IN THE SUPREME COURT OF THE STATE OF WASHINGTON

CERTIFICATION FROM THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF WASHINGTON IN	)	No. 99956-2 (certified 2:21-cv-00060-JCC)
DAVID J. DEARINGER, and GANNA P. DEARINGER, individually and the marital community composed thereof,	)	Filed: June 2, 2022
Petitioners-Plaintiffs,	)	
v.	)	
ELI LILLY AND COMPANY, a Corporation,	)	
Respondent-Defendant.	)	

OWENS, J. — Under the learned intermediary doctrine, a prescription drug manufacturer satisfies its duty to warn patients of a drug's risks when it adequately warns the prescribing physician. The United States District Court for the Western District of Washington asks us via certified question whether Washington law recognizes an exception to the learned intermediary doctrine when a prescription drug

manufacturer advertises its product directly to consumers. We answer this question in the negative: there is no direct-to-consumer advertising exception. The policies underlying the learned intermediary doctrine remain intact even in the direct-to-consumer advertising context. Further, existing state law sufficiently regulates product warnings and prescription drug advertising. Accordingly, we hold regardless of whether a prescription drug manufacturer advertises its products directly to consumers, the manufacturer satisfies its duty to warn a patient when it adequately warns the prescribing physician of the drug's risks and side effects.

I. FACTS AND PROCEDURAL HISTORY

Plaintiff David Dearinger alleges he suffered a hemorrhage leading to a stroke that caused him permanent disabilities less than two hours after consuming Cialis. Cialis is a prescription drug manufactured by defendant Eli Lilly and Co. (Lilly) to treat prostatic hyperplasia, pulmonary arterial hypertension, and erectile dysfunction.

Dearinger sued Lilly in federal court under the Washington products liability act (WPLA), chapter 7.72 RCW, for negligent design, negligent failure to warn, and breach of warranty.[1] The theory central to Dearinger's claims is that Lilly knew or should have known Cialis presented a risk of stroke to its users and failed to adequately warn users of this risk.

[1] Ganna Dearinger, Dearinger's wife, also brought a claim for loss of consortium.

Lilly moved to dismiss the complaint, claiming it provided adequate warnings to Dearinger's prescribing physician under the learned intermediary doctrine. In response, Dearinger claimed there is an exception to the learned intermediary doctrine for drug manufacturers who advertise directly to consumers. But no Washington court has considered this exception. Accordingly, Dearinger moved for the United States District Court to certify a question to this court asking whether Washington law recognizes such an exception, which the court granted.

Three amicus curiae submitted briefs. The Washington State Association for Justice Foundation (WSAJF) filed a brief in support of Dearinger, while the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Washington Defense Trial Lawyers submitted briefs supporting Lilly. Additionally, counsel for WSAJF and PhRMA presented oral argument before the court.

II. CERTIFIED QUESTION PRESENTED[2]

Does Washington law recognize an exception to the learned intermediary doctrine that requires prescription drug manufacturers to warn patients, not just prescribing physicians, when the manufacturer directly advertises to consumers? We review certified questions de novo. *In re F5 Networks, Inc.*, 166 Wn.2d 229, 236, 207 P.3d 433 (2009).

[2] We have the authority to reformulate certified questions. *Danny v. Laidlaw Transit Servs.*, 165 Wn.2d 200, 205, 193 P.3d 128 (2008) (plurality opinion). We exercise this authority here for clarity.

III. ANALYSIS

A. The Learned Intermediary Doctrine Is Settled Law in Washington

1. Washington Adopted the Doctrine through the Common Law

This case ultimately centers on product liability, which is governed by the WPLA. Under the WPLA, a product manufacturer may be liable for failing to provide adequate warnings about a product if it harms the user. RCW 7.72.030(1). Thus, a manufacturer has a duty to warn of dangers associated with using a particular product. *Id.* This case raises the question of who the manufacturer must warn.

