After *Karl*

Litigating the Learned Intermediary Doctrine

By Jon A. Strongman

Rejection of doctrine should remain an outlier, not a trend.

The process is familiar to nearly everyone. Perhaps you have an infection. Or perhaps you are fighting a chronic condition. You go to your doctor. The physician—based on his or her training and expertise—makes a diagnosis, recommends a medication, and hands you a prescription. You ask questions about the treatment, but in the end, you rely on your physician. Your physician is trained to make these types of decisions. It is what the practice of medicine is all about. After all, a patient cannot get a prescription medication in the United States without—well—a prescription.

For more than 50 years, courts across the country have recognized the practicalities of this process. They have acknowledged that it is the physician, not the patient, who possesses the expertise to evaluate the risks and benefits of a prescription drug. To this end, courts have widely held that a prescription drug manufacturer's duty to warn runs to the physician, not directly to the patient. This has become known as the "learned intermediary doctrine." The learned intermediary doctrine has been accepted in virtually every jurisdiction. Before 2007, no court had outright rejected the doctrine. However, the West Virginia Supreme Court's decision in *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899 (W. Va. 2007), changed that. In *Karl*, the West Virginia Supreme Court went against decades of well-established policy and declined to adopt the learned intermediary doctrine, holding that the justification for the doctrine was "outdated" and "unpersuasive." *Id.* at 906.

This article will discuss the background of the learned intermediary doctrine, the *Karl* decision and its impact, why West Virginia got it wrong, and practical ways to litigate the learned intermediary doctrine in the wake of *Karl*.

Background on the Learned Intermediary Doctrine

The Origins

The learned intermediary doctrine reaches all the way back to 1948. In *Marcus v. Specific Pharmaceuticals*, the plaintiff sued a drug manufacturer claiming that his child died as a result of an overdose of suppositories prescribed by the child's physician. 77 N.Y.S.2d 508, 509 (N.Y. Sup. Ct. 1948). The physician prescribed two child-sized tablets while the proper dosage for the child was only one-half tablet. *Id.* The court held that the manufacturer could not be liable to the plaintiff: "[I]t is difficult to see on what basis this [manufacturer] defendant

■ Jon A. Strongman is an associate in the Pharmaceutical and Medical Device Litigation Division of Shook, Hardy & Bacon, L.L.P., in Kansas City, Missouri, where he focuses on defending complex products liability litigation in state and federal courts across the country.

can be liable to plaintiff. It made no representation to plaintiff, nor did it hold out its product to plaintiff as having any properties whatsoever. To physicians it did make representations.... It may be safely conceded that these allegations would be sufficient if the product were sold to the public generally as a drug for which no physician's prescription was necessary. The situation alleged is materially different." *Id.* at 509–10. This was the start of a clear legal distinction between products sold directly to the public and those for which a prescription was needed.

The actual phrase "learned intermediary" surfaced almost 18 years later in the Eighth Circuit case *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966). The court stated: "we are dealing with a prescription drug rather than a normal consumer item. In such a case the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer." *Id.* Over the decades that followed, the learned intermediary doctrine became widely accepted.

The Rationales

There have been numerous justifications discussed for the learned intermediary doctrine, but in the end, they boil down to three main rationales: (1) due to the complexity of prescription drugs, physicians are in the best position to evaluate and filter the risks and benefits and make an appropriate treatment decision; (2) manufacturers are unable to effectively communicate with patients directly as compared to the prescribing physicians; and (3) requiring manufacturers to warn patients directly would obstruct the nature of the physician-patient relationship. *See Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 763–64 (Ky. 2004).

