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LEARNED-INTERMEDIARY OPINION SETS BAD POLICY

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Prescription drugs pose risks, which is why they are subject to U.S. Food and Drug Administration regulation, including detailed warning requirements. For the same reason, pharmaceuticals are available only upon prescription from licensed physicians — unlike virtually all other products — so no one can take a prescription drug legally until after consulting with a doctor who has determined that the benefits outweigh the risks for that patient. In this context, courts and legislatures have adopted the learned-intermediary doctrine to govern how drug manufacturers discharge their duty to warn of risks associated with their products.

As the U.S. District Court for the Eastern District of Texas observed in *In Re: Norplant Contraceptive Products Liability Litigation* (2000), the overwhelming majority of jurisdictions, including Texas, have adopted the learned-intermediary doctrine to define a pharmaceutical company's duty to warn.

This doctrine provides an exception to the general rule that imposes a duty on manufacturers to warn consumers about product risks. It excuses drug manufacturers from warning each patient when they properly warn prescribing physicians. The manufacturer's warning obligation extends only to the physician, who acts as a learned intermediary between the manufacturer and the ultimate consumer and who has the responsibility for advising individual patients of the risks associated with the drug.

Texas had good reason to adopt the learned-intermediary doctrine: It is premised on both practical reality and sound public policy. Pharmaceutical manufacturers do and should communicate risk information to expert health-care professionals in scientifically precise and technically accurate terms practitioners are able to understand, as the FDA requires. Those experts then do and should exercise their professional judgment in determining which drugs to prescribe and what risk information to disclose to patients based on each individual's circumstances.

The learned-intermediary doctrine rests on the legal determination that prescribing doctors are best positioned to communicate proper risk information to patients in ways they comprehend. In this way, the doctrine respects the doctor's crucial role as a gatekeeper who determines which, if any, prescription drugs to prescribe and how best to communicate appropriate risk information. In 2000, the 6th

Court of Appeals in Texarkana confirmed these principles in *Wyeth-Ayerst Laboratories v. Medrano*, holding that the learned-intermediary doctrine applies in Texas, even when a physician makes no individualized judgment in prescribing a prescription drug for a particular patient, as long as a physician-patient relationship existed.

On June 27, however, the West Virginia Supreme Court broadly assailed the learned-intermediary doctrine in *West Virginia v. Karl*. Its 3-2 decision categorically rejected the doctrine, relying heavily on two developments: "the proliferation of direct-to-consumer advertising" by drug companies and "the development of the internet as a common method of dispensing and obtaining prescription drug information." The majority also was influenced by the New Jersey Supreme Court's creation of a limited exception to the doctrine in that state for drugs subject to direct-to-consumer advertising. But *Karl* went further, rejecting the doctrine outright.

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According to *Karl*, public policy requires manufacturers to ensure that they convey all risk information associated with any prescription drugs directly to the ultimate users, regardless of whether those manufacturers have adequately informed prescribing doctors.

This rejection of the learned-intermediary doctrine is ill-advised, and the *Karl* court's reasoning does not withstand scrutiny.

That pharmaceutical companies may now engage in direct-to-consumer marketing for some (not all) prescription drugs provides no reason to jettison the learned-intermediary doctrine. Regardless of any advertising, consumers still cannot legally acquire those drugs except upon prescription by doctors. Further, such advertising merely suggests that consumers ask their doctors whether particular pharmaceuticals are right for them, which really just encourages the physician-patient dialogue on which the learned-intermediary doctrine is based. And as the *Karl* dissent noted, the majority's assumption that the presence of pharmaceutical advertising in society relegates the role of physician to a mere dispensary of prescriptions upon request is "simply not true." Frankly, the court's premise is insulting to health-care professionals in West Virginia and across the land.

The suggestion that the development of the Internet undermines the learned-intermediary doctrine is equally dubious. To be sure, the Internet provides a means for direct communication; companies, including pharmaceutical manufacturers, may use the Internet to make information broadly available to those who use it. But the Internet's existence in no way calls into question the legal and normative judgments underlying the learned-intermediary doctrine that, first, risk information about prescription drugs is best provided to patients by doctors in the physician-patient context; and, second, manufacturers discharge their warning obligations by adequately disclosing risk information to physicians in a scientifically accurate manner.

Moreover, *Karl*'s approach, which is ostensibly pro-consumer, may threaten to do consumers more harm than good, by creating incentives for drug manufacturers to engage in the sort of "overwarning" the FDA denounced in 2006 as having a "negative effect on patient safety and public health" when promulgating new labeling rules. In response to *Karl*, drug manufacturers trying to communicate to consumers the highly technical scientific information provided to expert physicians may be influenced to over-simplify and thus overstate drug risk information. That could discourage use of beneficial FDA-approved drugs by those who may need them most.

In short, Texas has it right. The West Virginia Supreme Court's *Karl* decision provides no reason to doubt the continued vitality of the learned-intermediary doctrine. That outlier decision rests on the wrong-headed assumption that physicians are no longer sufficiently learned or intermediate to warrant adherence to this time-honored rule of law. Unless the law is no longer committed to respecting the vital intermediate role of doctors as to drugs available only by prescription, the learned-intermediary doctrine should continue to define a prescription drug company's duty to warn in Texas. TNL

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