In the context of prescription drugs, the learned intermediary doctrine provides "the manufacturer satisfies its duty to warn the patient of the risks of its product where it properly warns the prescribing physician." *Taylor v. Intuitive Surgical, Inc.*, 187 Wn.2d 743, 757, 389 P.3d 517 (2017) (citing *Terhune v. A.H. Robins Co.*, 90 Wn.2d 9, 14, 577 P.2d 975 (1978)). In other words, "[t]he manufacturer's duty to provide warnings to patients transfers to the doctor, who is in a better position to communicate them to the patient." *Id.*

The learned intermediary doctrine has been a fixed part of Washington law since this court adopted it in *Terhune* in 1978. Courts applying the learned intermediary doctrine have done so without recognizing an exception. *See Sherman v. Pfizer, Inc.*, 8 Wn. App. 2d 686, 440 P.3d 1016 (2019), *review denied*, 194 Wn.2d 1015 (2019); *see also Luttrell v. Novartis Pharm. Corp.*, 894 F. Supp. 2d 1324, 1342 (E.D. Wash. 2012) (court order), *aff'd*, 555 F. App'x 710 (9th Cir. 2014). Indeed, we

have consistently reiterated *Terhune*'s central principle that a manufacturer satisfies its duty to warn patients of product risks by warning the prescribing physician, who then takes on the responsibility of communicating those warnings to the patient. *Taylor*, 187 Wn.2d at 757-58; *Young v. Key Pharm., Inc.*, 130 Wn.2d 160, 168, 922 P.2d 59 (1996) (plurality opinion); *Ruiz-Guzman v. Amvac Chem. Corp.*, 141 Wn.2d 493, 506, 7 P.3d 795 (2000); *Rublee v. Carrier Corp.*, 192 Wn.2d 190, 208-09, 428 P.3d 1207 (2018).

Washington is far from alone in adopting the learned intermediary doctrine. Every state in the country, along with the District of Columbia and Puerto Rico, has adopted the learned intermediary doctrine in some iteration. *See* Br. of Resp't at 47-66; *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 158 n.17 (Tex. 2012) (collecting cases). Thus, not only is the learned intermediary doctrine a fixed part of Washington law, it is also universally followed across the country.

2. The WPLA Neither Abrogates the Doctrine nor Provides for an Advertising Exception

While Dearinger and Lilly recognize the learned intermediary doctrine as an active part of our state's common law, WSAJF argues the learned intermediary doctrine is contrary to the WPLA's text and is either ineffective or limited in scope and therefore inapplicable in the context of direct-to-consumer advertising. WSAJF claims "the WPLA's plain language requires product warnings be given directly to consumers." Br. of WSAJF at 14. In effect, WSAJF argues the WPLA abrogates our

common law embrace of the learned intermediary doctrine or otherwise modifies the doctrine to warrant an advertising exception.

To abrogate the common law, there must be "clear evidence of the legislature's intent to deviate from the common law." *Potter v. Wash. State Patrol*, 165 Wn.2d 67, 77, 196 P.3d 691 (2008). Such intent may be evident where "the provisions of a later statute are so inconsistent with and repugnant to the prior common law that both cannot simultaneously be in force." *State ex rel. Madden v. Pub. Util. Dist. No. 1 of Douglas County*, 83 Wn.2d 219, 222, 517 P.2d 585 (1973). The WPLA itself recognizes this principle, stating, "The previous existing applicable law of this state on product liability is modified only to the extent set forth in this chapter." RCW 7.72.020(1).

We adopted the learned intermediary doctrine in *Terhune* three years before the legislature enacted the WPLA. Accordingly, the learned intermediary doctrine is previous existing applicable law under RCW 7.72.020(1). We look to the four provisions cited by WSAJF to determine whether the WPLA modifies the learned intermediary doctrine by use of inconsistent language.

First, WSAJF cites RCW 7.72.010(4), which provides a "product liability claim" includes, among other things, claims for harm caused by "warnings" or "marketing." On its face, this provision does not modify the learned intermediary doctrine. The learned intermediary doctrine itself recognizes a product liability claim for inadequate warnings. Thus, RCW 7.72.010(4) tells us what we already know.

