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DIRECT ADVERTISING OF PRESCRIPTION DRUGS: THE DUTY TO WARN AND THE LEARNED INTERMEDIARY RULE

*Jack E. Karns**

INTRODUCTION

The most recent development in pharmaceutical marketing strategy, is that of direct advertising of prescription drugs, such as the television advertisements for Viagra and periodical ads for Propecia.¹ These ads openly encourage viewers to consult their physicians about prescribing a particular drug.² One manufacturer has gone so far as to use celebrities in the direct advertising of a particular drug.³ This new

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¹Bob Van Voris, *Drug Ads Could Spell Legal Trouble*, NAT'L L.J., July 21, 1997, at B1. (“[L]awyers on both sides of the issue agree that plaintiffs will use the ads to assault the learned intermediary defense”). See *ESQUIRE*, October 1999, at 60-61 (Merck Pharmaceutical advertisement for Propecia – hair loss for men).

²*Perez v. Wyeth Lab., Inc.*, 734 A.2d 1245, 1251 (N.J. 1999) [hereinafter *Perez II*] (quoting an example of direct advertising the Claritin advertisement: “[a] kind voice instructs the viewer to ‘see your doctor about Claritin’”).

³Viagra is just one of many prescription drugs that are now actively advertised through various media outlets. However, Viagra may presently have the most well-known celebrity spokesperson, former Senator Robert Dole. Other recently Food and Drug Administration (hereinafter FDA) approved drugs receiving much attention are Nolvadex (breast cancer), Glucophage (diabetes), Celebrex (arthritis) and Paxil (social anxiety). Drug manufacturers even advertise prescription arthritis medicine, Rimadyl, for dogs. The foregoing prescription ads can be found in *PEOPLE WEEKLY*, Oct. 4, 1999, at 43-44 (Rimadyl), 54-57 (Nolvadex), 83-84 (Glucophage), 98-100 (Celebrex) and 128-130 (Paxil). Another recently FDA approved

direct advertising approach has generated a direct tort action assault on pharmaceutical companies.⁴ Litigation in this area has focused on warnings that are included in media advertisements and prescription packaging purchased by the consumer.⁵

One of the important issues related to direct advertising litigation is the effect this marketing approach will have on the established Learned Intermediary Rule (LIR or the Rule).⁶ The Rule dictates that a manufacturer of a pharmaceutical fulfills its duty to warn about ultimate or possible side effects of a drug if the manufacturer provides accurate drug information to the prescribing physician.⁷ The physician then has a duty to relay all pertinent facts about the drug to the patient.⁸

Notwithstanding this well-established rule, plaintiffs claim that Food and Drug Administration (FDA) regulations do not preempt state tort law.⁹ Plaintiffs have argued state tort claims, which expand a manufacturer's duty to warn, when suing manufacturers.¹⁰ Often, the application of state tort law creates a higher standard to which the manufacturer would be held.¹¹ Some courts have found that FDA regulations do not preempt state tort law.¹² In addition, plaintiffs are now claiming that the LIR should not apply when pharmaceutical manufacturers take their product directly to the consuming public rather than relying on a health care practitioner to provide the information.¹³

drug receiving much attention is Xenical. This medication is aimed at overweight individuals and curbs a person's appetite in order to lose weight. See *Patient Information About XENICAL Capsules* (revised May 1999) <<http://www.rocheusa.com/products/xenical/ppi.html>>.

⁴See *In re Norplant Contraceptive Prod. Liab. Lit.*, 165 F.3d 374, 377, 379 (5th Cir. 1999) [hereinafter *In re Norplant*].

⁵See *id.*

⁶See *In re Norplant*, 165 F.3d at 376. See generally *Martin v. Hacker*, 628 N.E.2d 1308, 1311-12 (N.Y. 1993) (describing the issue on appeal as the "nature and extent of prescription drug manufacturer's obligation to make known the potential hazards of its products"); *Perez II*, 734 A.2d at 1252 ("[the] utilization of direct consumer marketing raises questions and issues addressing manufacturer liability").

⁷See *Edwards v. Basel Pharm.*, 933 P.2d 298, 300 (Okla. 1997).

⁸See *id.*

⁹See *id.* at 301-02.

¹⁰See *id.* at 300.

¹¹See *In re Norplant*, 165 F.3d at 376.

¹²See *Edwards*, 933 P.2d at 302-03.

¹³See *In Re Norplant*, 165 F.3d at 377.

