

FOOD AND DRUG LAW JOURNAL

*Analyzing the Laws, Regulations, and Policies
Affecting FDA-Regulated Products*

A Defense of the Learned Intermediary Doctrine

*Richard B. Goetz
Karen R. Growdon*



VOLUME 63 NUMBER 2 2008

A Defense of the Learned Intermediary Doctrine

RICHARD B. GOETZ*
KAREN R. GROWDON**

I. INTRODUCTION

The learned intermediary doctrine provides that a prescription drug manufacturer fulfills its duty to warn by providing an adequate warning of the medicine's risks to the medical practitioner—the “learned intermediary”—who prescribes the medicine. The doctrine was first recognized in case law over 50 years ago, and since that time has been recognized and applied in nearly all jurisdictions in the country.

In the last two decades, the marketing of prescription drugs directly to potential end-users through television, radio, print and internet advertising has grown significantly. Claimants in products liability cases, with some regularity, now seek to hold prescription drug manufacturers liable for failing to include adequate warnings of prescription drug risks in their advertisements. Nine years ago, the New Jersey Supreme Court, while recognizing the general applicability of the learned intermediary doctrine, ruled that the doctrine does not apply in the case of drugs marketed directly to consumers and that in those circumstances manufacturers have a duty to warn consumers directly.¹ Last year the highest court in West Virginia, without noting whether or not the injured patient even saw an advertisement for the drug involved, simply rejected the learned intermediary doctrine in its entirety.² Advertising certain prescription drugs to consumers is now commonplace, and plaintiffs can be expected to continue to urge other courts to carve out an exception to the learned intermediary doctrine for drugs marketed in this fashion, if not to abolish the doctrine altogether.

This article examines the rationale for the learned intermediary doctrine and considers whether the doctrine is now outdated in light of the prevalence of direct-to-consumer (DTC) advertising. The authors conclude that, when a prescription medicine is obtained in the course of a physician-patient relationship,³ the rationale for applying the learned intermediary doctrine is still valid. Prescription drug manufacturers are subject to stringent and detailed risk disclosure requirements applicable to the drug information that they provide physicians and to advertisements for prescription drugs directed to consumers. Engrafting on those existing requirements a new rule that permits juries to impose tort liability on manufacturers for failing to warn consumers directly of the risks of an advertised drug would be counterproductive both from a policy and a practical standpoint.

* Mr. Goetz is a Partner at O'Melveny & Myers LLP in Los Angeles, California.

** Ms. Growdon is a Counsel at O'Melveny & Myers LLP in Los Angeles, California. Both Mr. Goetz and Ms. Growdon practice in the areas of mass torts and products liability. Robert Hunt and Stephanie Sperber, Associates at O'Melveny & Myers LLP, assisted in the preparation of this article.

¹ *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245 (N.J. 1999).

² *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899 (W. Va., 2007).

³ The learned intermediary doctrine also applies to claims for injuries from medical devices obtainable only by prescription. *E.g.*, *Lacy v. G.D. Searle & Co., Inc.*, 567 A.2d 398, 400 (Del. 1989) (intrauterine device).

II. THE RATIONALE FOR THE LEARNED INTERMEDIARY DOCTRINE

As a general matter, in products liability law, a manufacturer of a product has a duty to warn consumers directly of risks associated with the use of its product.⁴ In products liability actions involving prescription drugs, however, the law in nearly all jurisdictions requires a pharmaceutical manufacturer to fulfill its duty to warn by directing warnings about its product's risks to the physician who prescribes the medicine and who acts as a "learned intermediary" between the manufacturer and the patient.⁵ The drug manufacturer discharges its duty to warn if it provides an adequate warning to the physician, and the manufacturer is absolved of liability under a failure-to-warn theory to the end-user of the prescription drug.⁶

The rationale behind the learned intermediary rule is that patients rely on their physicians to weigh the benefits and risks of medicines and to choose the medicine that best meets their unique needs. The physician is viewed as the primary source of guidance and communication to the patient about the patient's medical treatment and care and about the risks associated with a given medicine.⁷ As a seminal case in this area has explained:

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 individualized medical judgment bottomed on a knowledge of both patient and palliative. *Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.*⁸

The doctrine is also based on the concern that requiring drug manufacturers to provide highly complex information about medical side effects directly to consumers would lead to patient confusion and misunderstanding.⁹

⁴ RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(c) & cmt. (i) (1998) ("Commercial product sellers must provide reasonable instructions and warnings about risks of injury posed by their products.")

⁵ *E.g.*, *Carlin v. Super. Ct. (The Upjohn Co.)*, 920 P.2d 1347, 1354 (Cal. 1996) ("[I]n the case of prescription drugs, the duty to warn runs to the physician, not to the patient."); *Martin v. Hacker*, 628 N.E.2d 1308, 1311 (N.Y. 1993) ("Warnings for prescription drugs are intended for the physician, whose duty it is to balance the risks against the benefits of various drugs and treatments and to prescribe them and supervise their effects."); *Schaerr v. Stewart Plaza Pharmacy, Inc.*, 79 P.3d 922, 928 (Utah 2003) ("[M]anufacturers of prescription drugs have a duty to warn only the physician prescribing the drug, not the end user or patient."); *see also* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) & cmt. (d) (citing cases that stand for the proposition that "manufacturers of prescription drugs discharge their duty of care to patients by warning the health-care providers who prescribe and use the drugs to treat them").

⁶ *E.g.*, *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 803 (E.D. Tex. 2002); *Brown v. Super. Ct. (Abbott Labs.)*, 751 P.2d 470, 478 n.9 (Cal. 1988) ("[A] manufacturer fulfills its duty to warn if it provides adequate warning to the physician."); *Martin*, 628 N.E. 2d at 1311.

⁷ *E.g.*, *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 770 (Ky. 2004) ("[O]nly health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy."); *Vitanza v. Upjohn Co.*, 778 A.2d 829, 837 (Conn. 2001); ("The learned intermediary doctrine... is based on the principle that prescribing physicians act as 'learned intermediaries' between a manufacturer and consumer and, therefore, stand in the best position to evaluate a patient's needs and assess the risks and benefits of a particular course of treatment.") (internal citations omitted).