More notable is what this provision does not say, namely, that warnings or marketing must be directed at a consumer. Because this provision does not alter a manufacturer's duty to warn, it provides no basis for an exception to the learned intermediary doctrine.

Second, WSAJF relies on RCW 7.72.030(1)(b), which states a product may not be reasonably safe if adequate warnings were not provided with the product when the manufacturer could have provided the warnings or instructions that the claimant alleges would have been adequate. Like the previous provision, this provision does not explicitly state warnings must be given directly to the end-user. *See Taylor*, 187 Wn.2d at 754 (WPLA does not specify who should receive warnings). Rather, RCW 7.72.030(1)(b) states warnings must be provided "with the product." This requirement to provide warnings with the product falls well short of WSAJF's claim that the warning must be directed at the consumer as opposed to a physician in the case of prescription medications.

Third, WSAJF relies on RCW 7.72.030(3), which dictates, "In determining whether a product was not reasonably safe . . . the trier of fact shall consider whether the product was unsafe to an extent beyond that which would be contemplated by the ordinary consumer." According to WSAJF, relying on consumers' expectations in determining the safety of a product opens the door to an advertising exception because direct-to-consumer advertising influences consumers' expectations. Even if we accept this premise, we have never said the consumer expectations test is the sole metric of

whether a product is unsafe under the WPLA. To the contrary, a plaintiff may establish liability by using either a risk-utility test or a consumer expectation test for failure to warn claims. *See Ayers v. Johnson & Johnson Baby Prods. Co.*, 117 Wn.2d 747, 765, 818 P.2d 1337 (1991); *Falk v. Keene Corp*., 113 Wn.2d 645, 651, 782 P.2d 974 (1989). Moreover, RCW 7.72.030(3) addresses only the standard for the adequacy of the warning—it says nothing about *who* the manufacturer must warn. While we could infer RCW 7.72.030(3) requires manufacturers to directly warn consumers, such an inference is not "clear evidence of the legislature's intent to deviate from the common law." *Potter*, 165 Wn.2d at 77.

Fourth, WSAJF cites RCW 7.72.050(1), which permits a trier of fact to consider evidence about whether a product complied with legislative or administrative regulations. WSAJF claims this provision conflicts with the learned intermediary doctrine because United States Food and Drug Administration (FDA) regulations require prescription drug manufacturers to directly warn consumers when advertising products. *See* 21 C.F.R. § 202.l(e). We do not dispute the relevance of RCW 7.72.050(1) and FDA regulations. In many cases, including the prescription drug context, evidence of a manufacturer's compliance with regulations is crucial to determining a product's safety. But we disagree with WSAJF over whether this provision abrogates the learned intermediary doctrine. In our view, there is no tension between RCW 7.72.050(1) and the learned intermediary doctrine. To the contrary, RCW 7.72.050(1) instructs a fact finder to consider FDA regulations in determining

whether a manufacturer's warning to the prescribing physician is adequate. And as both parties agree, there is considerable FDA regulation over a drug manufacturer's warnings to prescribing physicians. The cohesion of RCW 7.72.050(1) and the learned intermediary doctrine leads us to conclude that the WPLA does not modify the learned intermediary doctrine.

In short, nothing in the WPLA's text detracts from our common law embrace of the learned intermediary doctrine. With no textual basis to abandon or modify the learned intermediary doctrine, we turn to policy.

B. We Decline To Adopt an Exception for Direct-to-Consumer Advertising

Dearinger asks this court to carve out an exception to the learned intermediary doctrine. Under Dearinger's proposed rule, when a drug manufacturer directly advertises to consumers, it must provide adequate warnings directly to the consumer.