Plaintiffs argue that, by voluntarily and openly choosing to take their product directly to consumers, the manufacturers obviate the protection provided by the LIR.¹⁴ Notably, these are two separate issues that plaintiffs are questioning. First, the preemption of FDA regulations involves whether the manufacturer's warnings were adequate under the federal and state laws.¹⁵ Second, the issue of whether the LIR applies only relates to the question of to "whom the manufacturer warned," not whether the warning was adequate.¹⁶

The purpose of this article is to address the current case law related to both of these issues. The article will review the LIR as it existed prior to the onslaught of direct pharmaceutical advertising and to make some observations concerning the Rule in light of current litigation.¹⁷ Some observations will be made suggesting when pharmaceutical companies directly advertise their product to the consumer they have more to lose than to gain by virtue of circumvention of the LIR.

BACKGROUND

As previously stated, the LIR dictates that any prescription drug manufacturer will have discharged its duty to warn the patient-user about the side effects of a drug simply by supplying physicians with accurate information about these hazards.¹⁸ The manufacturer is obligated to warn of any dangers that it knew or should have known as the result of exercising reasonable care.¹⁹ Manufacturers inform physicians in several ways, but the most common methods are including the warnings in the Physician's Desk Reference (PDR) and the package inserts.²⁰

¹⁴See *id.* at 377 (asserting that the LIR should not apply because Norplant was marketed directly to the end users).

¹⁵See *Hurley v. Lederle Lab. Div. of Am Cyanamid Co.*, 863 F.2d 1173, 1179 (5th Cir. 1988).

¹⁶*Id.* at 1178.

¹⁷See *Perez II*, 734 A.2d at 1246-47 (describing the change in health care and advertising of pharmaceuticals).

¹⁸See *Odgers v. Ortho Pharm. Corp.*, 609 F. Supp. 867, 872-73 (E.D. Mich. 1985).

¹⁹See *Martin v. Hacker*, 628 N.E.2d 1308, 1311 (N.Y. 1993).

²⁰See *id.* at 1311.

Essentially, the Rule has provided a buffer zone for pharmaceutical companies by interjecting prescribing physicians as the “learned intermediary.”²¹ These “learned intermediaries” provide information, which the manufacturer has compiled, to the patient regarding side effects or other important information discovered as a result of research and development projects.²² The prescribing physician is effectively a filtering device. This ensures that consumers obtain the opinion of an independent party—the physician—to help determine whether the drug’s side effects offset the potential gain.²³ The court in *Edwards v. Basel Pharmaceuticals*²⁴ succinctly described the physician’s role as the intermediary. In *Edwards*, the court stated:

Where a product is available only on prescription or through the services of a physician, the physician acts as a “learned intermediary” between the manufacturer or seller and the patient. It is his duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise independent judgment, taking into account his knowledge of the patient as well as the product. The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. The physician decides what facts should be told to the patient...The doctrine extends to prescription drugs because, unlike over the counter medications, the patient may obtain the drug only through a physician’s prescription, and the use of prescription drugs is generally monitored by a physician.²⁵

The physician, based on knowledge about his or her patient, must determine what information should be discussed with the patient.²⁶ Once the physicians make this determination, prescriptions are

²¹See *Edwards*, 933 F.2d at 300.

²²See *Martin*, 628 N.E.2d at 1311-12 (discussing the contents of warnings that manufacturers must provide physicians).

²³*Martin*, 628 N.E.2d at 1311.

²⁴See *Edwards*, 933 F.2d at 298.

²⁵*Edwards*, 933 P.2d at 300-01.

²⁶*Id.*

scrutinized again by a pharmacist prior to filling the order.²⁷ Due to the LIR, the drug manufacturer has the attending physician (and presumably the pharmacist) as a buffer against litigation emanating from potential side effects of prescription drugs.²⁸

The current LIR requires drug manufacturers to provide adequate warnings to physicians and health care providers, not to consumers directly.²⁹ The LIR was created when there were no advertising campaigns directed to the consumer drug user.³⁰ The Rule's legal rationale is based on the premise that the critical task of balancing the benefits and risks of prescription drugs should lie with the prescribing physician.³¹ The physician's role is intended to provoke a meaningful discussion between patient and physician prior to making any decision to prescribe the drug. The courts have substantiated this legal rationale. Courts have found prescribing physicians liable when the drug was properly labeled and the prescribing physician failed to inform a patient regarding a prescription drug's relevant side effects.³² Essentially, the health care professional's duty to warn provides a separate protective shield against liability for the drug manufacturer.³³ However, when the manufacturer breaches the duty to warn the physician, the manufacturer is held directly liable to the patient, not the physician, for a breach of duty.³⁴ These tort cases have typically been framed in the context of the LIR failure to warn language.³⁵

²⁷*Martin*, 628 N.E.2d at 1311-12.

²⁸*Id.* at 1311.

²⁹*See id.*

³⁰*See Perez II*, 734 A.2d at 1247.

³¹*See Martin*, 628 N.E.2d at 1311.

³²*See id.* at 1310-13.