⁸ *Reyes v. Wyeth Labs, Inc.* 498 F.2d 1264, 1276 (5th Cir. 1974) (emphasis added).

⁹ *See, e.g., Norplant*, 215 F. Supp. 2d at 815 ("[S]tates [that] recognize the learned intermediary doctrine are concerned that patients cannot comprehend complex medical information...."); *Carmichael v. Reitz*, 95 Cal. Rptr. 381, 400 (1971) ("The doctor is intended to be an intervening party in the full sense of the word.... Were the patient to be given the complete and highly technical information on the adverse possibility associated with the use of the drug, he would have no way to evaluate it....").

The learned intermediary rule is the logical corollary to the fact that prescription drugs are legally obtainable only through a physician or other licensed healthcare provider.¹⁰ It is fully consistent with the purpose of the warnings that the Food and Drug Administration (FDA) requires in prescription drug labeling. It is a fundamental premise of FDA's labeling regulations that the highly technical scientific language in which full information about drug risk and proper usage must necessarily be expressed is best directed to physicians rather than consumers:

The purpose of prescription drug labeling is to provide health care practitioners information necessary for safe and effective use.... Requiring that language used in prescription drug labeling be tailored to a lay audience would result in a loss of the clarity and precision needed to effectively communicate to practitioners a product's benefits and risks.¹¹

The learned intermediary doctrine appears to have first been enunciated over 50 years ago.¹² Since then, it has been adopted and applied by most jurisdictions, and today is a rule of near-universal applicability in the United States. In 31 jurisdictions, the doctrine has been adopted and applied by the highest appellate court or by statute.¹³ Intermediate appellate courts in an additional seven jurisdictions

¹⁰ See, e.g., *Vitanza*, 778 A.2d at 846; *Edwards v. Basel Pharms.*, 933 P.2d 298, 300 (Okla. 1997); *Schaerrer*, 79 P.3d at 929 (noting also that manufacturers are "limited in their ability to distribute FDA-regulated drugs" because they lack "direct access" to the patient).

¹¹ Final Rule: Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3961 (cmt. 112) (Jan. 24, 2006). See also Final Rule: Labeling and Prescription Drug Advertising: Content and Format for Labeling for Human Prescription Drugs, 44 Fed. Reg. 37434, 37438-37439 (June 26, 1979) ("[T]he prescription drug labeling to which [the FDA labeling] regulations apply is directed to health care professionals and not to the ultimate consumer of the drugs." (item 21) "[S]tandardization of prescription drug labeling in lay language is not warranted because the labeling for prescription drugs is directed to the health care professional and not the layperson; therefore, the labeling should be that most capable of informing the professional practitioner." (item 26)).

¹² See *Marcus v. Specific Pharms.*, 77 N.Y.S.2d 508, 509-10 (N.Y. Sup. Ct. 1948) ("[I]t is difficult to see on what basis this defendant can be liable to plaintiff. It made no representation to plaintiff, nor did it hold out its product to plaintiff as having any properties whatsoever. To physicians it did make representations. And should any of these be false it might be claimed with propriety that they were made for the benefit of the ultimate consumers. But there is no such claim...."). The phrase itself appears to have been first used in *Sterling Drug Co. v. Cornish*, 370 F.2d 82, 85 (1966). ("[I]n this case 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.")

¹³ See *Stone v. Smith, Kline & French Labs.*, 447 So. 2d 1301, 1304-05 (Ala. 1984); *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1200 (Alaska 1992); *West v. Searle & Co.*, 806 S.W.2d 608, 614 (Ark. 1991); *Carlin*, 920 P.2d at 1350-55 (California); *Vitanza*, 778 A.2d at 836-39 (Connecticut); *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 399-401 (Del. 1989); *Mampe v. Ayerst Labs.*, 548 A.2d 798, 802 n.6 (D.C. 1988); *Felix v. Hoffmann-LaRoche, Inc.*, 540 So. 2d 102, 104 (Fla. 1989); *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003); *Craft v. Peebles*, 893 P.2d 138, 154-56 (Haw. 1995); *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 513 N.E. 2d 387, 392-93 (Ill. 1987); *Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 929 (Kan. 1990); *Larkin*, 153 S.W.3d at 770 (Kentucky); *Cottam v. CVS Pharmacy*, 764 N.E. 2d 814, 820-21 (Mass. 2002); *Gray v. Badger Min. Corp.*, 676 N.W.2d 268, 275-76 (Minn. 2004); *Janssen Pharm., Inc. v. Bailey*, 878 So. 2d 31, 56-58 (Miss. 2004); *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143, 146-47 (Mo. 1967); *Hill v. Squibb & Sons*, 592 P.2d 1383, 1387-88 (Mont. 1979); *Freeman v. Hoffman-LaRoche, Inc.*, 618 N.W.2d 827, 841-42 (Neb. 2000); *Perez v. Wyeth Labs, Inc.*, 734 A.2d at 1259-62 (New Jersey); *Martin*, 628 N.E.2d at 1311 (New York); N.C. GEN. STAT. § 99B-5(a) (1995); OHIO REV. CODE ANN. § 2307.76(C) (2006); *Tracy v. Merrell Dow Pharms., Inc.*, 569 N.E.2d 875, 878 (Ohio 1991); *Edwards v. Basel Pharms.*, 933 P.2d at 298,300-01 (Okla. 1997); *McEwen v. Ortho Pharm.*, 528 P.2d 522, 529 (Or. 1974) (learned intermediary doctrine applies in negligence actions); *Coyle v. Richardson-Merrill, Inc.*, 584 A.2d 1383, 1385-86 (Pa. 1991); *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994); *Schaerrer v. Stewart's Plaza Pharmacy*, 79 P.3d 922, 928 (Utah 2003); *Pfizer, Inc. v. Jones*, 272 S.E.2d 43, 44 (Va. 1980); *Washington State Physicians Ins. Exch. & Ass'n v. Fisons Corp.*, 858 P.2d 1054, 1061 (Wash. 1993); *Rohde v. Smiths Medical*, 165 P.3d 433, 435 n.5 (Wyo. 2007).

have applied the doctrine,¹⁴ and federal courts applying state law have predicted the doctrine's adoption in at least nine states in which the state appellate courts have not expressly addressed whether to apply the rule.¹⁵

III. THE FDA'S REGULATION OF THE PROVISION OF RISK INFORMATION IN DTC ADVERTISING

In assessing whether the learned intermediary doctrine has become outdated, the extent to which FDA regulates the content and means of presentation of risk information in prescription drug advertising should be taken into account.