Dearinger claims an exception is needed because the policy rationales underlying the learned intermediary doctrine have eroded due to changes in the doctor-patient relationship and increased direct-to-consumer advertising. Specifically, he claims reduced time with patients and changing health care providers, in addition to increased direct-to-consumer advertising, undermines patients' reliance on doctors' expertise. Further, Dearinger argues the learned intermediary doctrine, as it currently exists, encourages "irresponsible behavior." Opening Br. of Pet'r at 30-36. He claims the learned intermediary doctrine "hinders the patient-doctor relationship, encourages patients to choose drug-based solutions over lifestyle-based ones, it reduces the

amount spent on research and development, and increases spending on drugs without a corresponding health benefit." *Id.* at 36.

Dearinger's claims are largely unsubstantiated. The articles and studies he and WSAJF cite offer weak support to justify an exception other courts have flatly rejected. *See, e.g.*, *Centocor*, 372 S.W.3d at 162-63; *Watts v. Medicis Pharm. Corp.*, 239 Ariz. 19, 25, 365 P.3d 944 (2016). Indeed, only New Jersey has adopted a direct-to-consumer exception, but that decision has not been subsequently relied on. *See Perez v. Wyeth Labs*. *Inc.*, 161 N.J. 1, 734 A.2d 1245 (1999).

We, like many other courts, reject a direct-to-consumer advertising question and answer the certified question negatively for two reasons. First, the policies underpinning the learned intermediary doctrine remain true today. Second, state law sufficiently regulate product warnings and prescription drug advertising.

1. The Policies Underlying the Learned Intermediary Doctrine Still Support Limiting the Liability of Drug Manufacturers When They Warn Physicians

The overarching policy behind the learned intermediary doctrine is relying on a physician's expertise—i.e., acknowledging that a physician is in the best place to understand both the drug and the patient's medical history. In adopting the doctrine, this court stated:

> 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. The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. The physician decides what facts should be told to the patient. 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. It has also been suggested that the rule is made necessary by the fact that it is ordinarily difficult for the manufacturer to communicate directly with the consumer.

Terhune, 90 Wn.2d at 14 (footnote omitted). This rationale can be broken into four parts: (1) physicians exercise independent judgment, (2) patients primarily rely on a physician's independent judgment, (3) the physician decides what facts should be told to the patient, and (4) it is difficult for a manufacturer to communicate directly with the consumer.

Dearinger and WSAJF argue these rationales have eroded over time with changes to health care and increased direct-to-consumer advertising. Conversely, Lilly claims the central premise of relying on physician's expertise remains firm. Washington law supports Lilly. By legal design, a physician must exercise independent judgment in prescribing medication, and a consumer must rely on this judgment in obtaining a prescription for a drug like Cialis.

a. Physicians Still Exercise Independent Judgment in Prescribing Drugs

The first underlying premise of the learned intermediary doctrine is that a physician exercises "independent judgment, taking into account his knowledge of the patient as well as the product." *Id.*

This premise is reinforced by law. By statute, a physician can prescribe a medication only when it is within their scope of practice and for a legitimate medical purpose. RCW 69.50.101(nn); RCW 69.41.040(1); RCW 69.50.308(h). Prescribing a legend (prescription) drug for a nonlegitimate or therapeutic purpose constitutes unprofessional conduct subject to discipline. RCW 18.130.180(6). Further, incompetence, negligence, or malpractice that injures a patient or creates an unreasonable risk of harm is unprofessional conduct. RCW 18.130.180(4). Thus, law governing medical practice requires physicians to exercise independent judgment in deciding whether to prescribe a specific drug.

Dearinger does not present any evidence negating the premise that physicians exercise independent judgment when prescribing drugs. Rather, he points to the New Jersey Supreme Court's analysis in *Perez*. The *Perez* court reasoned, in part, "'the fact that manufacturers are advertising their drugs and devices to consumers suggests that consumers are active participants in their health care decisions, invalidating the concept that it is the doctor, not the patient, who decides whether a drug or device should be used.'" 161 N.J. at 19 (quoting Susan A. Casey, Comment, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19

WM. MITCHELL L. REV. 931, 956 (1993)). But a patient's active role in managing their health care does not support the conclusion that a physician abdicates their duty to exercise independent judgment. Again, a physician cannot prescribe a medication where there is no legitimate medical purpose. RCW 69.50.101(nn); RCW 69.41.040(1); RCW 69.50.308(h). Further, doctors are required to discuss the risks and benefits of treatment with the patient under the doctrine of informed consent. Indeed, this court has stated "a health care provider has a fiduciary duty to disclose relevant facts about the patient's condition and the proposed course of treatment so that the patient may exercise the right to make an informed health care decision." *Stewart-Graves v. Vaughn*, 162 Wn.2d 115, 122, 170 P.3d 1151 (2007).

