Published by *Product Liability Law360* on October 16, 2014. Also ran in *Life Sciences Law360*.

The Learned Intermediary Doctrine: A Historical Review

--By Keri L. Arnold and Sarah C. Duncan, Arnold & Porter LLP

Law360, New York (October 16, 2014, 9:57 AM ET) -- The learned intermediary doctrine is a long-recognized exception for manufacturers of prescription drugs to the general rule that manufacturers have a duty to warn end-users directly about the risks of their products. Specifically, the rule shields prescription drug manufacturers from product liability provided they have adequately warned the prescribing physician as opposed to the patient about the risks inherent in a drug.

The rule is premised on the assumption that a patient can only obtain prescription drugs from a doctor, and that the doctor is in the best position to assess the risks and benefits of a drug for a particular patient based on his intimate knowledge of the patient's medical history. As the Fifth Circuit explained in 1974:

> As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individual medical judgment bottomed on a knowledge of both patient and palliative.[1]

The common law principles underlying the learned intermediary doctrine date back to 1948, when the New York Supreme Court ruled in Marcus v. Specific Pharmaceuticals, 77 N.Y.S.2d 508 (N.Y. Sup. Ct. 1948) that a prescription suppository manufacturer could not be held liable for allegedly failing to warn the patient's parents directly of the drug's risks. The court in Marcus specifically noted that the plaintiff would have stated a legitimate claim "if the product were sold to the public generally as a drug for which no physician's prescription was necessary."

The term learned intermediary was first coined 20 years later in 1966 by the Eighth Circuit in Sterling Drug Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966). Since then, the learned intermediary doctrine has been adopted by the highest courts in 23 different states.[2]

To be sure, as the learned intermediary doctrine became more universally accepted, courts began to recognize a limited number of exceptions, primarily in situations where (at least in theory) a traditional doctor-patient relationship does not exist. Some courts held, for example, that manufacturers of vaccines distributed through mass immunization programs have an affirmative duty to warn recipients directly of potential adverse consequences.[3] A few courts held that manufacturers of contraceptives are not shielded from liability if they fail to provide adequate warnings directly to consumers, because, they rationalize, contraceptives are typically selected by "healthy" consumers who drive the decision to use those products, and prescribing physicians are "relegated to a relatively passive role."[4]

In the last 15 years, however, a small number of courts have expressed a more general resistance to the applicability of the learned intermediary doctrine altogether based on their view that the health care system, including the manner in which medications are prescribed and advertised, has changed so dramatically since the learned intermediary rule was developed that it may no longer be valid.

These concerns were front and center when the New Jersey Supreme Court became the first to more broadly question the learned intermediary doctrine in Perez v. Wyeth Laboratories Inc., 734 A.2d 1245 (1999). In that decision, the court reversed the traditional rulings of both lower courts that the doctrine precluded plaintiffs from pursuing claims for injuries allegedly sustained by implantation of a contraceptive device because the company had failed to warn them directly. In doing so, the court recognized that it was creating a new exception to the doctrine for manufacturers who affirmatively market their products directly to consumers.

The Perez Court began its opinion with a colorful account of the evolution of health care in the U.S., emphasizing that the "Norman Rockwell image of the family doctor no longer exists":

> At an earlier time, medical advice was received in the doctor's office from a physician who most likely made house calls if needed. ... For good or ill, that has all changed. Medical services are in large measure provided by managed care organizations. Medicines are purchased in the pharmacy department of supermarkets and often paid for by third-party providers. Drug manufacturers now directly advertise products to consumers on the radio, television, the Internet, billboards on public transportation and in magazines.

The court then set forth a detailed history of the rise in direct-to-consumer advertising, from the 1980s when the hair-loss treatment Rogaine became the first prescription drug marketed directly to consumers, through the late 1990s when prescription drug companies, even at that time, were spending $1.3 billion per year on advertising for a wide range of prescription medications.

In the new age of DTC advertising, the court explained that "[i]nformed consent requires a patient-based decision rather than the paternalistic approach of the 1970s." And it recognized that the modern system of managed care allows physicians far less time to talk to their patients about the individualized risks of medications. Finally, it noted that given recent expenditures in advertising, manufacturers can no longer credibly claim that they lack sufficient means to communicate with patients.

Thus, while the Perez Court could have invoked the previously recognized exception to the learned intermediary rule for contraceptive devices, it instead adopted a broader exception for manufacturers who engage in DTC advertising, which the court concluded, "belies each of the premises on which the learned intermediary doctrine exists."

In 2007, the West Virginia Supreme Court went much further and declined to adopt the rule altogether. In State ex rel. Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899 (W. Va. 2007), the court held that the manufacturer of Propulsid had the same duty to warn the ultimate consumers of its products as manufacturers of any other "consumer" product. The Karl Court drew heavily from the Perez Court's analysis of the changes in the modern health care system and the rise of DTC advertising, and their impact on the physician-patient relationship. It added that, since Perez, the Internet had become an important method of obtaining prescription drugs and had resulted in a further degradation of the traditional doctor-patient relationship. The Karl Court concluded that the "justifications for the learned intermediary doctrine [are] largely outdated and unpersuasive" and that it would be meaningless to adopt a doctrine that would require the "simultaneous adoption of numerous exceptions in order to be justly utilized."[5]

In 2008, a federal district court in Rimbert v. Eli Lilly and Co., 577 F. Supp. 2d 1174 (D.N.M. 2008), relying on both Perez and Karl, predicted that the New Mexico Supreme Court would not adopt the learned

intermediary doctrine and refused to apply it to a product liability action brought under New Mexico state law. The Rimbert Court reasoned that the doctrine's justification had become "outdated" as a result of both a dramatic increase in DTC marketing and patients' use of the Internet to conduct their own "medical research." The district court specifically described the recent emergence of "Do-It-Yourself Doctors," who research their own symptoms, diagnose their own problems and identify "appropriate" medications as the "biggest trend in American health care."