FDA regulates prescription drug advertisements, including those directed to consumers, under the authority of the Federal Food, Drug, and Cosmetic Act (FDCA).¹⁶ Advertisements, whether directed to physicians or consumers, may not be false or misleading.¹⁷ Under section 502(n) of the FDCA, prescription drug advertisements must include a "true statement" of "information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations...."¹⁸ By regulation, FDA requires that the "brief summary" provide "all the risk-related information in a product's approved package labeling."¹⁹ In order to provide a true statement of risk information, advertisements must not be

In three states, the highest appellate court, while not adopting the doctrine explicitly, has referred to the learned intermediary doctrine in terms that suggest that it is part of the law of that state. *See Hodges v. Brannon*, 707 A.2d 1225, 1227-28 (R.I. 1998) (upholding jury instructions that reflected application of the learned intermediary doctrine); *Allison v. Merck & Co., Inc.*, 878 P.2d 948, 958 n.16, 969 (Nev. 1994) (plurality opinion announcing ruling of the court stated that narrow "mass immunization" exception to learned intermediary doctrine, which operates when a vaccine is administered at a clinic without the involvement of a physician, applied; dissenting opinion stated that learned intermediary doctrine applied without exception); *Silman v. Aluminum Co. of Am.*, 731 P.2d 1267, 1270-71 (Idaho 1986) (referring to the learned intermediary doctrine with approval);

¹⁴ *See Dyer v. Best Pharmacal*, 577 P.2d 1084, 1087 (Ariz. App. 1978); *Hamilton v. Hardy*, 549 P.2d 1099, 1110 (Colo. App. 1976), *overruled on other grounds by State Bd. of Med. Examiners v. McCroskey*, 880 P.2d 1188 (Colo. 1994); *Ortho Pharm. Corp. v. Chapman*, 388 N.E.2d 541, 548-49 (Ind. Ct. App. 1979); *Kinney v. Hutchinson*, 468 So. 2d 714, 718-19 (La. App. 1985); *Brown v. Drake-Willock Intern., Ltd.*, 530 N.W.2d 510, 516 (Mich. App., 1995); *Serna v. Roche Labs.*, 684 P.2d 1187, 1189 (N.M. Ct. App. 1984); *Wyeth-Ayerst Labs. v. Medrano*, 28 S.W.3d 87, 92 (Tex. Ct. App. 2000).

¹⁵ *Brazzell v. United States*, 788 F.2d 1352, 1358 (8th Cir. 1986) (applying Iowa law); *Violette v. Smith & Nephew Dyonics, Inc.*, 62 F.3d 8, 13 (1st Cir. 1995) (applying Maine law); *Miller v. Bristol-Myers Squibb Co.*, 121 F. Supp. 2d 831, 838 (D. Md. 2000) (applying Maryland law); *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 656 (1st Cir. 1981) (applying New Hampshire law); *Ehlis v. Richwood*, 367 F.3d 1013, 1017 (8th Cir. 2004) (applying North Dakota law); *Guevara v. Dorsey Labs.*, 845 F.2d 364 (1st Cir. 1981) (applying law of Puerto Rico); *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1231 (4th Cir. 1984) (applying South Carolina law); *McElhanev v. Eli Lilly*, 575 F. Supp. 278 (D.S.D. 1983) (applying South Dakota law); *Menges v. Depuy Motech, Inc.*, 61 F. Supp. 2d 817, 830 (N.D. Ind. 1999) (applying Wisconsin law).

¹⁶ Federal Food, Drug, and Cosmetic Act § 1, 21 U.S.C. § 301. Prescription drug advertising is commercial speech protected by the First Amendment. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748, 770 (1976). For an analysis of decisions that have delineated the proper scope of the regulation of commercial speech, see Mark I. Schwartz, *To Ban or Not to Ban—That Is The Question: The Constitutionality of a Moratorium on Consumer Drug Advertising*, 63 FOOD DRUG L. J. 1 (2008).

¹⁷ 21 U.S.C. §§ 321(n) (prescription drugs), 352 (q)(1) (restricted medical devices).

¹⁸ 21 U.S.C. § 352(n).

¹⁹ 21 C.F.R. § 202.1(e)(1). "Reminder advertisements," *i.e.*, advertisements that mention the name of a prescription drug but do not give indications for use or dosage recommendations, are exempted from the requirements for the disclosure of risk information. 21 C.F.R. §§ 200.200, 202.1(e)(2)(i). As such, they cannot form the basis of any action claiming that a manufacturer failed to provide an adequate warning of a drug's risks to consumers, nor even constitute admissible evidence in actions raising that claim.

false or misleading and must be worded so as to present a “fair balance between information relating to side effects and contraindications and information relating to effectiveness.”²⁰ Although these requirements apply to advertisements in all media, the method by which sponsors of prescription drug advertisements meet these requirements varies with the medium.