On the other hand, WSAJF presents some evidence that direct-to-consumer advertising "alters physicians' prescribing practices" and "the judgment of physicians that is presumed to be 'independent.'" Br. of Amicus Curiae WSAJF at 21. This evidence comes in the form of two medical journal articles. *See id.* (citing Elizabeth Murray et al., *Direct-to-Consumer Advertising: Physicians' Views of Its Effects on Quality of Care and the Doctor-Patient Relationship*, 16 J. AM. BOARD FAM. PRAC. 513, 521-22 (2003); Lisa M. Schwartz, *Medical Marketing in the United States, 1997-2016*, 321 J. AM. MED. ASS'N 80, 88-90 (2019)).

We are not persuaded by this evidence. Again, by law we can presume a physician exercises independent judgment when prescribing drugs. *See Terhune*, 90 Wn.2d at 14; RCW 69.50.101(nn); RCW 69.41.040(1); RCW 69.50.308(h). So, to the

extent a physician fails to exercise independent judgment, modifying the learned intermediary doctrine is unnecessary—causes of action like medical malpractice and breach of fiduciary duty and discipline by the Washington Medical Commission provide a sufficient remedy for the physician's error.

Moreover, the evidence WSAJF presents is equivocal. One of the studies cited by WSAJF contains data suggesting direct-to-consumer advertising has benefits within the doctor-patient relationship. *See* Br. of Resp't at 20-21. Additionally, PhRMA also presents data supporting the benefits of such advertising. For instance, a 2017 study cited by PhRMA found prescription drug ads helped consumers have better discussions with their health care providers and ensure informed consent. Helen W. Sullivan et al., *Direct-to-Consumer Prescription Drug Advertising and Patient-Provider Interactions*, 33 J. AM. BOARD FAM. MED. 279, 281 (2020); Elyse Krezmien et al., *The Role of Direct-to Consumer Pharmaceutical Advertisements and Individual Differences in Getting People to Talk to Physicians*, 16 J. HEALTH COMM. 831, 832 (2011).

In short, Washington law effectively creates a presumption that a physician will exercise independent judgment in prescribing medication to a patient. The existence of direct-to-consumer advertising does nothing to alter a physician's duties. Thus, the first central premise of the learned intermediary doctrine remains intact.

b. Patients Must Rely on Physicians' Judgment in the Context of Prescription Drugs

The second rationale supporting the learned intermediary doctrine is that patients primarily rely on a physician's independent judgment. *Terhune*, 90 Wn.2d at 14. By legal presumption, this premise also remains true.

As established above, a physician is legally required to exercise independent judgment in determining whether to prescribe a drug. Certain drugs can be obtained only via prescription. Under RCW 69.41.030, it is "unlawful for any person to sell, deliver, or knowingly possess any legend drug except upon the order or prescription of a physician." Thus, a patient seeking a legend drug like Cialis must rely on a physician's independent judgment because they cannot obtain the drug any other way. In effect, a physician is a gatekeeper to legend drugs like Cialis.

Neither Dearinger nor WSAJF present evidence showing patients place *primary* reliance on any source other than the prescribing physician. And to the extent patients rely on direct-to-consumer advertising, the physician's gatekeeper function prevents patients from primarily relying on advertising. Thus, the second rationale remains intact—patients rely on physician's independent judgment in obtaining prescription drugs.

c. Physicians Remain in a Superior Position To Communicate Risks to Patients

The third and fourth underlying premises are that the physician decides what facts should be told to the patient and that it is difficult for a manufacturer to

communicate directly with consumers. *Terhune*, 90 Wn.2d at 14. Together, these bases suggest physicians stand in a better position to convey risks to consumers.

