Modern Realities Render the Learned Intermediary Doctrine Obsolete

By Janet Gilligan Abaray and Erica Kern

Manufacturers typically have a duty to warn consumers about the risks associated with their products. In the area of pharmaceutical manufacturing, however, the learned intermediary doctrine provides an exception to that general rule. The doctrine eliminates pharmaceutical manufacturers' duty to consumers by requiring that they only warn physicians about the risks associated with their products. The doctrine presumes that physicians are in the best place to weigh the risks and benefits of a drug in deciding whether to prescribe it to a particular patient. In addition, courts historically have presumed that patients relied exclusively upon their doctors to make medical decisions for them. Although this doctrine may have been justified at one time, its rationale is now outdated. In the modern world, consumers are informed and active participants in their health care decisions; drug companies advertise directly to consumers; and decision making by doctors is constrained by insurance companies and influenced by advertising. In short, the learned intermediary doctrine is a myth that harms consumers.

Direct-to-Consumer Advertising

Courts generally have reasoned that drug manufacturers lack effective means to communicate directly with patients and therefore are justified in providing warnings only to physicians and not patients.[1] This justification for the learned intermediary doctrine may have been valid at one time, but it is no longer applicable. Pharmaceutical companies spend over $4 billion annually on direct-to-consumer advertising.[2] Consumers are inundated with ads on radio, television, the Internet, billboards, and public transportation, as well as in magazines.[3] Further, warnings can be placed on manufacturers' Internet websites, pharmacy printouts, or package inserts and labels.[4] Accordingly, one court has recognized that because manufacturers now have effective means to communicate with patients, they—at a very minimum—have a duty not to misinform or mislead consumers about potential risks of their products: "It is one thing not to inform a patient about the potential side effects of a product; it is another thing to misinform the patient by deliberately withholding potential side effects while marketing the product as an efficacious solution to a serious health problem."[5]

Slowly, courts are beginning to realize that direct-to-consumer advertising has transformed patients back into ordinary consumers.[6] And if patients are ordinary consumers, the original premise for the learned intermediary doctrine is undermined. Thus, the traditional manufacturers' duty to warn consumers should be restored to the area of pharmaceutical products.

Insurance Companies and Drug Formularies

Another often cited justification for the learned intermediary doctrine is that physicians exercise their professional judgment in selecting appropriate prescription drugs; thus, they are in the best position to provide appropriate warnings to patients.[7] Several developments have, however, driven a wedge between patient and doctor when it comes to prescription selection.

Drug selection is no longer determined solely by doctors. Rather, insurance companies, pharmacists, and the government all have a say in which drugs patients ultimately receive. Insurers now have formularies that list drugs that they will pay for and those that they will not. In addition, government formularies list generic drugs that pharmacists can freely substitute for those actually prescribed by a physician. Patients are receiving drugs at the pharmacy that may not be the best choice for treating their condition; rather, the drugs may be the only ones the doctor is permitted to prescribe. The irrebuttable presumption underlying the learned intermediary doctrine—that the doctor knows best and acts in the patient's best interest, weighing the benefits and risks of the drug prescribed—is nostalgic but inaccurate. In many cases, insurance plans control and limit the decisions of prescribing physicians.

In addition, even when patients do receive the drug ordered by their physician, a recent Food and Drug Administration study showed that only one-third of patients actually receive information from their physicians about the dangerous side effects of drugs they are prescribed.[8]

The learned intermediary doctrine was adopted to facilitate informed decision making about pharmaceutical products, not to undermine it. If patients are not getting essential risk information from their physicians or pharmacists, which is generally becoming the norm, the traditional manufacturers' duty to warn consumers should be restored. No one has ever advocated that patients should receive no warnings. Nevertheless, that is the exact effect of the continued application of the learned intermediary doctrine.

Mass Media and the Internet

Another rationale for this doctrine is that patients rely on their treating physician in selecting appropriate medications.[9] This justification is, however, severely undermined by the sheer amount of money that pharmaceutical companies spend on direct-to-consumer advertising. Surely pharmaceutical manufacturers would not be spending over $4 billion annually on direct advertising if patients

were not active participants in the drug selection process.[10]

The learned intermediary doctrine is based on the outdated, Norman Rockwell–style image of the family doctor who makes house calls.[11] The mass media, specifically the Internet, has drastically changed the way patients obtain health information. With direct-to-consumer advertising and the inception of websites like WebMD and Yahoo! Health, patients now come to the doctor self-diagnosed and with a certain prescription in mind. Physicians feel increased pressure to cede to patient drug requests or face losing patients to another doctor who will prescribe the requested drug.[12] Courts need to recognize that the doctor-patient dynamic has irrevocably changed. And this "changed landscape makes the justifications other courts have used for the learned-intermediary doctrine outdated and unpersuasive."[13]

Exceptions to the Exception

The learned intermediary doctrine is itself an exception to the traditional duty of a manufacturer to warn. Not surprisingly, courts began to construct exceptions to the doctrine shortly after it was created. Today, the litany of exceptions include vaccinations, oral contraceptives, contraceptive devices, drugs directly marketed to consumers, and drugs withdrawn from the market.

