Learned Intermediary Doctrine: Required By Fed Law?

*Tuesday, Jul 17, 2007* --- For decades, pharmaceutical companies have relied on the widespread acceptance of the learned intermediary doctrine, which protects companies from liability if they provide sufficient warnings to prescribing physicians (the “learned intermediaries”).

This state tort law rule has existed in harmony with FDA’s extensive regulation of physician warnings.

This harmony was substantially disrupted on June 27, 2007, when West Virginia’s Supreme Court of Appeals made it the first state to reject the learned intermediary doctrine.

In *In State ex. rel. Johnson & Johnson Corp. v. Karl*, West Virginia’s highest court broke with precedent from 48 other jurisdictions to hold that “manufacturers of prescription drugs are subject to the same duty to warn consumers about the risks of their products as other manufacturers.” – S.E.2d –, 2007 WL 1888777 (W. Va. June 27, 2007).

Although this West Virginia decision stands alone, Karl could have significant implications for patient labeling for prescription drugs distributed across the country.

The Karl decision is subject to obvious criticism on tort policy grounds.

But what is perhaps less immediately clear is the significant federal preemption issues presented by Karl. Karl’s use of state tort law to compel direct patient warnings for all prescription-only medicines has the strong potential to undermine the extensive federal regulation of pharmaceutical products.

I. Summary of Karl and its Potential Implications

Karl involved a product liability claim brought by the estate of a woman who died suddenly on the third day after she began taking Propulsid®.

Propulsid’s manufacturer argued that it was protected from liability by virtue of the express warnings it provided to the patient’s prescribing physician regarding the very risk at issue in the case.

After the trial court disagreed, the manufacturer appealed to West Virginia’s highest court, which refused to adopt the learned intermediary doctrine in West Virginia.
Although the Karl court acknowledged the primary justifications for the learned intermediary doctrine, it rejected these justifications as “largely outdated and unpersuasive.”

In reaching this conclusion, the court placed heavy emphasis on the relatively recent growth of direct-to-consumer (“DTC”) advertising and its purported adverse impact on the traditional physician/patient relationship.

However, rather than deciding to require direct patient warnings only in those cases where significant DTC advertising has affected the doctor-patient relationship—as the New Jersey Supreme Court did in 1999—West Virginia’s highest court abandoned the learned intermediary doctrine in all circumstances, regardless of whether DTC advertising has occurred.

The Karl decision carries potentially broad implications that may extend beyond the boundaries of West Virginia.

It is unclear how broadly the court’s decision will apply, but plaintiff lawyers may argue that the court’s rejection of the learned intermediary doctrine exposes manufacturers to liability for failure to provide adequate warnings to patients for any potential adverse effects or side effects, not just the most serious or most common effects, and for all types of prescription drugs, regardless of their risk/benefit profile or whether the risks relate to issues of patient compliance or behavior.

Under this reading, the Karl decision would create incentives to provide extensive patient warnings about all potential risks for any given drug, because a manufacturer has no way of knowing what potential risk may be the subject of litigation.

And because current drug distribution systems would make it challenging to provide warnings only in West Virginia, manufacturers may be compelled to provide such warnings to patients outside West Virginia as well.

In encouraging a broad scheme of patient-directed warnings, the Karl decision conflicts with the comprehensive system FDA has established for prescription drug labeling.

FDA encourages patient warnings that are short and simple and highlight what the patient most needs to know, including information specific to patient compliance and behavior modification while taking the drug.

For decades, the agency has carefully considered the best approach for patient-directed warnings and related communications, but the learned intermediary—the licensed prescriber, without whom a patient may not obtain a prescription medicine—remains at the heart of FDA’s system for prescription drug labeling.

II. Current FDA Regulatory Scheme for Patient Labeling
FDA’s regulatory scheme for patient prescription drug labeling derives from sections 502(f) and 503(b) of the Federal Food, Drug, and Cosmetic Act ("FDCA").

Section 502(f) states that a medication is misbranded unless its labeling bears adequate directions for use, which FDA has interpreted to mean adequate directions for the ultimate user (the patient).

Section 503(b) provides for prescription-only distribution of medications that are not safe for use except under the supervision of a practitioner licensed to administer the medicine, and authorizes FDA to promulgate regulations setting forth the conditions under which prescription drugs are exempt from the “adequate directions for use” requirement of section 502(f).

FDA’s regulations implementing the statutory scheme require a prescription drug manufacturer to provide adequate directions through dissemination of the approved professional prescribing information (also known as the package insert or “PI”) in connection with promotional activities, rather by providing information suitable for end users (patients).

The federal drug regulatory scheme thus implicitly adopts the learned intermediary doctrine.

The direct patient labeling requirements of section 502(f) are waived because prescription drugs, by definition, cannot bear adequate directions for patient use in the absence of professional labeling.

They are unsafe unless prescribed and dispensed under the supervision of a licensed medical practitioner, and the manufacturer is thus required to disseminate with its product prescribing information specifically directed to and designed to be read and understood by medically-trained professionals.