³³*See Krasnopolsky v. Warner-Lambert Co.*, 799 F. Supp 1342, 1346 (E.D.N.Y. 1992) (discussing that a "treating physician's decision not to inform a patient of a side effect acts as an intervening cause which shields the drug manufacturer from any possible liability under a failure to warn theory").

³⁴*McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522, 529 (Or. 1974).

³⁵*See id.*

ANALYSIS

Established Exceptions to the Learned Intermediary Rule

Even before the pharmaceutical companies began to take their products directly to the consuming public via direct advertising, courts were presented with plaintiff arguments in favor of a variety of exceptions to LIR.³⁶ Two of these arguments were held to be valid exceptions to LIR and have been recognized by the courts: 1) mass immunizations and 2) FDA mandated warnings directly to the consumer, not just warnings to the physician.³⁷ The first exception concerns the immunization of patients en masse.³⁸ In these immunization cases, courts have held that the health care provider is not functioning in the same learned intermediary role as during a traditional office visit.³⁹ The courts have simply stated that in the immunization cases, no physician-patient relationship is created and "the drug is not administered as a prescription drug."⁴⁰ Therefore, the role of the physician as learned intermediary does not exist.⁴¹ The courts have held the defendant inoculator is only liable under traditional theories of negligence and strict liability.⁴²

The second exception, however, has not been uniformly agreed upon.⁴³ Plaintiffs have argued that the LIR ought not to apply when the

³⁶See *Edwards v. Basel Pharm.*, 933 P.2d 298, 301-02 (Okla. 1997); *Krasnopolsky*, 799 F. Supp at 1364. For application of the "failure to warn" theory in other industries, see *Hamilton v. Accu-Tek Am. Arms, Inc.*, 935 F. Supp. 130 (E.D.N.Y. 1996) (handguns); *Fane v. Zimmer, Inc.*, 927 F.2d 124, 130 (2d Cir. 1991) (medical devices).

³⁷See *Edwards*, 933 F.2d at 301.

³⁸See *Allison v. Merck & Co., Inc.*, 878 P.2d 948, 959 (Nev. 1994); *Cunningham v. Pfizer & Co., Inc.*, 532 P.2d 1377, 1381 (Okla. 1975); *Brazzell v. United States*, 788 F.2d 1352, 1358 (8th Cir. 1986); *Reyes v. Wyeth Lab*, 498 F.2d 1264, 1275-76 (5th Cir. 1974).

³⁹See *Edwards*, 933 F.2d at 301.

⁴⁰*Id.*

⁴¹*Id.* See *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 68 (Mass. 1985) (stating that the LIR applies only when the "manufacturer's reliance on the intermediary is reasonable").

⁴²See *Reyes*, 498 F.2d at 1269-70.

⁴³See *Edwards*, 933 P.2d at 301. Some courts have refused to adopt this exception to LIR. See *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 401 (Del. 1989); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp 1293, 1305 (D. Minn. 1988); *Goodson v. Searle Laboratories*, 471 F. Supp 546, 546 (D. Conn. 1978).

FDA mandates that pharmaceutical manufacturers provide warnings to the consumer directly about prescription drugs and their side effects.⁴⁴ The FDA has an important role in the distribution of prescription drugs. The FDA's labeling authority consist of providing pre-market approval of all drugs, including any language which must appear on the drug package label, on the drug label, or on any package insert.⁴⁵

The standard information contained on the label includes product description, usage and dosage information, and any clinical pharmacology results.⁴⁶ The FDA labeling regulation requires only that the label include warnings regarding serious adverse consequences of the drug's consumption, including any potential safety hazards.⁴⁷ This includes specific language regarding pregnancy complications that may result from usage of the drug.⁴⁸ These side effects are based on scientific data.⁴⁹ The results of informal data collected through non-standardized research methods, which provides, at the very least, anecdotal evidence, are not required to be disclosed unless it can be demonstrated that the data is clinically relevant.⁵⁰ In addition, warning labels and inserts must be amended or revised "as soon as there is reasonable evidence of an association of a serious hazard with a drug."⁵¹ Manufacturers have an ongoing disclosure duty to the FDA with regard to any adverse drug incidents resulting from patient use.⁵² The FDA has the authority to mandate that the manufacturers directly warn consumers.⁵³ Plaintiffs have argued that an exception to the LIR

⁴⁴See *Edwards*, 933 P.2d at 301; *McKee v. Moore*, 648 P.2d 21, 25 (Okla. 1982); *Spychala v. G.D. Searle Co.*, 705 F. Supp 1024, 1033 (D.N.J. 1988); *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp 961, 965 (E.D. Wis. 1981).

⁴⁵See 21 U.S.C. § 355 (1994).

⁴⁶21 C.F.R. § 201.57. (1999).

