

The Learned Intermediary Doctrine

A Viable and Strong Defense For Pharmaceutical and Medical Device Manufacturers In the Age of Direct-to-Consumer Advertising

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For more than a half-century — a virtual lifetime in American law — pharmaceutical and medical device manufacturers have benefited from the learned intermediary doctrine as a defense in product liability cases alleging a failure to warn of a product's risks. The doctrine remains a strong and viable defense to this day. The learned intermediary doctrine, in recognition of the existence of the unique relationship between prescriber/physician and patient/consumer, provides that manufacturers of prescription drugs and medical devices can be held liable for failing to warn of the risks of a device or drug only when the manufacturer fails to warn the health care provider of risks attendant to a specific device or drug. *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 803 (E.D. Tex. 2002); Restatement (Third) of Torts: Prod. Liab. §6(d) cmt. a (1998). Thus, unlike all other manufacturers, a manufacturer of pharmaceuticals and medical devices need not warn the consumer directly. The doctrine is based on the well-accepted principle that a patient's prescribing physician is in the best — and the unique — position to educate the patient of the risks presented by a drug or device, given the patient's specific medical condition and therapeutic needs.

Recently, notwithstanding the defense's adoption in the majority of states, the Supreme Court of Appeals of West Virginia, in *Johnson & Johnson v. Karl*, declined to adopt the learned intermediary doctrine. The court concluded, incorrectly, that direct-to-consumer advertising (specifically in the context of pharmaceuticals) has eliminated the role of the prescribing physician in educating patients regarding the risks of prescription drugs. As set forth more fully below, this holding and its underlying rationale: 1) ignores and undervalues the duty of a physician to exercise medical judgment in the prescribing of drugs and medical devices based on his or her patient's individual and specific needs; 2) undermines the federal regulatory scheme that requires pharmaceutical and device manufacturers to provide warnings to physicians; and 3) deprives pharmaceutical companies of a long-standing, valid defense, apparently solely because, like

all manufacturers, such companies benefit financially from the sale of their products. As set forth herein, however, the very same reasons that prompted the development of the learned intermediary doctrine more than a half-century ago remain relevant and applicable today.

Johnson & Johnson v. Karl: Factual and Procedural Background

In *Johnson & Johnson v. Karl*, 647 S.E.2d 899 (W. Va. 2007) the West Virginia Supreme Court considered for the first time whether the learned intermediary doctrine was applicable in West Virginia. 647 S.E.2d at 900-01. In the underlying wrongful death suit, the plaintiff, the decedent's estate, alleged that death was caused by the ingestion of the prescription medication Propulsid®, which was prescribed by the decedent's physician. *Id.* at 901. The plaintiff filed a single action against the prescribing physician alleging medical malpractice and against the manufacturer alleging product liability. *Id.* Propulsid was manufactured and distributed by defendant Janssen Pharmaceutica, Inc., a wholly owned subsidiary of defendant Johnson & Johnson ("Janssen"). *Id.*

Janssen moved for summary judgment based on the learned intermediary doctrine. *Id.* The trial court denied the motion, finding that disputed issues of material fact precluded entry of judgment. *Id.* Thereafter, Janssen filed an *in limine* motion, again based on the learned intermediary doctrine, to exclude evidence purporting to show that Janssen had a duty to warn the decedent directly. *Id.* Janssen argued that its duty to warn ran solely to the prescribing physician under the learned intermediary doctrine. The trial court also denied Janssen's motion *in limine*, finding that West Virginia had not recognized the learned intermediary doctrine. *Id.* Accordingly, Janssen filed a writ of prohibition in the West Virginia Supreme Court, seeking to prohibit the enforcement of the trial court's order. *Id.*

The Karl Court's Rationale

Generally, in denying Janssen's writ, the West Virginia Supreme Court refused to recognize the learned

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intermediary doctrine as a viable defense in a failure to warn product liability case involving prescription pharmaceuticals and devices. As a justification for rejecting a well-established defense, the court first downplayed the number of jurisdictions around the country that have recognized the learned intermediary doctrine. Thereafter, the court rejected the primary bases for the existence of the learned intermediary doctrine. The court rejected these bases because in its view, the advent of direct-to-consumer advertising by the pharmaceutical industry in the “modern” world has rendered the physician’s special role, and, therefore, the learned intermediary doctrine, obsolete. Specifically, the court declined to recognize the continuing unique relationships that exist between doctors and patients in the context of prescription products. The court further expressed a desire to hold pharmaceutical companies liable in part because, in its view, manufacturers of prescription products are indistinguishable from other manufacturers that “benefit financially from the sales” of their products.

