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Drug Advertising and the Learned Intermediary Doctrine

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The Implications of Prescription Drug Advertising and Promotion on the Learned Intermediary Doctrine

Introduction

Under US product liability law, a manufacturer generally has a duty to warn consumers directly of all reasonably foreseeable risks. This obligation makes sense when the consumer himself weighs the risks and benefits of a product. Prescription drugs, however, pose a unique situation. Because federal law provides that prescription drugs are only available through a licensed physician, it is the physician - not the consumer - that weighs the risks and benefits of a particular drug. As a result, almost every jurisdiction has adopted the learned intermediary doctrine which provides that a prescription drug manufacturer discharges its duty by adequately warning the prescribing physician; the manufacturer has no duty to warn the patient directly. However, the extensive use of direct-to-consumer advertising (DTC) by prescription drug manufacturers may limit the uniform application of this important doctrine in prescription drug cases. To date, only one court has held that the learned intermediary doctrine does not apply to products that have been marketed directly to consumers. *See Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245 (N.J. 1999).

This chapter discusses the relationship between the learned intermediary doctrine and DTC advertising, including:

- The history and rationale of the learned intermediary doctrine.
- Exceptions to the learned intermediary doctrine.
- The prevalence of DTC prescription drug advertising.
- FDA regulation of prescription drug advertising.
- The New Jersey Supreme Court's holding in *Perez v. Wyeth* and its potential impact on the defence of pharmaceutical manufacturers.

Learned Intermediary Doctrine

History

The roots of the learned intermediary doctrine reach back to 1948 when a New York court recognised the distinction in product liability between a product sold directly to the public and one for which a physician's prescription was necessary. *Marcus v. Specific Pharmaceuticals, Inc.*, 77 N.Y.S.2d 508, 509 (N.Y. Sup. Ct. 1948).

The phrase "learned intermediary" first appeared in *Sterling Drug, Inc. v. Cornish*, a 1966 opinion issued by the U.S. Court of Appeals for the Eighth Circuit. 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. If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided.*" *Id.* Now, more than 40 years later, virtually every state has adopted the doctrine.

Rationale

Justification for the learned intermediary doctrine is generally based on the fact that consumers cannot buy prescription drugs without an order from a physician. Courts have identified four factors that support the application of the learned intermediary doctrine. *See, e.g.*, Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 Ga. L. Rev. 141, 157-159 (1997).

The Nature of the Physician-Patient Relationship

"The physician-patient relationship is a fiduciary one based on trust and confidence and obligating the physician to exercise good faith. As part of this relationship, both parties envision that the patient will rely on the judgment and expertise of the physician." *Tracy v. Merrell Dow Pharms., Inc.*, 569 N.E.2d 875, 879 (Ohio 1991) (citation omitted). Requiring a manufacturer to warn a consumer directly would undercut the very nature of this relationship.

Doctors are Able to Filter Information

Providing warnings directly to consumers could be counter-productive. Patients presented with all the possible risk information may overreact and hesitate to pursue the proper treatment. Physicians are an essential filter; they are able to sift through manufacturer warnings and present a patient with information tailored to his particular need. *See* Richard C. Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability For Prescription Drug Manufacturers?*, 37 Wake Forest L. Rev. 97, 109 (2002).

Ability to Reach Consumers

Providing warning information through physicians is efficient.

Prescription drugs are often sold to pharmacies in bulk and then repackaged for individual sale. Manufacturers do not have any contact with and are unable to reach the ultimate consumers. Physicians, on the other hand, are in the ideal position to discuss such information with their patients. *See Ausness*, supra, at 109-110.

Complexity

Consumers simply are not educated to understand the intricacies of prescription medications. "Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. 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 individualised medical judgment bottomed on a knowledge of both patient and palliative." *Reyes v. Wyeth Labs*., 498 F.2d 1264, 1276 (5th Cir. 1974).