⁴⁷*Id.*

⁴⁸*Id.*

⁴⁹21 C.F.R. § 201.57 (1999).

⁵⁰21 C.F.R. § 201.57(e) (1999).

⁵¹*Id.*

⁵²21 C.F.R. § 201.57(f)(4) (1999).

⁵³21 C.F.R. § 201.57(f)(2) (1999).

exists in situations where the FDA asserts this authority and requires the manufacturer to warn the consumers directly.⁵⁴

In *MacDonald v. Ortho Pharmaceutical Corporation*,⁵⁵ an argument for an exception to the LIR predicated on the FDA's mandated warning to consumers was met with some success.⁵⁶ The court noted that the prescription drug, the birth control pill, was subject to extensive regulation.⁵⁷ In fact, the FDA required the manufacturers to warn the consumer directly. The court recognized the following:

The FDA has promulgated regulations designed to ensure that the choice of "the pill" as a contraceptive method is informed by comprehensible warnings of potential side effects... "users of these drugs should, without exception, be furnished with written information telling them of the drug's benefits and risks"... [I]n the absence of **direct written warnings**, many potential users of "the pill" do not receive the needed information "in an organized, comprehensive, understandable, and handy-for-future-reference form."⁵⁸ (emphasis added)

In *MacDonald*, the court recognized that, due to several factors specific to "the pill,"⁵⁹ this type of prescription stood apart from other prescription drugs.⁶⁰ The Court held that a manufacturer of an oral contraceptive has an affirmative duty to warn users of possible side effects.⁶¹

⁵⁴See *Edwards*, 933 P.2d at 301; *McKee v. Moore*, 648 P.2d 21, 25 (Okla. 1982); *Spychala v. G.D. Searle Co.*, 705 F. Supp. 1024, 1033 (D.N.J. 1988); *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961, 965 (E.D. Wis. 1981).

⁵⁵See *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65 (Mass. 1985).

⁵⁶See *id.* at 70.

⁵⁷See *id.* at 69.

⁵⁸See *id.* at 69-70.

⁵⁹See *id.* at 70 (listing the specific factors).

⁶⁰*MacDonald*, 475 N.E.2d at 70.

⁶¹See *id.* (holding that "the manufacturer of oral contraceptives is not justified in relying on warnings to the medical profession to satisfy its common law duty to warn, and the manufacturer's obligation encompasses a duty to warn the ultimate user").

This exception has not been limited to cases involving contraceptives.⁶² The court in *Edwards* held that an exception to LIR existed for the prescription of nicotine patches, barring the use of the physician as a shield from liability.⁶³ The court stated:

When direct warnings to the user of a prescription drug have been mandated by a safety regulation promulgated for the protection of the user, an exception to the learned intermediary doctrine exists, and failure on the part of the manufacturer to warn the consumer can render the drug unreasonably dangerous.⁶⁴

The holdings in *MacDonald* and *Edwards*, however, have not been widely followed.⁶⁵ Not all courts have accepted the plaintiffs' arguments that the FDA mandated warnings create an exception to the LIR.

However, if the LIR exception is created this begs the question whether "the manufacturer has fulfilled its legal obligation once the warnings are approved by the FDA and transmitted to the user" when the LIR does not apply.⁶⁶ The courts have come to different conclusions when determining whether regulations issued by the FDA, pursuant to the Food, Drug and Cosmetic Act (FDCA),⁶⁷ preempt the plaintiff's common law failure to warn claims.⁶⁸ Manufacturers argue that once they have complied with FDA requirements, the duty to warn

⁶²See *Edwards v. Basel Pharm.*, 933 P.2d 298, 301 (Okla. 1997) (discussing that there is no reason not to extend this exception to nicotine patches available by prescription).

⁶³See *id.* at 303.

⁶⁴*Id.* at 301.

⁶⁵See *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 400-01 (Del. 1989); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp 1293, 1305 (D. Minn. 1988); *Goodson v. Searle Laboratories*, 471 F. Supp 546, 547-48 (D. Conn. 1978).

⁶⁶*Edwards*, 933 P.2d 298, 301 (Okla. 1997).

⁶⁷See *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024, 1029 (D.N.J. 1988).