A. *Print Advertisements*

In print advertisements, sponsors traditionally satisfied the brief summary requirement by appending to the advertisement the full approved text of risk information contained in the package insert (i.e., the professional labeling directed to healthcare providers)²¹ or, under an approach that FDA recommended in a 2001 guidance document (now superseded), the risk information in FDA-approved patient labeling if such labeling addressed the drug’s “most serious and most common risks.”²² In a draft guidance to industry issued in January 2004, FDA signaled an intent to encourage warnings in print advertisements that were easier for consumers to understand. FDA acknowledged that the highly technical language used in the risk-related portions of prescription drug labeling directed to physicians was “less than optimal for consumer-directed print advertisements because many consumers do not have the technical background to understand this information.”²³

To achieve the goal of making risk information more understandable to consumers, FDA recommended three alternative approaches for fulfilling the brief statement requirement. The first two alternatives are reprinting the full FDA-approved patient labeling or reprinting only the risk information from the patient labeling. Under either alternative, the risk information provided must include all contraindications, warnings, the “major” precautions, “including any that describe serious adverse drug experiences (as defined in 21 C.F.R. 312.032(a) & 314.80(a)) or steps to be taken to avoid such experiences;” and “the 3-5 most common nonserious adverse reactions most likely to affect the patient’s quality of life or compliance with drug therapy.”²⁴ The third alternative is inclusion of the risk information that would appear in the Highlights section of professional labeling (usually any Boxed Warnings, Contraindications, Warning/Precautions, and Most Common Adverse Reactions) for drugs subject to FDA’s labeling rule (“The Physician’s Labeling Rule”) that took effect in June 2006.²⁵

²⁰ *Id.* § 202.1(e)(5).

²¹ Draft Guidance for Industry on Improving Information About Medical Products and Health Conditions; Withdrawal Availability, 69 Fed. Reg. 6308 (Feb. 10, 2004) (“Currently, it is commonplace for manufacturers to comply with the brief summary requirements by presenting verbatim and in small type the entire risk-related sections of the FDA-approved professional labeling.”).

²² Draft Guidance for Industry on Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements; Availability, 66 Fed. Reg. 20468-01, at 2 (Apr. 23, 2001).

²³ FDA, Draft Guidance For Industry: Brief Summary: Disclosing Risk Information In Consumer-Directed Print Advertisements (Jan. 2004) (“2004 Guidance”) at 2, available at <http://www.fda.gov/cder/guidance/5669dft.htm>.

²⁴ *Id.* at 5.

²⁵ *Id.* at 6. For the Physician’s Labeling Rule, see 21 C.F.R. §§ 201.56, 201.80; Final Rule: Requirements on the Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006). The changes in the format that are mandated by the Physician’s Labeling Rule were still under consideration when the January 2004 Guidance was issued. One of the significant purposes behind the new labeling rule was to make it easier for health care providers to locate and absorb pertinent prescribing information. This was accomplished by mandating inclusion of a new section called “Highlights” that prominently displays and summarizes, among other things, the most significant risk information about the drug. The new rule mandates the enumerated labeling changes for all newly approved prescription drugs, for all drugs approved within five years of the effective date of June 30, 2006, and for all drugs whose label is changed after the effective date of the rule because of a newly approved use. 21 C.F.R. § 201.56(b)(1).

The 2004 Guidance clearly reflects a concern that risk information provided to consumers be stated in language comprehensible to a lay audience. It also reflects the view that over-warning—by disclosure of *all* risk information in warnings to consumers—can be counterproductive. For example, in suggesting the alternative of using the risk information in approved patient labeling to comply with the brief summary requirement, FDA noted that “omitting less serious, infrequent risks from patient labeling may actually increase the usefulness of this labeling for its audience by making the more important risks stand out more clearly.”²⁶ Thus, the approved risk information in patient labeling was “a better vehicle for communicating risk information to consumers than lengthy, technical FDA-approved professional labeling.”²⁷ More generally, the 2004 Guidance observed that “FDA believes that exhaustive lists of minor risks distract from and make it difficult to comprehend and retain information on the more important risks.”²⁸

B. *Broadcast Advertisements*

Advertisements broadcast on television or radio are of such short duration that as a practical matter it is impossible to include the brief summary in the advertisement itself. Instead, it is permissible for such an advertisement to identify only the “*major* side effects and contraindications” of the medicine in the audio or audio and visual parts of the advertisement.²⁹ This is done through what is referred to as the “major statement.” By an amendment that took effect March 25, 2008, the FDCA requires that the major statement in any television or radio advertisement “be presented in a clear, conspicuous and neutral manner.”³⁰

To meet the brief summary requirement, the sponsor “must make an adequate provision for the dissemination of the approved or permitted package labeling.”³¹ In 1997, FDA issued, in draft form, a guidance for industry (“the 1997 Guidance”), which set forth an approach that sponsors of broadcast advertisements could use to satisfy their obligation to make “adequate provision” for the statutorily mandated brief summary of side effects and contraindications.³² The 1997 Guidance, which

²⁶ 2004 Guidance at 4.

²⁷ *Id.*

²⁸ *Id.* at 2.

²⁹ 21 C.F.R. § 202(e)(1) (emphasis added).

³⁰ 21 U.S.C. § 352(n). This requirement was added by a provision of the Food and Drug Administration Amendments Act of 2007 (FDAAA) that took effect March 25, 2008. *See* Pub. L. No. 110-85, § 901(d)(3)(A).

The FDAAA includes other provisions that apply to the FDA’s regulation of drug advertising. FDA now has certain limited authority to prereview television advertisements. FDA may recommend changes to such advertisements that it deems necessary to protect consumers or that are consistent with the prescribing information for the drug. 21 U.S.C. § 353b (a)-(c). The FDAAA also authorizes FDA to require specific disclosures in television advertisements, such as a disclosure about a serious risk listed in the drug’s labeling, to ensure that the advertisements are not misleading. *Id.* § 353b (e)(1). A manufacturer that disseminates a direct-to-consumer advertisement that is false and misleading can be subject to civil penalties, but will not be required to pay a penalty if it submitted the advertisement to FDA and disseminated the advertisement only after incorporating all comments received from FDA. *Id.* § 333 (g)(1), (4).

The FDAAA also added a provision requiring that all print advertisements for drugs include the following statement: “You are encouraged to report negative side effects of prescription drugs to FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.” 21 U.S.C. § 352(n). FDA was directed to undertake a study to determine whether the same statement should also be required in television advertisements. Pub. L. No. 110-85, § 906(b), 121 Stat. 823 (Sept. 27, 2007).

³¹ 21 U.S.C. § 352(n).