Exceptions

In 1997, the Restatement (Third) of Torts: Product Liability adopted the learned intermediary doctrine. *See* § 6(d). The Restatement also incorporates a long-recognised exception to the doctrine. Section 6(d)(2) states that a manufacturer should provide warnings directly to patients "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." *Id*. Under this theory, some courts have declined to apply the learned intermediary doctrine to mass immunisation programmes due to the lack of physician-patient contact. *See* e.g., *Petty v. United States*, 740 F.2d 1428, 1440 (8th Cir. 1984). Certain birth control devices and oral contraceptive medications have also been excluded from the learned intermediary doctrine because patients actively participate in contraceptive decision making. *See, e.g., Odgers v. Ortho Pharm. Corp.*, 609 F. Supp. 867, 878 (E.D. Mich. 1985).

The drafters of the Third Restatement originally included an additional exception for prescription drugs advertised directly to consumers. Under the proposed exception, a prescription drug manufacturer would not be shielded from failure to warn claims when that manufacturer reached out to consumers through marketing and promotion. This exception was **not** included in the final draft of the Third Restatement. Instead, the drafters left the issue to "developing case law." *See* § 6(d) cmt.e. The New Jersey Supreme Court, citing the Third Restatement comment e, did adopt a DTC advertising exception in *Perez v. Wyeth Labs., Inc.* Before discussing *Perez* and its potential impact, it is important to understand the prevalence of DTC advertising for prescription drugs and the Food & Drug Administration's (FDA) regulation of such advertisements.

Prescription Drug Advertising

The Surge of DTC Prescription Drug Advertising

Before 1980, advertising prescription drugs to health care professionals was commonplace; advertising prescription drugs directly to consumers, on the other hand, was not done. In 1981, Boots Pharmaceuticals issued the first DTC advertisement, a price ad for its ibuprofen product, Rufen. *See* Wayne L. Pines, *A History and Perspective on Direct-to-Consumer Promotion*, 54 Food & Drug L.J. 489, 491 (1999). Merck Sharp & Dohme followed with a DTC advertisement for Pneumovax®, a pneumonia vaccine. *Id*.

In September of 1982, the FDA issued a voluntary moratorium on all DTC advertisements while it worked out its position on the issue. *Id*. at 492. Finally in 1985, after much debate, the FDA issued a notice allowing DTC advertisements, but stating that such advertisements must meet the same requirements as those aimed at health care professionals.

Under FDA requirements, advertisements focusing on the effectiveness or indication of a product were required to have a "brief summary" of all risk-related information. To satisfy this requirement, print advertisements would include the entire risk-related portion of the product label. This "brief summary" requirement made it extremely difficult to use broadcast media to disseminate advertisements on effectiveness or indication. As a result, manufacturers began to target consumers with two types of broadcast advertisements in particular, help-seeking advertisements and reminder advertisements. Help-seeking advertisements encourage consumers with a particular condition to see a doctor without mentioning a product name. Conversely, reminder advertisements do mention the product name, but do not include any information as to the condition the drug is intended to treat. By 1989, manufacturers were spending approximately $12 million per year on DTC advertising. *See id*. at 493.

While DTC advertising increased steadily throughout the early-to-mid 1990s, it boomed in 1997 when the FDA issued its "Draft Guidance for Industry: Consumer Directed Broadcast Advertisements." This draft guidance provided an avenue for manufacturers to efficiently advertise their products through radio and television. In 1997 alone, manufacturers spent $843 million on DTC advertising. *See* Yonni D. Fushman, *Perez v. Wyeth Labs., Inc.: Toward Creating a Direct-To-Consumer Advertisement Exception to the Learned Intermediary Doctrine*, 80 B.U. L. Rev. 1161, fn.60 (2000).