Prevalence of the Doctrine

The learned intermediary doctrine has been widely accepted all across the United States. In 2002, the United States District Court for the Eastern District of Texas did a comprehensive analysis of the doctrine and concluded that: "The overwhelming majority of jurisdictions to address the issue apply the learned intermediary doctrine.... [T]he doctrine either applies or is recognized, without an exception relevant to the Norplant cases, in 48 states, the District of Columbia, and Puerto Rico." *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 806 (E.D. Tex. 2002). More recently, the Eighth Circuit went so far as to call the precedent for the learned intermediary doctrine "truly overwhelming" and the policy behind it "sound." *Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013, 1017 (8th Cir. 2004).

Exceptions

The Restatement (Third) of Torts: Products Liability adopted the learned intermediary doctrine but also set out a previously recognized exception. The Third Restatement states that the doctrine will not apply "when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings." §6(d)(2). This exception has been adopted in circumstances such as mass immunizations and certain contraceptives. *See, e.g., Petty v. United States*, 740 F.2d 1428, 1440 (8th Cir. 1984); *Odgers v. Ortho Pharm. Corp.*, 609 F. Supp. 867, 878 (E.D. Mich. 1985).

The Third Restatement comments also mention a possible exception in the case of prescription drugs with direct to consumer ("DTC") advertising, but leave the issue to "developing case law." §6(d) cmt. e. The New Jersey Supreme Court subsequently adopted a DTC exception. *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245 (N.J. 1999). The *Perez* court also stated that if a manufacturer complied with the FDA regulations for such DTC advertisements, there would be a presumption that the manufacturer satisfied its duty to warn. *Id.* at 1259. To date, no other court has adopted the DTC exception.

The *Karl* Decision

While some courts had recognized limited exceptions to the learned intermediary doctrine, in 2007, the West Virginia Supreme Court in *State ex rel. Johnson & Johnson Corp. v. Karl* became the first court in the country to outright reject the learned intermediary doctrine altogether. 647 S.E.2d 899, 914 (W. Va. 2007).

The Facts

The *Karl* case revolved around Propulsid®, a prescription medication indicated for the treatment of heartburn. *Id.* at 901. The patient, Mrs. Nancy Gellner, was prescribed Propulsid® by her primary care physician, and on the third day after starting the medication, Ms. Gellner died suddenly. *Id.* The estate subsequently filed suit against both the manufacturer, Janssen, and the prescribing physician. *Id.* Janssen moved for summary judgment arguing that it had properly fulfilled its duty under the learned intermediary doctrine. *Id.* This motion was denied by the trial court. *Id.* Janssen then filed a motion *in limine* to preclude any evidence that it had a duty to warn the patient directly. *Id.* This motion was likewise denied. *Id.* Janssen then filed a petition in the Supreme Court of Appeals for a writ of prohibition requiring the trial court to apply the learned intermediary doctrine. *Id.*

The Holding and Rationale

The court in *Karl* ultimately rejected the learned intermediary doctrine, holding: "[U]nder West Virginia products liability law, manufacturers of prescription drugs are subject to the same duty to warn consumers about the risks of their products as other manufacturers. We decline to adopt the learned intermediary exception to this general rule." *Id.* at 914.

In justifying its decision, the court in *Karl* went to great lengths to attempt to downplay the prevalence of the doctrine. The court—expressly ignoring the numerous decisions of lower courts across the country—stated that the learned intermediary doctrine had only been recognized either by the highest court or by statute in 22 states, less than a majority. *Id.* at 904.

The court also attacked the rationale of the doctrine as "largely outdated and unpersuasive." *Id.* at 906. One of the primary factors in the decision was the recent emergence of DTC advertising. The court specifically noted that: "Significant changes in the drug industry have post-dated the adoption of the learned intermediary doctrine in the majority of states in which it is followed. We refer specifically to the initiation and intense proliferation of direct-to-consumer advertising, along with its impact on the physician/patient relationship, and the development of the internet as a common method of dispensing and obtaining prescription drug information." *Id.* at 907.