³² FDA, Guidance For Industry: Consumer-Directed Broadcast Advertisements (Aug. 1999), available at <http://www.fda.gov/cder/Guidance/1804fnl.htm>.

was finalized in 1999 and remains in effect today, identified four components of this approach:

- disclosure of a toll-free telephone number that consumers can call in order to obtain the package labeling (either by mail or by having the labeling information read over the telephone);
- inclusion of a mechanism to provide package labeling to consumers who lack access to the Internet or other sophisticated technology by, for example, providing the required information about side effects and contraindications in print advertisements that appear concurrently in publications that reach such consumers;
- disclosure of an Internet web page address where the package labeling can be accessed; and
- disclosure that pharmacists, physicians, and other health care providers are a source of additional product information.³³

Although some advertising of prescription medicines to consumers was underway in the 1980s,³⁴ both print and broadcast advertisements directed to consumers proliferated in the 1990s, especially after issuance of the 1997 Guidance. The 1997 Guidance has been widely viewed as making it easier for drug companies to broadcast advertising of prescription products by providing a feasible means of meeting the brief summary requirement.³⁵

C. Advertising on the Internet

In recent years, the internet has become a vast repository of information about prescription drugs, and advertising and promotion of prescription drugs on the internet has proliferated. Much of the information about prescription drugs on the Internet is not provided by drug manufacturers, and much of such information that manufacturers do provide should not be characterized as advertising. For example, as suggested in the 1997 Guidance, drug manufacturers post professional labeling information on the internet as a way of making adequate provision for dissemination of the complete risk information mandated by the brief summary requirement of the FDA regulations.³⁶

Explicitly promotional content about prescription medicines that drug manufacturers provide on the internet could in some instances be considered analogous to print advertising, in other instances analogous to broadcast advertising, or something entirely different from either. FDA has commented that Internet “promotions are neither purely print nor broadcast.”³⁷ FDA currently does not have regulations

³³ *Id.* at 2-3.

³⁴ Francis B. Palumbo & Daniel Mullins, *The Development of Direct-to-Consumer Drug Advertising Regulation*, 57 FOOD & DRUG L.J. 423, 424 (2002) (identifying a 1981 advertisement for the prescription drug Rufen as the first direct-to consumer print advertisement in the United States).

³⁵ See, e.g., J.S. Weissman, et al., *Physicians Report On Patient Encounters Involving Direct-To-Consumer Advertising*, HEALTH AFFAIRS W4-219 (Apr. 28, 2004), at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.219v1>; Bernard J. Garbutt III & Melinda E. Hofmann, *Recent Developments in Pharmaceutical Products Liability Law: Failure to Warn, the Learned Intermediary Doctrine, and Other Issues in the New Millennium*, 58 FOOD & DRUG L. J. 269, 274 (2003).

³⁶ See *supra* text accompanying note 33.

³⁷ 68 FED. REG. 47920, 47922 (Aug. 12, 2003); 60 FED. REG. 42581, 42584 (Aug. 16, 1995).

or guidance that specifically address Internet advertising, but has announced that a working group is developing a guidance on this topic.³⁸

IV. ATTACKS ON THE LEARNED INTERMEDIARY DOCTRINE BASED ON DTC ADVERTISING OF PRESCRIPTION DRUGS

It has become commonplace for parties claiming injuries from prescription drugs to assert that they were influenced by advertising to request specific drugs and that a drug manufacturer should not escape liability for failing to provide direct warnings of a drug's risks to consumers even if the prescribing physician received an adequate warning. In 1999, the New Jersey Supreme Court responded favorably to that argument and ruled in *Perez v. Wyeth Laboratories, Inc.*, that manufacturers had an obligation to warn consumers directly of the risks associated with prescription drugs that they advertised to the general public, thereby creating what is often viewed as an exception to the learned intermediary rule.³⁹ For several years after it was decided, no court in any other jurisdiction followed *Perez* by declining to apply the learned intermediary doctrine when a prescription drug was marketed to consumers.⁴⁰ However, last year the West Virginia Supreme Court of Appeals, relying extensively on *Perez*, went even farther and declined to adopt the learned intermediary doctrine at all.⁴¹

A. *The New Jersey Supreme Court's Adoption of a Narrow Exception for Direct-To-Consumer Advertising in Perez v. Wyeth Labs*

In *Perez v. Wyeth Labs.*, the plaintiffs, alleging injuries from the use of the Norplant contraceptive implant, contended that Wyeth, the manufacturer, had heavily advertised the implant without warning consumers of any risks or side effects that it posed.⁴² The lower courts ruled that the learned intermediary rule applied and that plaintiffs' claims were subject to dismissal because plaintiffs had failed to demonstrate that warnings to the prescribing physicians were inadequate and had failed to establish proximate causation by showing that a different warning to physicians would have altered their decisions to prescribe the implant.⁴³

The New Jersey Supreme Court disagreed. Quoting extensively from articles about the growing prevalence of DTC advertisements of prescription medicines, including several detailing the criticisms leveled toward such advertising by various interest groups, the court concluded that advertising prescription drugs to consumers undermined three of the four premises behind the learned intermediary doctrine: reluctance to interfere with the physician-patient relationship; what the court deemed an outmoded paternalistic approach under which the physician, not the patient, decided which medicines the patient should take; and the inability of drug manufacturers to communicate directly with patients.⁴⁴ (The court appeared

³⁸ See FDA, *Policy Development and Guidance to Industry*, available at http://www.fda.gov/cder/handbook/pol_guid.htm.

³⁹ *Perez v. Wyeth Labs.*, 734 A.2d 1245 (N.J. 1999).

⁴⁰ See *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 812 (N.D. Ohio, 2004).

⁴¹ *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899 (W. Va., 2007).

⁴² *Perez*, 734 A.2d at 1247-48.

⁴³ *Id.* at 1249.