By 2001, pharmaceutical manufactures were spending more than $2.5 billion annually on DTC advertising. *See* Gerald D. Jowers, Jr., *Drug Advertising and Accountability*, Trial, July 2003, at 68. The fact that DTC advertising generates sales does not mean that the role of a physician as learned intermediary has changed. Instead, it indicates that more people are consulting physicians regarding conditions that often fall beneath the radar. "*[DTC] advertising that encourages millions of Americans to consult their physicians can help to improve public health because a number of leading diseases are under-diagnosed or under-treated.*" Alan F. Holmer, Direct-To-Consumer Prescription Drug Advertising Builds Bridges Between Patients and Physicians, JAMA 380 (Jan. 27, 1999).

FDA Regulation of Prescription Drug Advertising

Since 1963, prescription drug advertising has been regulated by the FDA. The specific requirements for prescription drug advertisements can be found in the Federal Food, Drug, and Cosmetic Act (FDCA) and accompanying FDA regulations. The FDCA sets out the broad requirements while the FDA regulations add depth to these general rules.

All prescription drug advertisements must include the established name of the drug, the ingredients, and a brief summary of side effects, contraindications, and effectiveness. 21 U.S.C. 352(n). Additionally, FDA regulations mandate that prescription drug advertisements shall not be false or misleading and must present a balance between the effectiveness of a drug and its risks. *See* 21 C.F.R. § 202.1.

DTC advertisements fall into two categories, print advertisements

and broadcast advertisements. Print advertisements include "advertisements in published journals, magazines, other periodicals, and newspapers . . . ." Broadcast advertisements include "advertisements broadcast through media such as radio, television, and telephone communication systems." 21 C.F.R. § 202.1(l)(1). The methods for satisfying the above FDA requirements differ for each type of advertisement.

Print Advertisements

As stated above, FDCA and FDA regulations require that all prescription drug advertisements discussing the effectiveness or indications of the drug must include a brief summary of side effects, contraindications, and effectiveness (known as the "brief summary" requirement). *See* 21 U.S.C. § 352(n); 21 C.F.R. § 202.1(e). This brief statement must include all risk information contained in the approved labeling, including all side effects, contraindications, warnings, precautions, and adverse reactions. *See* 21 C.F.R. § 202.1(e)(3)(iii).

To satisfy the brief summary requirement in print advertisements, manufacturers will usually reprint the relevant sections of the package insert. The package insert is directed at health care providers and may be difficult for consumers to understand. As a result, the FDA has issued a Draft Guidance indicating that it does not intend to object to the use of FDA-approved patient labeling containing consumer-friendly language on contraindications, warnings, major precautions, and frequently occurring side effects. See Draft Guidance, Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisement, January 2004. Additionally, the FDA has proposed an amendment to its regulations that would require FDA-approved professional labeling to contain a section entitled Highlights of Prescribing Information ("Highlights"). The FDA's Draft Guidance also indicates that the FDA does not intend to object to the use of the information that would appear in the Highlights section to satisfy the brief summary requirement. *See id.*

Reminder advertisements and help-seeking advertisements are not subject to the brief summary requirement because they do not discuss the effectiveness or indications of the drug. *See* 21 C.F.R. § 202.1(e).

Broadcast Advertisements

Broadcast advertisements have limitations that print advertisements do not. Namely, broadcast advertisements are short in duration and unable to present the same volume of information as a print advertisement. As a result, broadcast advertisements have different requirements. First, a broadcast advertisement must include a statement of the most important risk information (known as the "major statement" requirement). Second, a broadcast advertisement must either include a brief summary, as with a print advertisement, or make "adequate provision . . . for the dissemination of the approved or permitted package labeling in connection with the broadcast presentation" (known as the "adequate provision" requirement). 21 C.F.R. § 202.1(e)(1). In its Guidance Document, the FDA indicated that a manufacturer can satisfy the adequate provision requirement by:

- providing a toll-free phone number for consumers to call for the approved labeling;
- referencing a printed advertisement or brochure that can be accessed with limited technology;
- providing reference to an internet website that contains the requisite labeling; and
- advising consumers to ask doctors or pharmacists for more information.