To rebut these premises, Dearinger again relies on *Perez*. The *Perez* court stated drug manufacturers "can hardly be said to 'lack effective means to communicate directly with patients'" because of the large amount of money drug manufacturers spend on advertising. 161 N.J. at 18-19 (quoting Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 158 (1997)). Piggybacking on this argument, Dearinger recites statistics about how much money drug manufacturers spend on advertising. A cursory glance at these figures shows drug manufacturers spend vast sums of money on advertising, demonstrating it is not difficult manufacturers to communicate with consumers.

Lilly does not dispute that manufacturers can directly communicate to consumers. Rather, Lilly argues physicians remain in a better position to communicate risks to patients. We agree for two reasons.

First, prescription drugs are complex and carry significant risks. For example, FDA guidelines require that warnings to physicians contain 18 safety sections, including information on dosage and administration, adverse reactions, use in specific populations (i.e., pregnant persons or persons 65 and older), drug abuse, overdosage, clinical pharmacology, and storage and handling. 21 C.F.R. § 201.57(c). Physicians comprehend this complex information in a way the average lay person cannot.

Indeed, the FDA has recognized the information on the prescribers' label is of "questionable" value when provided directly to patients and "relatively inaccessible to consumers." Direct to Consumer Promotion; Public Hr'g, 60 Fed. Reg. 42,581, 42,583 (Aug. 16, 1995).

Second, physicians can give personally tailored warnings to patients in a way manufacturers cannot. A physician can personalize warnings to a patient based on that patient's medical history and needs. *See McKee v. Am. Home Prods., Corp.,* 113 Wn.2d 701, 711, 782 P.2d 1045 (1989) ("it is only the physician who can relate the propensities of the drug to the physical idiosyncrasies of the patient"); *Ruiz-Guzman*, 141 Wn.2d at 508 ("[a] physician possesses the medical training to assess adverse health effects of a medical product and to tailor that assessment to a particular patient"). Conversely, drug manufacturers cannot create individualized warnings because they do not know consumers' medical information. Thus, manufacturers issue broad, complex warnings that must be simplified by a learned intermediary—the physician—before being given to patients.

Accordingly, the policy reasons for adopting the learned intermediary doctrine remain true today. A prescribing physician is a medical expert who is in the best place to inform a patient of whether a particular drug is in their best interests.

2. Existing State Law Sufficiently Regulates Product Warnings and Prescription Drug Advertising

Thematic in Dearinger's briefing is the idea that without an advertising exception, drug manufacturers like Lilly will "abuse" the learned intermediary doctrine by encouraging consumers to seek out drugs they may not need and providing inadequate warnings. But existing state law regulates product warnings and prescription drug advertising in two relevant ways.

First, under the learned intermediary doctrine, if the warning to the prescriber is inadequate, then the manufacturer is liable. RCW 7.72.030(1).[3] We reiterate that the learned intermediary doctrine has bearing only on *who* a manufacturer must warn. The adequacy of the warning to the physician is a separate inquiry. Thus, a fact finder must determine whether a warning is adequate. *See Little v. PPG Indus., Inc.*, 92 Wn.2d 118, 123, 594 P.2d 911 (1979) (generally, the adequacy of a warning is a question of fact). In answering this question of fact, a jury may consider FDA regulations about prescriber warnings under RCW 7.72.050(1).