First, the *Karl* court discussed at some length that because, in its view, the learned intermediary doctrine has not been accepted in the majority of states, the argument that it is a well-accepted doctrine failed to persuade the court of its merit. *Id.* at 903. The court based its determination solely on the number of jurisdictions where the doctrine has been recognized either by the highest court of the state or by statute, disregarding the numerous lower state court holdings and federal courts interpreting state law that would bring the number by some counts to as many as 44. *Id.* at 903-905. *See also In re Norplant*, 215 F. Supp. 2d at 806-09. As the dissent aptly noted, however, the adoption of the doctrine by 23 states would represent a significant number approaching a majority, even if the unchallenged state trial court decisions and federal court decisions interpreting state law, were not included. *Id.* at 914 n.1 (Allbright, J, dissenting). This is particularly true where, as here, the doctrine at issue has rarely been rejected — and never wholesale. Moreover, at least four of the highest state courts in the country have adopted the doctrine, even after the advent of direct-to-consumer marketing. *See, e.g., Vitanza v. Upjohn Co.*, 778 A.2d 829 (Conn. 2001); *McCombs v. Synthes*, 587 S.E.2d 594 (Ga. 2003); *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758 (Ky. 2004); *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827 (Neb. 2000).

Next, the *Karl* court addressed the “primary justifications” for the doctrine and its grounds for rejecting them. *Id.* at 905. These justifications include: 1) the difficulty involved in providing warnings to the end-user of prescription drugs; 2) reliance on the judgment of the treating physician in prescribing the appropriate medication for the patient; 3) that “physicians are in the best position to provide appropriate warnings to their patients”; and 4) “the concern that direct warnings to ultimate users would interfere with the doctor/patient relationship.” *Id.*

The *Karl* court found that “these justifications for the learned intermediary doctrine” are “largely outdated and unpersuasive” and that the doctrine is not “modern.” *Id.* at

906. Specifically, the court, largely relying upon law review articles, among other secondary sources, found that: 1) due to direct-to-consumer advertising, a patient decides which drug or device is used as part of his/her treatment, not the treating physician; and 2) direct-to-consumer advertising proves that manufacturers are capable of effectively communicating all potential adverse effects to the consumer himself or herself, without the need for input from the treating physician. *Id.* at 910. In sum, the court concluded that “[c]onsumer-directed advertising of pharmaceuticals belies each of the premises on which the learned intermediary doctrine rests.” *Id.*

In the course of this analysis, the court noted its agreement with the finding by the New Jersey Supreme Court in *Perez v. Wyeth Labs.*, 734 A.2d 1245 (1999), that drugs that pharmaceutical companies advertise directly to consumers should not benefit from the protections of the learned intermediary doctrine. *Id.* However, the court concluded that if exceptions to the doctrine were necessary in connection with its adoption, there was no benefit in adopting the doctrine in the first instance. *Id.* at 913.

Additionally, the *Karl* court advocated generally for requiring extensive patient warnings, and criticized existing direct-to-consumer advertising as supplying “partial or incomplete information.” *Id.* Although the court did not specify further with respect to these patient warnings, it seemed to suggest that a consumer should be directly warned of all known risks associated with a drug or medical device — yet another departure from well-established tort law in general, and pharmaceutical law in particular. *Id.*

Finally, the court, concluded: “[B]ecause it is the prescription drug manufacturer who benefits financially,” the learned intermediary doctrine should not apply. *Id.* at 913-14. The financial status of or benefits to a manufacturer, however, should have no bearing on the application of the learned intermediary doctrine, which has at its core recognition of the uniqueness of the doctor/patient relationship in the distribution of prescription medical products. Additionally, in so holding, the court also inexplicably adopted the trial court’s rationale that “West Virginia’s law as to comparative negligence among tortfeasors will adequately address the issues of warnings as between the manufacturer” and the physician. *Id.* at 914 (citation omitted). The court, however, failed to address the fact that this approach in and of itself erodes the role of the physician.