⁶⁸See *Edwards*, 933 P.2d at 301-02 (discussing *Medtronic Inc. v. Lehr*, 518 U.S. 470 (1996) the court noted the adequacy of warnings is a question of state law and *Spychala v. G.D. Searle & Co.*, 705 F.Supp at 1024, holding "compliance with FDA requirements is sufficient to bring a case back within the learned intermediary rule").

is fulfilled.⁶⁹ However, plaintiffs propose that even though the manufacturer has conformed to FDA requirements, state law may still impose a stricter duty to warn on the manufacturer.⁷⁰ In *MacDonald v. Ortho Pharmaceutical Corporation*, the court held that even though FDA standards were met, the manufacturer's duty to warn and to comply with state law were not absolved.⁷¹ In addition, the court in *Edwards* upheld the plaintiff's argument to expand the manufacturer's duty, stating:

[T]he common law duty to warn is controlled by state law....Although the common law duty we today recognize is to a large degree coextensive with the regulatory duties imposed by the FDA, we are persuaded that, in instances where a trier of fact could reasonably conclude that a manufacturer's compliance with FDA labeling requirements or guidelines did not adequately apprise [prescription drug] users of inherent risks, the manufacturer should not be shielded from liability by such compliance.⁷²

*Hurley v. Lederle Laboratories Division of American Cyanamid*⁷³ also dealt with the issue of FDA labeling requirements versus the conflict with state law failure to warn claims.⁷⁴ In *Hurley*, the Fifth Circuit stated that there may be a preemption issue; however, the holding has not been adopted by other jurisdictions.⁷⁵ Even though the decision has not been widely adopted,⁷⁶ the advent of direct advertising of prescription drugs may force another look at *Hurley*. In the *Hurley* case, the plaintiffs alleged that their child suffered extreme neurological

⁶⁹See *Edwards*, 933 P.2d at 299.

⁷⁰See *id.* at 301.

⁷¹See *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 70 (Mass. 1985); *Spychala v. G.D. Searle & Co.*, 705 F.Supp. at 1033; *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 401-02 (Del. 1989).

⁷²*Edwards*, 933 P.2d at 302-03.

⁷³See *Hurley v. Lederle Lab. Div. of Am. Cyanamid*, 863 F.2d 1173 (5th Cir. 1988).

⁷⁴See *id.* at 1176.

⁷⁵See *id.* at 1175-77.

⁷⁶See *id.*

injuries as a result of a particular vaccine.⁷⁷ Plaintiffs argued that the vaccine was unreasonably dangerous because there was an alternative vaccine that did not pose a comparable risk.⁷⁸ Plaintiffs also contended that the defendant did not provide adequate warnings.⁷⁹ The district court granted a partial summary judgment in favor of the drug manufacturer reasoning that federal laws preempt any state law claims pursuant to the federal scheme to encourage vaccination.⁸⁰ However, the Fifth Circuit reversed the lower court's holding, rejecting the defendant's argument that the statutes were sufficient to implicitly preempt all state product liability claims.⁸¹ The Fifth Circuit recognized "FDA regulation does not generally preempt stricter state law standards for medical products."⁸²

The *Hurley* court made clear that the failure of the FDA to approve an alternative vaccine did not prevent the trial court from concluding that the vaccine used was unreasonably dangerous.⁸³ However, the Fifth Circuit held that the plaintiffs' state law claims for failure to warn were potentially at odds with FDA regulations, and were, therefore, preempted.⁸⁴ The court expressed that any common law duty requiring a pharmaceutical manufacturer to provide warnings that were at variance with those established by the FDA created a potential conflict with the FDA's requirements.⁸⁵ The court explained:

[T]hey [the manufacturers] argue that state law would impermissibly conflict with federal law if it required a warning different from that approved and required by the FDA...In the area of approving warnings, although the FDA

⁷⁷See *Hurley*, 863 F.2d at 1175.

⁷⁸See *id.*

⁷⁹See *id.* at 1175-77.

⁸⁰See *id.* at 1175 (discussing that the Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301 (1994), and the Public Health Service Act (PHSA), 42 U.S.C. §§ 247(b), 262 preempt state law claims).

⁸¹See *Hurley*, 863 F.2d at 1176 (noting that the majority of courts have ruled against preemption).

⁸²See *id.* at 1177.

⁸³See *id.* at 1179.

⁸⁴See *id.*

⁸⁵See *id.*

takes an active role in designing the warning, it remains a partially passive agency. That is, it accepts information given by manufacturers proposing the licensing of a particular vaccine, and determines a proper warning based upon the information provided. A state law determination on this issue should not be interjected to overrule the decision of the FDA. Such a procedure would place vaccine manufacturers in a position where they could not comply with both obligations...It would be patently inconsistent for a state then to hold the manufacturer liable for including that precise warning when the manufacturer would otherwise be liable for not including it. Thus, assuming that the FDA has processed all the relevant and available information in arriving at the prescribed warning, its decision as to the proper wording must preempt by implication that of a state.⁸⁶

Thus, the court left open the possibility of liability being imposed upon a manufacturer for failure to warn if it fails to provide the FDA with relevant information necessary for the development of an adequate consumer warning.⁸⁷ The FDA depends primarily upon manufacturers to provide safety information that is used in formulating label requirements and other information published on package inserts.⁸⁸ Other courts have rejected the *Hurley* decision and have held that FDA labeling requirements do not preempt state failure to warn claims.⁸⁹

This issue is of particular importance to plaintiffs looking to state failure to warn claims rather than relying on federal law.⁹⁰ Due to the direct advertising campaign of these prescription pharmaceuticals, the issue has been revived. The state failure to warn claims will certainly be utilized as an argument for plaintiffs who have claims related to direct marketing of prescription drugs. Plaintiffs will claim that federal preemption does not require that a litigant forgo his or her right to

⁸⁶See *Hurley*, 863 F.2d at 1179.