Second, if the manufacturer adequately warns the physician but the physician fails to communicate those risks to the patient, then the physician is liable for breach of fiduciary duty. *Stewart-Graves*, 162 Wn.2d at 123; RCW 7.70.050. Similarly, a

[3] Other states have recognized this principle. *See McEwen v. Ortho Pharm. Corp.*, 270 Or. 375, 386-387, 528 P.2d 522 (1974); *Alm v. Alum. Co. of Am.*, 717 S.W.2d 588, 592 (Tex. 1986); *Tracy v. Merrell Dow Pharm., Inc.,* 58 Ohio St. 3d 147, 149, 569 N.E.2d 875 (1991); *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994); *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 764 (Ky. 2004); *Watts*, 239 Ariz. at 24.

physician may be liable for medical malpractice if they fail to exercise the standard of care of a reasonably prudent health care provider in prescribing medication. *See Frausto v. Yakima HMA, LLC*, 188 Wn.2d 227, 231, 393 P.3d 776 (2017); RCW 7.70.040.

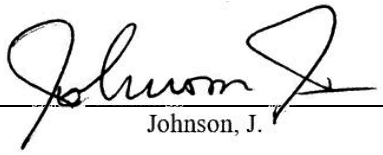
Accordingly, consumers are not left without any redress if either a drug manufacturer or physician provides an inadequate warning.

IV. CONCLUSION

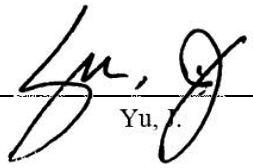
We answer the certified question in the negative—Washington law does not recognize an advertising exception to the learned intermediary doctrine. Rather, a drug manufacturer is protected under the learned intermediary doctrine even when they advertise directly to consumers, provided they give adequate warnings to the prescribing physician. Of course, whether a warning is adequate remains a question of fact for a jury to decide.

Owens, J.

WE CONCUR:



Johnson, J.



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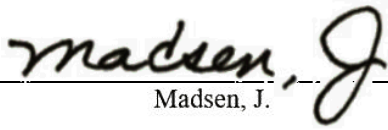

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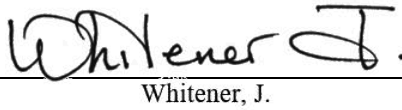
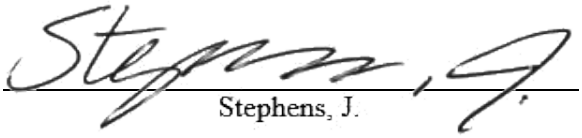


Whitener, J.



Stephens, J.

Melnick, J.P.T.

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GORDON McCLOUD, J. (concurring)—I agree with the majority's holding that the "manufacturer satisfies its duty to warn a patient when it adequately warns the prescribing physician of the drug's risks and side effects." Majority at 2. I agree that this holding applies even where, as in this case, the prescription drug manufacturer advertises its product directly to consumers. And I agree with the majority's analysis of the common law origins of this doctrine, the legislature's preservation of this doctrine, and the weakness of most of the policy reasons offered by Dearinger for abrogating this doctrine.

Except for one. The majority asserts, without much support, that physicians are in the best position—and impliedly the only position—to communicate drug risks to patients. In fact, the majority opines, "Physicians comprehend . . . complex [prescription drug risk/benefit] information in a way the average lay person cannot." Majority at 16.

I cannot agree with the majority's unsupported assumptions that all physicians "comprehend … complex information" better than all patients. And I cannot agree with the consequence of that assumption, that is, that it is better to

withhold complex information from patients about their own medical condition than to reveal it to them in a commonsense, understandable way.

There are certainly other sources that seem capable of revealing complex information to the public in a commonsense, understandable way. The explosion of websites devoted to public health, traditional medicine, alternative medicine, prescription drugs, etc., shows this. Some of that information is very accurate; some of those websites are owned by reputable organizations, government agencies, or respected educational institutions. Many of them use plain language—language that is easier to read than package inserts. The majority's assertion that "the average lay person cannot" "comprehend" complex medical information might be an accurate description of manufacturers' warnings as currently written and directed at physicians. But it is not an accurate description of how prescription drug information must be written.

My disagreement with the majority on this single policy matter does not change my conclusion about the importance of retaining the learned intermediary doctrine at this time. I therefore respectfully concur.

Gordon McCloud, J.

González, C.J.