⁴⁴ *Id.* at 1254-56.

to acknowledge in passing that a fourth premise of the doctrine—the complexity of the subject matter—was still present.)⁴⁵

The court reasoned that direct-to-consumer advertising, together with the growth of managed care, meant that what the court termed the “Norman Rockwell” image of the family doctor was no longer accurate; that managed care meant that physicians had less time to inform patients about the risks of a drug; and that manufacturers, having embraced and spent large sums on direct-to-consumer advertising, could no longer be said to lack the means to communicate effectively with consumers.⁴⁶ The court concluded that the learned intermediary doctrine was outmoded in the case of drugs marketed directly to consumers and that drug manufacturers were subject to a duty to warn consumers directly of the risks of drugs that they advertised to the general public.

However, the *Perez* court significantly limited the potential scope of this ruling by holding that when an advertisement complies with all FDA requirements, a rebuttable presumption arises that the advertisement has fulfilled the manufacturer’s duty to warn consumers of risks associated with the drug.⁴⁷ The court relied on a New Jersey statute that provides for a rebuttable presumption that a manufacturer’s duty to give an adequate warning of a drug’s risks to physicians is met when the manufacturer has complied with FDA labeling requirements. As for what would be sufficient to rebut the presumption, the court observed only that “absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive” of a failure to warn claim.⁴⁸

Finally, the court turned to the issue of proximate causation and ruled that a physician’s decision to prescribe a medication was not an intervening event that would break the chain of causation when there had been an inadequate consumer warning.⁴⁹

B. *The West Virginia Supreme Court’s Rejection of the Learned Intermediary Doctrine in its Entirety*

In 2007, in *State ex rel Johnson & Johnson v. Karl*, the West Virginia Supreme Court of Appeals, deciding what it termed an issue of first impression in West Virginia, followed a more extreme course than *Perez* and rejected the learned intermediary doctrine in its entirety.⁵⁰ In the trial court, the plaintiff contended that his wife’s death had been caused by the prescription drug Propulsid. The manufacturer and its corporate parent, relying on the learned intermediary doctrine, sought reversal of the trial court’s denial of their motion *in limine* to exclude evidence or argument that the manufacturer had any duty to warn consumers of the risks associated with the drug.⁵¹ The supreme court declined to adopt the learned intermediary doctrine and held that “manufacturers of prescription drugs are subject to the same duty to warn consumers about the risks of their products as other manufacturers.”⁵²

⁴⁵ *Id.* at 1255.

⁴⁶ *Id.* at 1255-56.

⁴⁷ *Id.* at 1259.

⁴⁸ *Id.*

⁴⁹ *Id.* at 1260-63.

⁵⁰ *Johnson & Johnson*, 647 S.E.2d at 900.

⁵¹ *Id.* at 901.

⁵² *Id.* at 914.

The *Johnson & Johnson* court traced the growth of direct-to-consumer advertising and the criticisms of the practice, quoting extensively from *Perez*, and concluded, like the *Perez* court, that the prevalence of such advertising and the advent of managed care had undermined the premises of the learned intermediary doctrine.⁵³ Pointing to judicially established exceptions to the learned intermediary doctrine, the court reasoned that there was little benefit in adopting a doctrine that, in the court's view, would have to be subject to numerous exceptions, including one for DTC advertising, in order to be justly applied.⁵⁴

The court made no attempt to address any of the staggering practical problems raised by its ruling. For example, the majority opinion did not suggest how manufacturers are to warn consumers about the risks of the thousands of prescription drugs that are not advertised and do not have FDA-approved patient labeling. Nor did the court offer any guidance on how the adequacy of warnings to consumers should be determined under West Virginia law, which, unlike New Jersey, does not have an express "safe haven" provision based on compliance with FDA risk information disclosure requirements.

V. THE CASE FOR CONTINUING TO ADHERE TO THE LEARNED INTERMEDIARY DOCTRINE

The holdings in *Perez* and *Johnson & Johnson* remain distinctly minority positions. Other courts have expressly rejected the *Perez* rationale when the claimant obtained the prescription drug from a physician in the course of the traditional physician-patient relationship and have refused to adopt the *Perez* court's ruling.⁵⁵

Despite the general reluctance of courts to follow the lead of *Perez*, however, *Johnson & Johnson* may be perceived as a renewed basis for arguments to limit or abolish the learned intermediary doctrine. Moreover, courts in a handful of jurisdictions have indicated in *dicta* a willingness to apply an exception to the learned intermediary doctrine for prescription medicines marketed directly to consumers.⁵⁶ Plaintiffs in products liability actions thus are likely to continue to assert that other courts should follow *Perez* and *Johnson & Johnson* and create an exception

⁵³ *Id.* at 902-10.

⁵⁴ *Id.* at 913.

⁵⁵ See *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 803 (E.D. Tex. 2002); *Vitanza v. Upjohn Co.*, 778 A.2d 829, 847 (Ct. 2001) ("[W]e see no reason to create an entirely new exception on the facts of the present case, where the traditional doctor-patient relationship existed, there were no communication problems, and adequate warnings were provided to the prescribing physician."). Cf. *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1147-48 (D. Ore. 1989) (applying Oregon law) (learned intermediary doctrine applied where a doctor exercised his or her "individualized medical judgment" before prescribing the product to plaintiff, even where the manufacturer promoted its product directly to consumers.) See also *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 547 n.30 (E.D. Pa. 2006), *aff'd*, ___ F.3d ___, 2008 WL 927848 (3d Cir. Apr. 8, 2008) (noting that Pennsylvania cases had refused to follow *Perez*); *In re Meridia*, 328 F. Supp. 2d at 812 n.19, 814.

⁵⁶ See, e.g., *Garside v. Osco Drug, Inc.*, 764 F. Supp. 208, 211 n.4 (D. Mass., 1991) ("In 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.'"), *rev'd on other grounds*, *Garside v. Osco Drug, Inc.*, 976 F.2d 77 (1st Cir. (Mass.), 1992); *Shanks*, 835 P.2d at 1200; *Wyeth-Ayerst Labs. Co.*, 28 S.W.3d at 93 n.5.