⁸⁷See *id.*

⁸⁸See *id.* at 1179-80.

⁸⁹See *In re Tetracycline Cases*, 747 F.Supp. 543, 544 (W.D. Mo. 1989).

⁹⁰One of the primary reasons for individuals looking to take their claims to state court rather than federal court is the limitation within the ERISA statute that limits damages to the amount of the procedure that was denied as opposed to wrongful death claims.

litigate appropriate claims in state court. The manner in which *Hurley* may be interpreted by subsequent court cases will be most critical with regard to resolving the federal preemption question. It can fairly be stated that the pharmaceutical companies will look for dicta within *Hurley* that may support a holding that they are regulated by the FDA rather than state statutes dealing with the failure to warn issue.

Direct Advertising as a New Exception to the LIR

Another argument that plaintiffs are likely to advance is that an exception to LIR is created when the manufacturer advertises directly to the public.⁹¹ Plaintiffs have already made this claim, arguing that if the physician prescribes an elective prescription drug which has been advertised to the consumer directly, the LIR no longer applies.⁹² This exception to the LIR mandates a change in the warning standard. Warnings must be pitched toward the reasonably prudent patient-consumer rather than the prescribing physician.⁹³

Proponents of this position argue that those drugs receiving the most exposure in direct advertising, particularly those on television and print media,⁹⁴ are drugs that are not necessarily designed to cure or mitigate a serious physical ailment or disease.⁹⁵ In fact, these are elective drugs, most likely prescribed for either cosmetic or non-life threatening health situations.⁹⁶ Plaintiffs argue the should not apply in the standard fashion so as to provide a protective barrier for the manufacturer.⁹⁷ Rather, the prescribing physician is merely acceding to a request from the patient that is deemed both elective and medicinally non-interventionist, not to mention cultivated as the result of the drug manufacturer's direct advertising effort.⁹⁸ Enforcing the duty of a prescribing physician to warn under these circumstances, then, would go further than that which a reasonably prudent health care provider is

⁹¹See *Perez II*, 734 A.2d 1245, 1251 (N.J. 1999)

⁹²See *id.*

⁹³See *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 68 (Mass. 1985).

⁹⁴See *id.*

⁹⁵See *id.* at 71.

⁹⁶See *id.*

⁹⁷See *id.*

⁹⁸See *MacDonald*, 475 N.E.2d at 69.

obligated to inform pursuant to current law. Currently, the plaintiffs who have advanced this argument have received differing judgments from the courts.⁹⁹

In *Perez v. Wyeth Laboratories, Inc.*,¹⁰⁰ plaintiffs argued that the direct advertising of the prescription drug put the drug manufacturer beyond the protection of the LIR.¹⁰¹ The plaintiff's argument was based on a footnote in *Garside v. Osco Drug, Inc.*¹⁰² This footnote stated:

[i]n an appropriate case, the advertising of a prescription drug to the consuming public may constitute a third exception to the learned intermediary rule. By advertising directly to the consuming public, the manufacturer bypasses the traditional patient-physician relationship, thus lessening the role of the "learned intermediary."¹⁰³

The New Jersey Superior Court was not persuaded by the direct advertising argument.¹⁰⁴ However, the New Jersey Supreme Court reversed the lower court's decision.¹⁰⁵

On appeal, the court noted that the manufacturer began a massive direct advertising campaign in 1991, which lacked information about the drug's side effects.¹⁰⁶ The court discussed the four theoretical bases for the LIR and determined that at least three of these are absent in the direct advertising context.¹⁰⁷ The court concluded that direct

⁹⁹See *Perez II*, 734 A.2d 1245, 1251 (N.J. 1999) (holding that the "learned intermediary" doctrine does not apply to direct marketing of prescription drugs to consumers); *In re Norplant*, 165 F.3d 374, 379 (5th Cir. 1999) (holding that Texas' intermediary doctrine precluded manufacturers' liability).

¹⁰⁰See *Perez v. Wyeth Lab., Inc.*, 713 A.2d 588 (N.J. Super. 1997) *rev'd*, *Perez II*, 734 A.2d at 1251.

¹⁰¹*Id.* at 593.