In the area of oral contraceptives, an affirmative duty to warn consumers is federally mandated. The United States Code of Federal Regulations states that "[t]he safe and effective use of oral contraceptive drug products requires that patients be fully informed of the benefits and the risks involved in their use."[14] These regulations also require that a patient package insert be dispensed to the patient directly in addition to any warnings given by a learned intermediary.[15]

The Court of Appeals for the Ninth Circuit Court of Appeals in *Davis v. Wyeth Laboratories, Inc.*, held in 1968 that manufacturers of the polio vaccination had a duty to warn patients directly of the fatal risks associated with vaccination.[16] The court reached this conclusion because the vaccine was being given with little or no physician supervision in mass immunizations clinics.[17]

In *Perez v. Wyeth Laboratories, Inc.*, the New Jersey Supreme Court recognized in 1999 that the "Norman Rockwell" image of health care was outdated and held that the learned intermediary doctrine was inapplicable to drugs directly marketed to consumers.[18] The court gave several reasons for its decision. First, the court noted, informed consent requires a patient-based decision rather than the paternalistic approach of a bygone era. Second, many of the drugs marketed directly to consumers

Modern realities have rendered the learned intermediary doctrine obsolete because its application allows pharmaceutical manufacturers to escape their traditional duty to warn at the expense of consumer health and well-being.

are lifestyle drugs that are not medically necessary, and so it is not the physician weighing the risks and benefits but the patient. Third, managed care has decreased the time allotted per patient, and physicians often are not even dispensing the risk information to patients. Finally, drug manufacturers are already spending billions on advertising to consumers, so it is clear they have effective means of communicating with consumers.

In 1989, the Eighth Circuit then expanded this exception to contraceptive devices in *Hill v. Searle Laboratories*.[19] The court concluded that it is the patient who decides whether to use a contraceptive device and her choice is usually based on effectiveness, convenience, or cost, rather than medical necessity. Moreover, the physician has little direct contact with the patient after the initial visit. Thus, the physician is not acting as an intermediary using his individualized medical judgment, and so the reasons for the learned intermediary doctrine do not apply.

The last recognized exception is for drugs withdrawn from the market.[20] In *Nichols v. McNeilab, Inc.*, the court held that the learned intermediary doctrine is inapplicable to drugs withdrawn from the market because, while a patient needs a physician to obtain a prescription, a physician is not necessary to *continue* taking a prescription drug that has been withdrawn from the market. The *Nichols* court cited numerous examples of when warnings about withdrawn drugs are supplied only to physicians and would not reach the ultimate consumer. The court concluded that manufacturers, and not physicians, are in the best place to provide warnings to consumers when drugs are withdrawn from the market.

Too Many Exceptions Lead to Rejection

Recently, several courts have refused to adopt the learned intermediary doctrine in its entirety. In 2007, in *State ex rel. Johnson & Johnson v. Karl*, the West Virginia Supreme Court of Appeals considered the myriad of jurisdictions that have developed exceptions to the doctrine to address its shortcomings.[21] The court noted that the justifications other courts have given for adoption of the doctrine are "largely outdated and unpersuasive." If manufacturers were already providing warnings to consumers under the numerous exceptions to the doctrine, "then they should experience no substantial impediment to providing adequate warnings to consumers in general." Because drug manufacturers spend billions of dollars on direct-to-consumer advertisements that praise the beneficial effects of a drug, the *Karl* court reasoned that it is fair to impose a duty on them to educate consumers about the risks of their products. In refusing to adopt the

Origins of the Doctrine

In 1925, the Court of Appeals for the Eighth Circuit was the first court to suggest that, in the case of prescription drugs, a manufacturer's duty to the ultimate consumer might be limited.[i] Then, in 1948, a New York state court became the first court to conclude that a manufacturer's duty to warn was satisfied by simply providing warnings to prescribing physicians.[ii] In adopting this doctrine, courts found it significant that manufacturers made no representations directly to patients.[iii] However, this underlying premise comes into question in today's world of direct-to-consumer advertising and mass media.