The California legislature is currently considering a bill that would add a provision to the California Civil Code declaring that "[m]anufacturers of prescription pharmaceutical products shall not be relieved of a duty to warn consumers of the risks and side effects solely because the product was prescribed to a patient by a physician." See A.B. 2690, 2007-08 Reg. Sess. (Cal. 2008).

to the learned intermediary doctrine, if not abandon the doctrine outright, on the ground that it is outmoded. For example, the plaintiffs in three Vioxx cases that were tried in California in 2006 and 2007 filed motions asking the court to rule that the learned intermediary doctrine did not apply because Merck had advertised Vioxx directly to consumers.⁵⁷

For the reasons that will be discussed in this section, courts should reject such arguments and continue to adhere to the learned intermediary doctrine in pharmaceutical products liability cases as long as the prescription medicine was obtained in the course of the physician-patient relationship. There is no clear evidence that the underlying assumption of *Perez* and *Johnson & Johnson*—that advertising and the movement to managed care have undermined the reasons for the learned intermediary doctrine—has been borne out in fact. Plaintiffs today may take a more active role in their healthcare decisions than in the past. However, the fundamental restrictions on access to prescription medicines remain, and the involvement of the physician in making such drugs available to patients is still required. Both patients and physicians continue to see the physician as the primary source of information about the risks and benefits of a particular patient's taking a particular medicine. Imposing on pharmaceutical manufacturers a broad duty to warn consumers directly is unsound as a matter of policy as it would lead to a serious risk of over-warning and information overload from the standpoint of consumers, and would leave trial courts with no meaningful guidance on the standard by which the adequacy of a direct warning to consumers should be determined.

A. *The Questionable Factual Assumptions That the Perez Court Made*

The exponential growth of DTC advertising from the 1980s to today has motivated a flood of commentary, both positive and negative. Surveys and other forms of study have been undertaken to accomplish the difficult task of measuring the impact of such advertising on patients and physicians and on the patient-physician relationship. Undoubtedly, the debate over the pros and cons of such advertising will continue, and parties seeking to convince a court to discard the learned intermediary doctrine in cases involving drugs marketed to consumers will no doubt continue to cite *Perez* and *Johnson & Johnson* and point to criticisms of DTC advertising as support for their position.

A key assumption of arguments for limiting or abolishing the learned intermediary doctrine, *albeit* one not always clearly expressed, is that DTC advertising not only alters the physician-patient relationship but essentially eliminates the physician's role in the choice of a prescription medicine. Perhaps the best example

⁵⁷ See Plaintiffs' Motion In Limine No. 7 To Exclude Any Evidence Or Argument Regarding The Learned Intermediary Doctrine, Grossberg v. Merck and Co., Inc.; Arrigale v. Merck & Co., Inc. (Los Angeles County Superior Court Case No. JCCP 4247, Docket Nos. BC327729 and 05CC03136) (filed May 19, 2006); Plaintiffs' Motion In Limine No. 7 To Exclude Any Evidence Or Argument Regarding The Learned Intermediary Doctrine, Arrigale v. Merck & Co., Inc.; Appell v. Merck & Co., Inc. (Los Angeles Superior Court Case No. JCCP 4247, Docket Nos. 05CC03136 and BC328858) (filed Oct. 13, 2006); Plaintiffs' Motion For Directed Verdict On Defendant's Affirmative Defense Of The Learned Intermediary Doctrine, Arrigale v. Merck & Co., Inc.; Appell v. Merck & Co., Inc. (Los Angeles Superior Court Case No. JCCP 4247, Docket Nos. 05CC03136 and BC328858) (filed Dec. 18, 2006); Plaintiff's Motion in Limine No. 7 To Exclude Any Evidence Or Argument Regarding The Learned Intermediary Doctrine, Berwick v. Merck & Co., Inc. (Los Angeles County Superior Court Case No. JCCP 4247, Docket No. BC328855) (filed March 5, 2007).

of this reasoning is this statement in *Perez*: “The fact that manufacturers are advertising their drugs and devices to consumers suggests that consumers are active participants in their healthcare decisions, *invalidating the concept that it is the doctor, not the patient, who decides whether a drug or device should be used.*”⁵⁸ Here, the court revealed the flawed logic that it followed. The conclusion—implicit in the quoted statement—that physicians do not independently weigh relevant risks and benefits in prescribing an advertised drug does not follow from the fact that the drug was advertised.⁵⁹

Other courts have recognized this fallacy in the *Perez* rationale and have rejected such reasoning. They have, instead, adopted the commonsense view that as long as a prescription drug was obtained from a physician’s prescription, the active participation of the physician in the decision to take the medicine cannot be discounted and the learned intermediary doctrine still operates.⁶⁰

The results of studies to assess the impact of DTC advertising on patients and physicians suggest that these courts were correct in concluding that the learned intermediary doctrine should not be discarded. As one example, between 1999 and 2003, FDA conducted two surveys of patients and one survey of physicians designed to obtain information about how both groups felt about DTC advertising and about how it has influenced the physician-patient relationship.⁶¹ The majority of patients reported that their primary sources of additional information about a drug after exposure to advertisements were health care providers and that exposure to advertising had not minimized the role their physicians played in decisions about medical products.⁶²

A majority of responding physicians, for their part, reported that patients exposed to prescription drug advertisements asked thoughtful questions during their visits and that they believed that such advertisements made patients more involved in their healthcare.⁶³ These are goals that proponents of prescription drug advertising have long contended are served by such advertising, but they are not developments that call for a new exception to or abrogation of the learned intermediary doctrine. The vast majority of physicians reported that their patients understood that the drugs were available only by prescription and that only a physician could make a decision about the appropriateness of a given drug.⁶⁴ Further, a majority of physicians reported no patient pressure to prescribe a particular drug and almost no physicians reported any pressure to prescribe a particular drug that would have been harmful to the patient.⁶⁵

⁵⁸ *Perez*, 734 A.2d at 1256 (emphasis added).

⁵⁹ See *Johnson & Johnson*, 647 S.E. 2d at 917 (Albright, J., dissenting) (“[T]o presume, as the majority appears to, that the mere presence of pharmaceutical advertising in our society relegates the role of the physician to a mere dispensary of prescriptions is simply not true.”).