¹⁰²See *Garside v. Osco Drug, Inc.*, 764 F.Supp. 208 (D. Mass. 1991) *rev'd*, *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 83 (1st Cir. 1992).

¹⁰³*Id.* at 211 n.4.

¹⁰⁴See *Perez*, 713 A.2d at 593-94.

¹⁰⁵See *Perez II*, 734 A.2d at 1264.

¹⁰⁶See *id.* at 1248.

¹⁰⁷See *id.* at 1255.

advertising of pharmaceuticals “belies each of the premises on which the learned intermediary doctrine rests.”¹⁰⁸ In addition, the *Perez* opinion recognized that many elective drugs cause substantial side effects, making consumer protection extremely important because these pharmaceuticals are not medically necessary.¹⁰⁹ The court found that as a result of direct advertising patients now enter their physician’s office with preconceived expectations about their treatment.¹¹⁰ Based on the foregoing, the court held that the LIR would not apply when a manufacturer misleads or deceives the consumer in direct advertising.¹¹¹

Justice Pollock’s dissenting opinion in *Perez* rejected the plaintiffs’ arguments that a new LIR exception be created.¹¹² The dissent explained that the LIR is implemented not because the manufacturer directly markets to the physician, but because the physician is in a position to make an individualized evaluation of the drug’s risks.¹¹³ This allows the physician to warn each patient based on the individual’s health status.¹¹⁴ In addition, the patient is unable to obtain the drug absent a physician’s prescription.¹¹⁵ The dissent explained that direct advertising should not affect the application of the LIR.¹¹⁶ Similarly, the court in *In re Norplant Contraceptives* found that direct marketing of Norplant to the consumers did not create an exception to the LIR.¹¹⁷ The court noted that regardless of direct advertising, a physician continues to have the responsibility of weighing the risks and benefits before prescribing an elective drug.¹¹⁸

Notwithstanding these dissenting views, plaintiffs could argue that, as long as the physician determines that the patient is sufficiently healthy and does not exhibit any signs that the side effects are likely to

¹⁰⁸*Id.* at 1256.

¹⁰⁹*See id.* at 1257.

¹¹⁰*See Perez II*, 734 A.2d at 1260.

¹¹¹*See id.* at 1264.

¹¹²*See id.* at 1268-69 (Pollock, J., dissenting).

¹¹³*See id.* at 1266.

¹¹⁴*See id.*

¹¹⁵*See Perez II*, 734 A.2d at 1266.

¹¹⁶*See id.* at 1268.

¹¹⁷*See In re Norplant*, 165 F.3d 374, 379 (5th Cir. 1999)

¹¹⁸*See id.*

occur in the individual, judicial prudence dictates that the prescribing physician not be held to the learned intermediary standard.¹¹⁹ For elective prescriptions, ultimately the patient is making this decision whether to take the drug. Absent any obvious or known physical conditions of which the physician is aware, the patient is most likely to get what he or she wants.¹²⁰ The consumer may try to talk the prescribing physician into writing the prescription without a sufficient physical examination to meet the Rule's standard.¹²¹ If a physician declines to prescribe the elective drug the zealous patient can always shop for a physician willing to write the requested prescription, and the issue as to whether an exception to the Rule should be developed in these cases will remain unanswered. Any patient who is ultimately successful in the pursuit of a prescription for a particular elective drug is not likely to resort to the courts to resolve the question of whether an individual has a right to be his or her own prescribing physician in elective drug cases.

However, defendants argue that it is not possible to mitigate or reduce a physician's legal duty of care with regard to exercising professional judgment in prescribing elective drugs.¹²² The power of the media, the influence of the advertisement and the ultimate impact on the prospective patient make it necessary for a prescribing physician to exercise some type of filter or buffer role.¹²³ The cases upholding the two types of established exceptions to the LIR exemplify that, in some situations, it is practical and necessary to expand the manufacturer's duty to warn.¹²⁴ As courts begin to face challenges stemming from direct advertising suits, it is possible that another widely acknowledged exception will be created.

¹¹⁹*See id.*

¹²⁰*See Perez II*, 734 A.2d at 1260 (Physicians complain that it is impossible to compete with pharmaceutical companies' massive advertising budgets, and resign themselves to the fact that if consumers make enough noise, they will eventually relent to patient pressure).

¹²¹*See id.* at 1260 (discussing that physicians may relent to patient pressure).

¹²²*See id.*

¹²³*See Hamilton v. Accu-Tek Am Arms Inc.*, 935 F. Supp. 1307, 1316 (E.D.N.Y. 1996).

¹²⁴*See In re Norplant*, 955 F. Supp. 374, 379 (5th Cir. 1999).