DTC advertising, according to the *Karl* court, rebuts the very notion underlying

the learned intermediary doctrine that it is the physician that makes a prescribing decision. *Id.* at 910. The court also emphasized that DTC advertising refuted the idea that a manufacturer is unable to reach each consumer directly. *Id.*

The court ultimately concluded that "[B]ecause it is the prescription drug manufacturers who benefit financially from the sales of prescription drugs and possess the knowledge regarding potential harms, and the ultimate consumers who bear the significant health risks of using those drugs, it is not unreasonable that prescription drug manufacturers should provide appropriate warnings to the ultimate users of their products." *Id.* at 913.

All indications are that *Karl* does not represent a trend, but an anomaly.

Why West Virginia Got It Wrong

The West Virginia Supreme Court got the *Karl* decision wrong for at least two reasons: (1) while the court focused on what has recently changed in the prescription drug atmosphere, it ignored what necessarily remains the same; and (2) the court failed to appreciate the negative consequences of an environment where prescription drug manufacturers are required to warn the patient directly.

The Foundation of the Learned Intermediary Doctrine Remains the Same

While the court in *Karl* focused almost exclusively on the recent emergence of DTC advertising for prescription drugs, the court failed to address in any notable detail the single most important rationale underlying the learned intermediary doctrine: that the physician is the only one with the training and expertise required to truly understand not only the risks of the medication, but also the benefits for the patient. This fact has not changed since the inception of the learned intermediary doctrine, and cannot change so long as the law requires the sign off from a licensed physician before a patient can receive a prescription medication.

Justice Albright discussed this in the dissent in *Karl*: "Just because a warning can be printed and advertised as part of the marketing plan for a prescription drug does not mean that a consumer, especially one not educated in medical jargon, can digest or comprehend the significance of that warning in a useful fashion." *Id.* at 915.

Several cases and authorities have properly recognized this fact. The Restatement (Third) of Torts: Products Liability acknowledged that: "[O]nly health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy." §6, cmt. b; *see also, e.g., Thomas v. Hoffman-LaRoche, Inc.*, 731 F. Supp. 224, 229 (N.D. Miss. 1989), *aff'd*, 949 F.2d 806 (5th Cir.), *cert. denied*, 504 U.S. 956 (1992) (the physician "through education, experience and specialized training is in the best position to make a benefit/risk analysis in making the determination to prescribe a particular drug for a specific patient").

The majority in *Karl* only addressed this argument by attempting to minimize the role of the physician, stating that because "managed care has reduced the time allotted per patient, physicians have considerably less time to inform patients of the risks and benefits of a drug." *Karl*, 647 S.E.2d at 910. Yet, what has not changed is that it is the physician's duty to weigh the risks and benefits of any drug they prescribe—irrelevant of the time allotted. This is not something a physician can delegate. In other words, regardless of DTC advertising and regardless of the evolution of managed care, at the end of the day, it is the licensed physician that must sign his or her name on the prescription pad approving the drug. As the Supreme Court of Delaware concluded: "In the final analysis it is the physician who ultimately prescribes the drug or device." *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 400 (Del. 1989).

Warning All Patients Directly Would Be Counterproductive

Requiring a prescription drug manufacturer to directly warn all consumers would have one of two potential consequences. Either consumers would be so overwhelmed with information and warnings that they would simply ignore the risks, or they would be unwilling to take a medication they may desperately need after being scared away by all the conceivable risks, no matter how remote. Neither situation is healthy for patients.

These concerns have likewise been highlighted by cases applying the learned intermediary doctrine. For example, the Fourth Circuit has recognized that "[i]f pharmaceutical companies were required to warn of every suspected risk that could *possibly* attend the use of a drug, the consuming public would be so barraged with warnings that it would undermine the effectiveness of these warnings." *Doe v. Miles Labs., Inc.*, 927 F.2d 187, 194 (4th Cir. 1991).

The California Court of Appeals has also stated that "[w]ere the patient to be given the complete and highly technical information on the adverse possibility associated with the use of the drug, he would have no way to evaluate it, and in his limited understanding he might actually object to the use of the drug, thereby jeopardizing his life." *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 989 (1971) (quoting Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947, 987 (1964)).