See Guidance for Industry, Consumer-Directed Broadcast Advertisements, August 1999.

Perez v. Wyeth Labs Inc.

Background

Perez v. Wyeth Labs., Inc., 734 A.2d 1245 (N.J. 1999), involved the Norplant System (Norplant), a contraceptive implant placed under a woman's skin. The implant consists of six closed capsules containing the synthetic hormone levonorgestrel. This hormone is continually diffused into the woman's blood stream, preventing pregnancy for up to five years.

Beginning in 1995, numerous New Jersey plaintiffs filed suits against Wyeth claiming that Norplant had caused a variety of injuries. As part of their claim, plaintiffs alleged that Wyeth failed to adequately warn of the side effects associated with Norplant. In support, plaintiffs cited Wyeth's large Norplant advertising campaign aimed at consumers.

All New Jersey Norplant cases were eventually consolidated in Middlesex County. Wyeth then filed a motion for summary judgment based on the learned intermediary doctrine. Following a case management conference, five bellwether plaintiffs were selected to challenge Wyeth's motion.

The trial court granted Wyeth's motion for summary judgment, holding that the learned intermediary doctrine applied. The trial court reasoned that "*a physician is not simply relegated to the role of prescribing the drug according to the woman's wishes," and accordingly, "the physician retains the duty to weigh the benefits and risks associated with a drug before deciding whether the drug is appropriate for the patient.*" *Id.* at 1249. The Appellate Division affirmed the trial court's holding. The New Jersey Supreme Court granted plaintiff's petition for certification and reversed the judgment of the Appellate Division.

Holdings

The New Jersey Supreme Court opinion had three key holdings: (1) the learned intermediary doctrine did not apply to prescription drugs advertised directly to consumers; (2) if a DTC advertisement satisfies FDA requirements, the manufacturer is entitled to a rebuttable presumption that it satisfied its duty to warn; and (3) the role physicians play in prescribing drugs does not necessarily break the causal chain.

DTC Advertising Exception

After analysing the rationale behind the learned intermediary doctrine, the court found that these justifications simply did not exist in the DTC advertising context. The court focused on three factors: patients play a more active role in medical decision making than ever before; managed care had reduced the amount of time physicians spend with patients; and the large amounts of money spent on DTC advertising was proof that manufacturers could effectively reach patients. Ultimately, the court concluded that, "*[w]hen all of its premises are absent . . . the learned intermediary doctrine, 'itself an exception to the manufacturer's traditional duty to warn consumers directly of the risk associated with any product, simply drops out of the calculus, leaving the duty of the*

manufacturer to be determined in accordance with general principles of tort law." *Id.* at 1256 (citations omitted).

Rebuttable Presumption

The New Jersey Supreme Court did provide prescription drug manufacturers some hope. The court held that when a manufacturer complies with FDA regulations concerning prescription drug advertisements, there should be a rebuttable presumption that the manufacturer satisfied its duty to warn patients directly. The court stated: "*For all practical purposes, absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be dispositive of [failure to warn] claims.*" *Id.* at 1259.

Proximate Cause

Wyeth argued that the chain of causation is broken when the physician writes the prescription. The court rejected this argument, holding that the physician's prescription decision is altered when a patient enters the physician's office with a preconceived notion of what treatment they want. Id. at 1260. On policy grounds, the court decided not to insulate manufacturers simply because the physician may have given a better warning. Id. at 1261. Manufacturers were still left with the option of seeking contribution or indemnity from the physician. Id. at 1263.

The Impact of *Perez*

The threat posed by the decision in *Perez* has been just that - a threat. Since *Perez*, no court in any jurisdiction has created a DTC advertising exception to the learned intermediary doctrine. *Perez*, however, has still had an effect on courts outside of New Jersey.