Instead of requiring patient warnings in all instances, the current drug regulatory scheme provides four primary mechanisms through which manufacturers can communicate safety information to patients:

(1) “information for patients” sections of the package insert, which contain information regarding the safe and effective use of the product that a physician or pharmacist should consider communicating directly to patients;

(2) patient package inserts (“PPIs”), which can be physically provided to the patient by manufacturers, prescribers, or dispensers;

(3) medication guides ("MedGuides"), which must be distributed to patients when required; and

(4) manufacturer promotional labeling and advertising to consumers.

FDA must approve PIs (including any “information for patients” section) and MedGuides.
While manufacturers are not required to obtain FDA approval of their PPIs, in practice, companies virtually always seek agency approval of these materials.

FDA retains oversight over promotional labeling through its authority under section 502(a) of the FDCA to prohibit labeling that is false or misleading in any particular.

FDA has acknowledged the importance of conveying information on the safe use of prescription drugs directly to consumers in limited circumstances.

The agency has required MedGuides for a small group of drugs where FDA determined that either serious risks or the need to influence patient behavior militated in favor of supplemental communications to patients.

Likewise, FDA can also require an “information for patients” section of the PI as a condition of approval where the agency deems it necessary.

While FDA has encouraged the communication of information to patients about the safe use of prescription drugs more generally, the agency has remained steadfast that these additional communication methods (whether mandatory or not) should work to stimulate discussion between patients and their medical professionals and reinforce the risk messages provided by the physicians.

III. Preemption Arguments Against Rejection of Learned Intermediary Doctrine

A drug manufacturer can argue that Karl’s use of state tort law to compel direct-to-patient warnings for prescription medications is preempted by the federal system of prescription drug labeling.

The Supremacy Clause of the United States Constitution preempts state laws that conflict with federal law, including state tort suits that seek to compel action that conflicts with federal regulations.


Karl’s use of state tort law to compel widespread patient warnings stands as an obstacle to the federal regulatory plan for prescription drug labeling in three important respects.

First, the role of the prescribing physician—the “learned intermediary”—is central to FDA’s prescription drug labeling requirements.

Prescription drugs, which are among the most closely and comprehensively
regulated products in commerce, inherently carry some risk and cannot be made completely “safe.”

The learned intermediary is crucial to ensuring that prescription drugs are used as safely and effectively as possible in patients for whom their use is appropriately indicated.

Information about the risks of prescription drugs is, by its nature, highly technical and difficult to translate into lay terms without loss of potentially significant scientific nuances.

For this reason, although FDA has recognized the importance of providing safety information to patients, that effort is focused on enhancing patient-physician dialogue, and the agency has never attempted to require that all potential risks associated with all prescription drugs be conveyed directly to patients.

The federal prescription drug labeling requirements are built around the premise that it is necessary to filter the complete information about prescription drugs through the learned intermediary, who is uniquely positioned to convey the most appropriate information about a drug to the particular patient in each individual circumstance.

A state’s rejection of the learned intermediary doctrine would effectively require the full range of warnings to be provided directly to consumers for all prescription drugs.

Such a result would significantly undermine the extensive federal system for the regulation of prescription drug labeling that Congress established and that FDA has implemented with great care and special expertise.

Second, the use of state tort law to compel comprehensive patient warnings would conflict with the goals of the federal scheme by diluting the impact of warnings that are scientifically justified and by chilling appropriate and beneficial use of drugs.

FDA has repeatedly expressed concerns about “overwarning.” Courts have recognized that an abundance of warnings may cause essential warnings to go unheeded, and that unjustifiably alarmist warnings or those about remote risks may deter patients from using drugs that are important or even critical to their successful treatment.

FDA’s obligation to protect the public health includes ensuring that important new medicines are available to the patients who need them as well as assuring that the labeling of these drugs appropriately emphasizes the most important safety information.

State tort schemes that leave patients awash in a sea of warnings stand as an obstacle to FDA’s fulfillment of this overarching obligation.
Finally, the simple act of requiring extensive patient warnings could stand as an obstacle to the federal regulatory scheme by causing FDA to be inundated with patient warnings that it neither wants nor finds appropriate.

While manufacturers would not be obligated to seek FDA approval for all patient-directed warning materials, as a practical matter many if not all are likely to do so, just as they currently do for PPIs.

Manufacturers will want assurance that FDA does not consider these materials to be false or misleading or otherwise misbrand the drug and that the agency views the patient labeling as consistent with the mandatory labeling directed to the learned intermediary.

FDA is not staffed to handle the deluge of patient warnings that Karl would compel, nor is this an efficient use of agency resources that are better directed towards activities that promote the public health.

Similar state tort law regimes that threaten FDA’s efficient function by encouraging companies to inundate FDA with unwanted filings have been deemed preempted by the United State Supreme Court. See Buckman Company v. Plaintiffs’ Legal Committee, 531 U.S. 341 (2001).

Conclusion

Drug manufactures will want to give careful attention to how they respond to the Karl decision’s apparent attempt to use state tort law to mandate direct-to-patient warnings in West Virginia and potentially throughout the country.

One response to the decision that should be considered is offering appropriate preemption arguments that challenge the way in which it conflicts (and other decisions like it would conflict) with federal law.

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The views of the authors do not necessarily reflect the views of their firm, nor should this article be considered legal advice, which depends on the facts of each case.

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