035. WSHA is wrong to contend that Harrison could not have understood warnings about learning curves or positive margin rates.

WSHA also argues that providing warnings to Harrison (and other purchasers) would "dilute" the warnings given to physicians. Amicus at 12. This assertion is not only baseless, but runs contrary to the very warnings ISI knew of, but failed to provide. Any doctor advising a patient about robotic surgery would want information on positive margin rates and the learning curve. There is no basis for claiming that ISI – or any manufacturer – would have to develop two different sets of warnings.

In sum, WSHA's argument that warning a doctor obviates the duty to warn everyone else decreases patient safety. This contradicts the learned intermediary doctrine, upon which WSHA's argument is premised, as well as the Hospitals' independent duty of care to its patients. This Court should reject this ill-conceived and dangerous argument.

B. WSHA's argument that the learned intermediary doctrine obviates any other duty to warn product purchasers misinterprets the WPLA and again ignores Harrison's role in patient safety.

WSHA claims that since Washington has adopted the learned intermediary doctrine, there can be no other WPLA duty to warn purchasers of an unavoidably unsafe medical device. Amicus at 12-14. Their sole support for that assertion is that "cases" applying the learned intermediary doctrine "recognize [that it] is a special application of the WPLA to 'unavoidably unsafe' products." *Id.* at 12. WSHA relies on *Ruiz-Guzman's* supposed recognition that comment *k* is applied "within the context of the WPLA." *Id.*

This argument is a series of non sequiturs and inaccuracies. Assuming, as WSHA claims, the learned intermediary doctrine is a "special application" of the WPLA to unavoidably unsafe products, does not suggest that it is the **only** application of the WPLA to

unavoidably unsafe products. *Id.* The learned intermediary doctrine is an exception to the rule that manufacturers would otherwise have to warn the consumer, here the patient. It does not however, re-write the rule. ***Ruiz-Guzman***, 112 Wn.2d at 506.

Assuming, as WSHA claims, that ***Ruiz-Guzman*** recognizes that comment *k* is applied within the context of the WPLA, there still may be a WPLA duty to warn an entity other than the prescribing doctor. Amicus at 12. Comment *k* is a narrow exception to the WPLA rule that manufacturers are strictly liable for product defects. ***Ruiz-Guzman***, 112 Wn.2d at 506. It has nothing to do with the duties manufacturers owe.

But in any event, ***Ruiz-Guzman*** actually states that “[b]ecause comment *k* was not expressly provided for in the WPLA, we must be sparing in its application lest we defeat the letter or policy of the WPLA.” 141 Wn.2d at 506. Again, comment *k* is a narrow exception to the WPLA strict-liability rule. *Id.* That it must be narrowly applied directly contradicts WSHA’s assertion that comment *k* obviates any duty to warn imposed under the WPLA, other than the duty to warn prescribing doctors. Amicus at 12.

WSHA next claims that under the learned intermediary doctrine, “there is no duty to warn parties that merely purchase the

product.” *Id.* The only truth to that statement is that the learned intermediary doctrine assumes that manufacturers adequately warn doctors who will then warn patients, the “mere purchaser.” The doctrine does not address duties owed to any entity other than the patient.

Moreover, Harrison did not “merely purchase” the da Vinci robot. *Id.* As it has throughout its brief, WSHA ignores that Harrison established credentialing requirements and determined that Bildsten met them. It is only through those judgments that the dangerous robot reached – and injured – Fred Taylor.

WSHA argues that manufacturers must warn only “consumers” under RCWs 7.72.030(1) 7.72.030(1)(c), and 7.72.030(3). Amicus at 12-13. These statutes do not support WSHA’s assertion. RCW 7.72.030 does not simply say that warnings must be “provided,” but makes clear that they must be provided “with the product.” *Compare* Amicus at 12-13 *with* RCW 7.72.030(1)(b). The only way to provide warnings “with the product” was to provide them to Harrison, who purchased the robot. BA 39-42.

RCW 7.72.030(1)(c) provides that manufacturers must warn “product users” when a manufacturer becomes aware, after selling

the product, that its warnings are not adequate. RCW 7.72.030(1)(a) – unsafe design – and (b) – inadequate warnings – do not use the term “user.” It plainly contradicts well-founded canons of statutory construction to borrow a term from one section of the statute, and graft it onto others. ***Koenig v. City of Des Moines***, 158 Wn.2d 173, 182, 142 P.3d 162 (2006) (“When the legislature employs different terms in a statute, we presume a different meaning for each term”).

RCW 7.72.030(3) provides that in determining whether a product is not reasonably safe, the trier of fact applies the “ordinary consumer” standard. This does not remotely suggest that a manufacturer must only warn a prescribing doctor, particularly where Harrison is a consumer – one who buys goods or services, or “utilizes economic goods.” <http://www.merriam-webster.com/dictionary/consumer>. This is yet another example of WSHA ignoring that Harrison not only purchased the robot, but made it available to surgeons, and through them, to the public.

Finally, WSHA argues that it makes no sense to warn Harrison because they do not “use” the da Vinci robot. Amicus at 13. WSHA claims that the “highly technical and detailed information” that accompanies “prescription medical products” “would only be meaningful to the prescribing physician.” *Id.* The only way WSHA

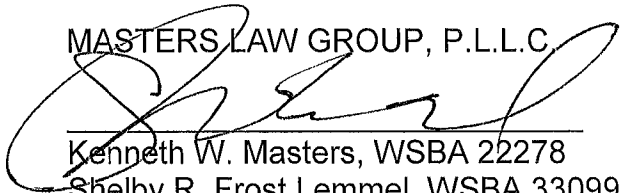
can suggests that proper warnings would be meaningless to Harrison is by ignoring that the da Vinci robot is plainly unlike a prescription drug, vaccine, or single-user medical device obtainable only through a physician. Again, without Harrison, the da Vinci could not have injured Fred. Harrison may not “use” the robot, but Bildsten could not have used the robot without Harrison’s purchase and credential.

CONCLUSION

This Court should reject WSHA’s claims that manufacturers of dangerous medical devices have no duty to warn the hospitals through, whom these products reach the public. Such a policy conflicts with existing law and decreases patient safety.

RESPECTFULLY SUBMITTED this 19th day of December, 2014.

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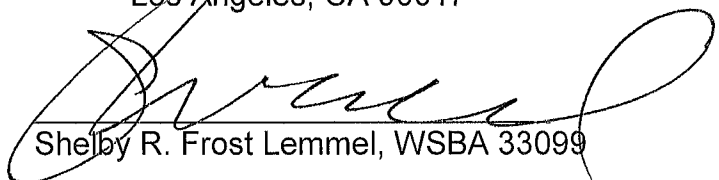
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