Endnotes

i. Hruska v. Parke, Davis & Co., 6 F.2d 536 (8th Cir. 1925).

ii. Marcus v. Specific Pharms., Inc., 77 N.Y.S.2d 508, 509 (N.Y. Sup. Ct. 1948).

iii. *Id.* at 509.

doctrine, the court noted that "[g]iven the plethora of exceptions to the learned intermediary doctrine, we ascertain no benefit in adopting a doctrine that would require the simultaneous adoption of numerous exceptions in order to be justly utilized."[22]

Similarly, in *Rimbert v. Eli Lilly & Co.*, the New Mexico District Court declined to adopt the learned intermediary doctrine. The district court reasoned that the New Mexico Supreme Court would likely not adopt the doctrine "given the changing dynamics between doctors and patients, patients' self-diagnosis, and DTC [direct-to-consumer] advertising by drug manufacturers."[23] Citing both the *Perez* and *Karl* opinions, the court recognized that the "changed landscape" of health care has made the doctrine obsolete. Dismissing the oft-cited justification that consumer warnings would destroy the doctor-patient relationship, the *Rimbert* court reasoned that informed patients would actually help (not hinder) a physician's exercise of professional judgment.

Conclusion

The learned intermediary doctrine is "itself an exception to the manufacturer's traditional duty to warn consumers directly of the risks associated with any product."[24] Courts now have developed multiple exceptions to the exception, creating a confusing and at times inconsistent legal framework.[25] Modern realities have rendered the learned intermediary doctrine obsolete because its application allows pharmaceutical manufacturers to escape their traditional duty to warn at the expense of consumer health and well-being. ■

Janet Gilligan Abaray acts as managing shareholder for the Cincinnati office of Burg Simpson Eldredge Hersh & Jardine, P.C. Since 1987, she has represented plaintiffs in many over-the-counter and prescription drug cases, including the L-Tryptophan Multidistrict Litigation and the Copley Albuterol class action litigation.

Erica Kern is an associate in the firm's Cincinnati office. She has worked on the multidistrict litigations involving Ortho Evra and contaminated Heparin.

Endnotes

1. Perez v. Wyeth Labs., Inc., 734 A.2d 1245, 1255–56 (N.J. 1999), *overruled on other grounds*, Knipe v. Smithkline Beecham, 583 F. Supp. 2d 602, 630 (E.D. Pa. 2008).
2. Julie M. Donohue et al., *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 N. Eng. J. Med. 673–81 (2007).
3. *Perez*, 734 A.2d at 1252.
4. State *ex rel.* Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899, 920 (W. Va. 2007).
5. *Perez*, 734 A.2d at 1257.
6. Patrick Cohoon, *An Answer to the Question Why the Time Has Come to Abrogate the Learned Intermediary Rule in the Case of Direct-to-Consumer Advertising of Prescription Drugs*, 42 S. Tex. L. Rev. 1333, 1350 (Fall 2001).
7. *Karl*, 647 S.E.2d at 905.
8. Cohoon, *supra* note 9, at 1355.
9. *Karl*, 647 S.E.2d at 905.
10. *Perez*, 734 A.2d at 1256.
11. *Karl*, 647 S.E.2d at 908; *Perez*, 734 A.2d at 1246–47, 1255.
12. *Perez*, 734 A.2d at 1260.
13. Rimbert v. Eli Lilly & Co., 577 F. Supp. 2d 1174, 1218 (D.N.M. 2008).
14. 21 C.F.R. § 310.501.
15. The Code of Federal Regulations has also recognized the affirmative duty of manufacturers to warn consumers directly of drug products containing estrogen. 21 C.F.R. § 310.515. In the area of direct-to-consumer marketing of prescription drugs, 21 C.F.R. § 202.1 lays out extensive regulations for advertisement of prescription drugs. The regulation mandates a fair balance between efficacy information and side effects and contraindications. 21 C.F.R. § 202.1(e)(5).
16. Davis v. Wyeth Labs., Inc., 399 F.2d 121, 130–31 (9th Cir. 1968).
17. *Id.* at 131.
18. Perez v. Wyeth Labs., Inc., 734 A.2d 1245, 1255–56 (N.J. 1999).
19. Hill v. Searle Labs., 884 F.2d 1064 (8th Cir. 1989).
20. Nichols v. McNeilab, Inc., 850 F. Supp. 562 (E.D. Mich. 1993).
21. State *ex rel.* Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899, 911 (W. Va. 2007).
22. *Id.* at 913.
23. Rimbert v. Eli Lilly & Co., 577 F. Supp. 2d 1174, 1222 (D.N.M. 2008).
24. Edwards v. Basel Pharms., 116 F.3d 1341, 1343 (10th Cir. 1997).
25. *Karl*, 647 S.E.2d at 911.