IMPACT OF DIRECT ADVERTISING

The movement toward direct advertising of prescription drugs has been swift and all encompassing.¹²⁵ As a consumer oriented society that relies on the capitalist system of commerce, the direct advertising of pharmaceuticals presents interesting and unusual problems. One aspect of drug advertisements that may elude consumers' notice is the length of fine print or verbiage detailing the conditions of ingestion and possible side effects. Clearly these drug advertisements are careful to take steps to protect "consumer choice," but do so through "dilut[ion]"¹²⁶ of the risks relative to the drug's benefits. Drug companies punctuate every advertising effort by directing the consumer to "ask your doctor."¹²⁷ Such direction hurls liability back into the lap of the prescribing physician. In essence, having articulated its duty to warn of potential side effects directly to the consumers, drug companies expect to rely on the LIR to escape product liability. The question in emerging caselaw will be whether or not courts will allow drug companies to have it both ways.

These new developments in direct advertising of pharmaceutical companies coincide with the adoption of the RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY (1997), which adopted a "tepid endorsement" of the LIR.¹²⁸ In essence, the American Law Institute recognized that the LIR is inappropriate in situations where a physician assumes a "much-diminished role as an evaluator or decisionmaker."¹²⁹ While some sought to solidify an exception to the LIR doctrine explicitly in instances of direct advertising of pharmaceutical companies in the RESTATEMENT, the issue was ultimately left to "developing case law."¹³⁰ Indeed, developing caselaw has acknowledged that "direct advertising of drugs to consumers alters the calculus of the learned intermediary doctrine"¹³¹ such that pharmaceutical companies may not rely on the LIR

¹²⁵See *Perez II*, 734 A.2d at 1252.

¹²⁶See *id.*

¹²⁷See *id.* at 1252-53.

¹²⁸See *id.* at 1253 (citing Charles J. Walsh, *The Learned Intermediary Doctrine: The Correct Prescription for Drug Labeling*, 48 RUTGERS. REV. 821, 869 (1994)).

¹²⁹See *id.* at 1253 (citing RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY (1997)).

¹³⁰See *Perez II*, 734 A.2d at 1253.

¹³¹See *id.* at 1254.

in direct-advertising cases. As sales of Viagra soar to \$788 million secondary to celebrity endorsements and clever ads,¹³² pharmaceutical companies may be forced to re-think their marketing strategy once product liability claims begin to offset these profits.

Ultimately, in response to developing caselaw, the Restatement may officially adopt an exception to the LIR, leaving pharmaceutical companies completely vulnerable to product liability claims. "Patient choice is an increasingly important part of our medical-legal jurisprudence."¹³³ However, by "encroaching"¹³⁴ on the patient-physician relationship with consumer-directed advertising, pharmaceutical companies may find themselves saddled with the liability that goes along with it.

CONCLUSION

The LIR has traditionally shielded drug manufacturers from liability as long as the manufacturer has fulfilled its duty to warn by providing physicians with all the side effects of the drug.¹³⁵ However, the courts have established two exceptions to the LIR.¹³⁶ With the increase in direct advertising, the pharmaceutical companies have created the potential of a valid new LIR exception. As a result of direct advertising, it is likely that many more lawsuits will be filed. For instance, Viagra lawsuits will most likely ensue and will determine whether or not the manufacturer, Pfizer Company, is shielded by physician's due to the LIR. One of the issues certainly to be debated heavily with regard to Viagra is the fact that Pfizer has chosen to initiate an extremely vigorous and long-term direct advertising campaign.¹³⁷ Pfizer does not always make clear in its advertisements that Viagra is an optional drug for the consuming public.¹³⁸ Perhaps the

¹³²See *id.* at 1252.

¹³³See *id.* at 1257.

¹³⁴See *id.* at 1256.

¹³⁵See *Odgers v. Pharm. Corp.*, 609 F. Supp 867, 872-73 (E.D. Mich. 1985).

¹³⁶See *supra*, pp. 241-51.

¹³⁷See *supra*, note 3.

¹³⁸The term "optional drug" refers to a medication typically sought by patients on an elective basis for non-life threatening situations. Referral to "vanity" treatments is more

absence of these warnings was intended to be the basis for invoking the LIR, since the ad's spokesperson always suggests that a physician be consulted. This advertising tactic, however, may not succeed as courts have begun to hold that direct advertising can serve as an exception to the LIR.¹³⁹

pejorative, but the term confers the essential view that the described treatment is one of personal choice, ostensibly in conjunction with the advice and consent of a physician. In current advertising, drug costs are not considered relevant to the purchase choice. The advertisements give the impression that any patient who wants the prescription drug can afford it. The primary difficulty raised by this Article is whether optional choices made by the patient displace the traditional protections afforded health care providers by the Learned Intermediary Rule.

¹³⁹See *Perez II*, 734 A.2d 1245, 1263-64 (N.J. 1999).