Not surprisingly, some observers began to question whether Perez, Karl and Rimbert signaled the beginning of the end for the protection pharmaceutical companies have enjoyed under the learned intermediary rule. Yet, despite this uncertainty, other courts have held firm to the view that a prescription drug manufacturer does not have a duty to warn consumers directly of their products' inherent dangers.

For example, in Centocor Inc. v. Hamilton, 372 S.W.3d 140 (Tex. 2012), the Texas Supreme Court issued an opinion in which it rejected the analysis of these prior decisions, expressly adopted for the first time the learned intermediary doctrine and refused to adopt an exception for DTC advertising.

The Centocor Court reasoned that, despite recent changes in the health care system, the following core principles underlying the doctrine still apply: (1) patients still cannot obtain prescription drugs from anyone but a physician and (2) physicians are still "best suited to weigh the patient's individual needs in conjunction with the risks and benefits of the prescription drug." In rejecting the DTC exception, the court focused on both U.S. Food and Drug Administration oversight of advertising and on the particular facts of the case, including that there were no allegations of intentionally misleading statements by the manufacturer and that the DTC advertising at issue was an informational video provided to patients for individual viewing.

Thus, although the Centocor Court left the door open for a limited exception to the learned intermediary doctrine if presented with different facts, its affirmation of the policies underlying the rule establish that in Texas, the learned intermediary doctrine is not in danger of being eliminated anytime soon.

The fact remains that, besides the West Virginia Supreme Court in Karl, not one state court has refused to adopt the learned intermediary doctrine altogether. Nor has the DTC advertising exception been adopted in any other state, or followed by any other court in New Jersey, in the 15 years since the Perez decision was issued. On the contrary, several courts — in addition to Centocor — have expressly refused to apply a DTC advertising exception to expand liability for manufacturers who advertise directly to consumers of their medications.[6]

There is no question that our health care system will continue to evolve in a direction further away from the Rockwellian image fondly remembered by the New Jersey Supreme Court in Perez, and that counsel for plaintiffs will continue to challenge its applicability. Yet, as the Centocor Court correctly recognized, the policies underlying the learned intermediary doctrine do not rest on that outdated image, but on broad principles that remain in force today. The learned intermediary doctrine thus remains a mainstay of protection against product liability for prescription drug manufacturers.

[1] Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir. 1974).
[2] State ex rel. Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899, 903-904 & n.6 (W. Va. 2007); Centocor Inc. v. Hamilton, 372 S.W.3d 140 (Tex. 2012).
[3] See, e.g., Davis v. Wyeth Labs. Inc., 399 F.2d 121, 130-31 (9th Cir. 1968); Mazur v. Merck & Co., 964 F.2d 1348, 1364 (3d Cir. 1992).
[4] MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 69 (Mass. 1985); see also Hill v. Searle Labs., 884 F.2d 1064 (8th Cir. 1989); Stephens v. G.D. Searle & Co., 602 F. Supp. 379 (E.D. Mich. 1985). But see, e.g., Terhune v. A.H. Robins Co., 577 P.2d 975, 978-79 (Wash. 1978); Hanhan v. Johnson & Johnson, No. 1:11 oe 40007, 2013 WL 5939720, at *3 (N.D. Ohio Nov. 5, 2013).
[5] Notably, a few years later in White v. Wyeth, 705 S.E.2d 828, 838 (W. Va. 2010), the West Virginia Supreme Court held that consumers could not bring statutory consumer fraud claims arising from prescription pharmaceutical products, in part, because, "[T]he intervention by a physician in the decisionmaking process necessitated by his or her exercise of judgment whether or not to prescribe a particular medication[,] protects consumers in ways respecting efficacy that are lacking in advertising campaigns for other products."
[6] See, e.g., Allgood v. GlaxoSmithKline PLC, No. 06-3506, 2008 WL 483574, at *3-4 (E.D. La. 2008); Porter v. Eli Lilly and Co., No. 1:06-CV-1297-JOF, 2008 WL 544739, *8-9 (N.D. Ga. 2008); Beale v. Biomet Inc., 492 F. Supp. 2d 1360, 1376-77 (S.D. Fla. 2007); Cowley v. Abbott Labs. Inc., 476 F. Supp. 2d 1053, 1060 n.4 (W.D. Wis. 2007); In re Meridia Prods. Liab. Litig., 328 F. Supp. 2d 791, 812 n.19 (N.D. Ohio 2004).

Keri Arnold is a partner in Arnold & Porter's New York office.

Sarah Duncan is an associate in Arnold & Porter's Washington, D.C. office.