In re Norplant Contraceptive Products Liability Litigation, 215 F. Supp. 2d 795 (E.D. Tex. 2002), was a federal court multidistrict litigation (MDL) also involving Norplant. Wyeth moved for summary judgment in the MDL, arguing that the learned intermediary doctrine barred recovery. Id. at 803. The MDL court handled *Perez* thusly:

"*New Jersey's advertising exception renders the learned intermediary doctrine wholly inapplicable to Norplant cases in this multidistrict litigation, but only to the extent that this court is required to follow the substantive law of New Jersey in deciding the instant motion. This means that New Jersey law is in direct conflict with the law of every other jurisdiction in the United States. Because the court must determine which jurisdiction's law to apply by looking at each individual case in this litigation, the court will examine pending cases that have a factual nexus to New Jersey and perform a choice of law analysis, if necessary.*" *Id.* at 812. Ultimately, the MDL court held that the DTC advertising exception to the learned intermediary doctrine applied to plaintiffs who had Norplant implanted in New Jersey. *Id.* at 819-21. The MDL court, however, declined to apply the exception to plaintiffs who filed in New Jersey, but who had Norplant implanted in another jurisdiction. *Id.* at 817-18.

The MDL Court in the *In re Meridia Products Liability Litigation* declined to apply Perez to any of the plaintiffs, including those with a nexus to New Jersey. 328 F. Supp. 2d 791, 812 n.19 (N.D. Ohio 2004), *aff'd*, 447 F.3d 861 (6th Cir. 2006). The court stated:

"*Plaintiffs encourage this Court to apply the Perez court's reasoning to all plaintiffs' claims. Although the Perez opinion is certainly well-reasoned, plaintiffs' argument poses a major federalism problem. This Court is a federal court with jurisdiction over plaintiffs' claims based on diversity of citizenship. As such, it must apply the law of each state, or where a state's law is silent on a particular issue, its prediction of what that state's supreme court would hold. Five years have passed since the New Jersey Supreme Court decided Perez. In the intervening period, no other state has followed New Jersey's lead. The Court thus could not apply Perez's logic even if it desired to do so.*

Plaintiffs further argue, that at a minimum, the New Jersey cases should survive summary judgment based on Perez. This argument sounds persuasive until one finishes reading Perez. The Supreme Court of New Jersey held that compliance with FDA rules and regulations creates a rebuttable presumption that the manufacturer fulfilled its duty to adequately warn consumers . . . . Plaintiffs have provided no reason to believe that defendants violated the FDA's rules and regulations. Therefore, even applying Perez gets the Plaintiffs nowhere." *Id.*

Conclusion

While no other jurisdiction has followed the lead of *Perez*, manufacturers must be aware of the potential impact of DTC advertising on the learned intermediary doctrine. On the one hand, the learned intermediary doctrine is a critical defense; it provides stability for pharmaceutical manufacturers and respects the nature of the patient-physician relationship. On the other hand, DTC advertising has proven to be a valuable and effective tool to inform consumers of treatment options. Moving forward, pharmaceutical manufacturers must balance the benefits of increased DTC advertising with the potential risk that other jurisdictions will decide that such advertising justifies an exception to the learned intermediary doctrine.

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Harvey is regarded as one of the nation's top trial lawyers. According to *Chambers USA*, "…he is described by grateful beneficiaries of his expertise as 'one of the premier pharmaceutical lawyers in the country;'" and he was 1 of 7 US lawyers nominated by *Chambers* for its 2007 Award of Excellence in product liability litigation. In naming him one of the 500 leading litigators in America, Lawdragon said: "For the makers of drugs and implants, he's the antidote to product liability claims." *The Legal 500 US* described him as follows: "Kaplan is deemed 'a trial lawyer foremost and a master strategist.'" He was recognised as one of the most highly regarded lawyers globally by *The International Who's Who of Business Lawyers* where he was described as "… an 'eminent practitioner with international experience and standing' and an expert in the pharmaceutical field." And Harvey was selected by *Missouri & Kansas Super Lawyers* as one of the top ten lawyers in both states.

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