Ultimately, requiring manufactures to warn all patients directly would push the physician's expertise to the sideline and would result in treatment decisions being made either without full consideration of legitimate risks or out of fear of remote risks.

The Impact of *Karl*

As of the current time, the *Karl* decision remains on an island. No other court has followed suit and explicitly rejected the learned intermediary doctrine. All indications are that *Karl* does not represent a trend, but an anomaly.

This fact, however, raises the obvious question: what is a manufacturer supposed to do now in West Virginia? One of the choices is to increase DTC advertising. The irony is that—after criticizing DTC advertising—the West Virginia Supreme Court has essentially invited more of it. Yet, it does not make practical or economic sense to advertise every single prescription drug available. There are other options available for manufactures such as providing patient information sheets in West Virginia that must accompany every

prescription written. Again, this increases the cost and would also increase the burden on either a physician or a pharmacy. It is also possible that the extra cost would then be passed on to the patients.

The West Virginia Supreme Court was attempting to empower and protect West Virginia patients. Yet, in the end, the decision in *Karl* will have the opposite impact. Patients will potentially be flooded with information that is beyond their expertise, and ultimately, may even see the cost of prescription drugs rise.

Practical Tips for Litigating the Learned Intermediary Doctrine after *Karl*

A lawyer defending a prescription drug products liability case must now think about how to prevent the decision in *Karl* from reaching out beyond the boarders of West Virginia and invading other jurisdictions. Below are a few practical tips to help lock in the applicability of the learned intermediary doctrine.

Develop a Plan Early

Do not wait until discovery in the case is complete to determine how the learned intermediary doctrine interplays with your defense. At the outset, become familiar with the status of the doctrine in the relevant state and know any applicable exceptions. Incorporate the learned intermediary theme into every stage of the litigation where possible—from the answer, to written discovery, to depositions, to experts, and even to jury instructions.

Know the DTC Advertising That Was Done for Your Product

Early on it is important to be familiar with the DTC advertising, if any, that was done for the product at issue in the case. Having a handle on the advertising that was done, where it went, and what risks were discussed will help either minimize the impact of the advertising on the learned intermediary doctrine, or enable you to use it to your advantage.

Address Relevant Issues in the Plaintiff's Deposition

There are several ways to weave the learned intermediary doctrine theme into your questioning of a plaintiff.

Emphasize the plaintiff's reliance on the prescribing physician. Establish that the plaintiff relies on the prescribing physician to warn of risks and to weigh the benefits of the drug. You can also establish that the plaintiff admittedly does not have the same knowledge and expertise to understand prescription medication that the physician does. The vast majority of the time, plaintiffs will freely agree to these concepts.

In addition, identify the role any advertising played in the plaintiff's decision to take a particular drug. Getting a plaintiff to admit that they did not rely on any particular DTC advertisement will make it hard for a court to kick the learned intermediary doctrine to the curb based on such advertising.

Take Every Opportunity to Educate the Judge

It is not uncommon to be in front of a judge who is unfamiliar with prescription drug litigation and its nuances. As with any other unique legal issue, it can take a judge some time to really understand and grasp how the doctrine applies in a given case. Therefore, it is always helpful to use every opportunity available to inform the judge of the relevant law in your given jurisdiction, to explain how the learned intermediary doctrine operates, and to highlight why the doctrine is based on sound policy.

Conclusion

The learned intermediary doctrine has framed prescription drug litigation for decades. In *Karl*, the West Virginia Supreme Court became the first court to reject the doctrine, turning its back on years of well-conceived (and still applicable) legal reasoning. To date, it appears that *Karl* will continue to be an outlier, not a trend. That being said, knowing about the *Karl* decision and its rationale will help practitioners defend against any further erosion of the learned intermediary doctrine in other jurisdictions. FD