For all of these reasons, the court ultimately concluded that the trial court was correct in “denying Janssen’s *in limine* motion and declining to adopt the learned intermediary doctrine.” *Id.* at 914.

The Fallacy of the Karl Court’s Reasoning and The Far-Reaching Policy Consequences

The *Karl* court’s rejection of the learned intermediary doctrine is flawed for a number of reasons. First, it fails to recognize the continuing role and duty of physicians in patient care. Second, it is inconsistent with the federal regulatory scheme for drug labeling that requires physician

warnings. Third, it deprives manufacturers of prescription medical products of a rational, valid and core defense solely because such manufacturer “benefits financially” from the sale of its product.

First and fundamentally, the *Karl* court ignored the reality of the physician-patient relationship, as well as treating physician’s professional, legal and ethical duties, which are long-standing and non-delegable. The court failed to address the fact that patients can obtain prescription drugs and devices only through a physician. Thus, the physician remains the core educator and provider of information in the decision making process regarding whether to prescribe a drug or device. The court makes no mention of the fact that prescribing physicians are both licensed and regulated by state government — as is their ability to write prescriptions. As the dissent recognizes, the advent of direct-to-consumer advertising has not altered the obligations and responsibilities placed upon prescribing physicians to understand risks of a drug or medical device and to exercise medical judgment in informing patients of risks, based on their patients’ individual health. *Id.* at 915 (Albright, J., dissenting). Instead of recognizing that a physician’s duty has not changed, the *Karl* court has rolled back the clock to the pre-modern era where the unique role of physicians in the distribution of products available only by prescription was not recognized. This does not constitute a modernization of the law, as the *Karl* court seems to think, but rather a return to the Dark Ages. Moreover, the fact that the advent of direct-to-consumer advertising in the “modern” world of pharmaceuticals should not impact the applicability of the learned intermediary doctrine is perhaps best illustrated by the dearth of courts and states that have reconsidered or modified its applicability, even in the decade following the 1999 Perez decision. Nothing in the *Karl* court’s reasoning should persuade a court or state otherwise.

Second, in attempting to mandate the substance of a company’s duty regarding patient-directed warnings, the *Karl* decision conflicts with the FDA regulations regarding prescription drug labeling. As a threshold matter, the FDA’s drug labeling requirements assume a significant role by the prescribing physician. The FDA does not and has never required that all potential risks associated with all prescription drugs be conveyed directly to patients. *See, e.g.*, 21 C.F.R. 201.57 (stating that Warnings and Precautions of the label only should include “clinically significant” adverse reactions

— not all reactions.) The *Karl* court gives no consideration to the current regulatory scheme for drug labels or the FDA’s determination as to which information should be contained therein. Furthermore, the *Karl* court’s seemingly implicit requirement that drug companies warn of all potential risks, would significantly undermine the FDA’s authority and the existing, long-standing drug labeling regulatory scheme. The sequella from the application of the construct seemingly proposed by the *Karl* court are potentially numerous and significant — from over-warning, to overly complex warning language directed to consumers resulting in confusion, to patients refusing to take a drug that might be beneficial and low-risk for that particular patient.

Finally, the court seemed determined to strip pharmaceutical and medical device manufacturers of the learned intermediary defense simply because they are businesses. The court concluded that because drug and medical device manufacturers, like all manufacturers, can benefit financially from the sale of their products, and may advertise directly to the consumer, the learned intermediary doctrine should not be available to them, and they must be treated the same as companies whose products are available directly to the general public. Again, this ignores the uniqueness of the prescriber/physician to patient/consumer relationship that exists solely in the context of pharmaceuticals and medical devices. Profit, universal to the business world, cannot serve, however, as a justification for rejecting a long standing, rationally based legal doctrine.

Conclusion

The role of a prescribing physician as an intermediary between the pharmaceutical and medical device manufacturers and patients has been recognized as an exception to the standard manufacturer’s duty to warn for over half a century. The advent of direct-to-consumer advertising has not altered this relationship, or the physician’s role as the learned adviser and decision-maker in his or her relationships with patients. The *Karl* court’s refusal to recognize the learned intermediary doctrine and rejecting it wholesale lacks a sound basis. It is a legal aberration that warrants a prompt legislative response to codify the learned intermediary doctrine in West Virginia. In the interim, pharmaceutical and medical device companies should preserve their rights by continuing to assert this important defense.

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