⁶⁰ See *supra* note 55 and accompanying text. The trial court in *Perez* reached the same conclusion in ruling that the learned intermediary rule applied. It reasoned that even if a prescription drug advertising campaign has influenced a consumer to request a particular drug, “a physician is not simply relegated to the role of prescribing the drug according to the woman’s wishes.” *Perez*, 734 A.2d at 1249 (quoting *Perez v. Wyeth Labs., Inc.*, 713 A. 2d 588, 588 (N.J. Law Div. 1997)).

⁶¹ FDA, Final Report: Patients and Physicians Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs (Nov. 19, 2004), available at <http://www.fda.gov/cder/ddmac/researchka.htm>.

⁶² *Id.* at 2, 5, 86, 88.

⁶³ *Id.* at 63, 90.

⁶⁴ *Id.* at 72, 74.

⁶⁵ *Id.* at 71.

In another physician survey released in 2004 the survey participants stated that a prescription drug was discussed in only 3.1 percent of the total patient-physician visits reported in the survey. Most of the visits in which an advertised drug was discussed did not result in a prescription for the drug—most commonly because a different drug was more appropriate than the advertised drug that was discussed, or was equally effective but less costly.⁶⁶ In nearly half of the visits that did result in a prescription for an advertised drug, the physician believed that the advertised drug was the most effective drug for the patient.⁶⁷ In most of the remaining cases, physicians thought drugs other than the requested drug were equally effective, but were willing to accommodate patients' requests for specific drugs. In 5.5 percent of the visits in which physicians accommodated a patient's request for a specific drug (that is, in 0.06 percent of the total visits), the physician believed a different drug or treatment option was more effective, but did not report that the prescribed drug was more dangerous to the patient than the other drug or treatment option.⁶⁸

There are, of course, obvious problems with relying on relatively small surveys of this nature to draw definitive conclusions about how physicians and patients across the country act in relation to advertised drugs.⁶⁹ Nonetheless, responses such as those summarized above, even if not conclusive, demonstrate the fallacy behind the *Perez* and *Johnson & Johnson* courts' conclusion that the learned intermediary doctrine is now outmoded. Contrary to what the courts in those cases seemed to assume, there is little basis to say that patients are now the primary decision makers or that physicians are simply acquiescing in patient's requests without considering (and warning patients of) risks posed by the prescribed drug. Patients today have more ways to obtain information about prescription drugs than in the past, but physicians have not abdicated their traditional role in prescribing drugs, and patients still look to their physicians for guidance on the medicines they should take.

B. *The Continued Viability of the Policy Behind the Learned Intermediary Doctrine*

Imposing a tort duty on pharmaceutical manufacturers to warn consumers directly of the risks posed by prescription medicines would be unsound as a matter of policy. A likely result would be patient confusion, information overload and over-warning.

In assessing whether the learned intermediary doctrine is still sound policy, it is helpful to consider some very basic attributes of prescription drugs. Such drugs, by definition, cannot be used safely without the supervision of an authorized

⁶⁶ Weissman, *supra* note 35, at W4-226.

⁶⁷ *Id.* at W4-229.

⁶⁸ *Id.* at W4-227 (Exh. 5), W4-230. In most of the visits falling into this small category, the prescribing physician was a surgeon. For this reason, the survey's authors suggested that the prescriptions for an advertised drug might have been attributable to the patients' preference for noninvasive treatment. *Id.* at W4-230.

⁶⁹ DTC advertising of prescription medicines generates a great deal of controversy. Both proponents and opponents of such advertising can find support for their positions in various surveys and studies undertaken in the last two decades. It is not the intent of this article to present a defense of such advertising *per se* or to attempt to draw conclusions from small samples about patient and physician attitudes and behavior in the population as a whole. Rather, the significance of study results such as those summarized is that they strongly suggest that there is not enough evidence that direct-to-consumer advertising has changed the attitudes and behavior of patients and physicians in ways that mean that the traditional reasons for the learned intermediary doctrine are no longer valid.

healthcare provider.⁷⁰ Access to prescription drugs is restricted precisely because the lay public, lacking medical or other scientific training, cannot be expected to understand highly technical information about drug risks and benefits. Thus, the physician, who does have the training to understand complex drug risk and benefit information, is placed in the position of providing pertinent instructions for usage and warnings to patients about side effects that can be tailored to provide meaningful information to patients in light of their specific medical needs and history. The prescription requirement is also imposed to prevent members of the public from obtaining drugs for the wrong purposes. Again, the physician is placed in the position to ensure that medicines are chosen appropriately.

FDA's regulations governing both labeling and advertising are grounded in this view. Professional labeling is directed toward physicians, not the lay public, and it must be detailed and specific in giving physicians full information about all known side effects, contraindications, and other risks — a goal that nearly always necessitates use of highly technical language.⁷¹ At the same time, FDA encourages manufacturers to use simpler language in consumer advertisements and to prioritize the risk information given, in order to avoid information overload and patient confusion.⁷² Under this approach, the manufacturer provides the complete, invariably complex, and often voluminous risk information to the physician, who, equipped with (and trained to understand) that information, is able to consider the risks and benefits most pertinent to a specific patient's medical needs and history. The manufacturer gives consumers the most important facts about the benefits and risks of a drug in understandable language and identifies sources to consult for further information.⁷³ The physician helps the patient understand which possible risks are most pertinent to the patient's specific situation. The learned intermediary doctrine as it has traditionally been applied is fully consistent with FDA's approach to regulating both labeling and advertising. This is a strong indication that the doctrine is still viable today.

The learned intermediary doctrine also still represents a sounder policy than imposing tort liability on manufacturers for failing to warn consumers directly. If courts chose the latter course, risk-adverse pharmaceutical manufacturers would have a strong motive to opt for a one-size-fits-all approach of giving as much information as possible in connection with consumer advertisements. For example, in print advertisements, they might revert to presenting the full information about all reported adverse events contained in the professional labeling for their products rather than the more streamlined risk information in patient labeling or the "High-lights" sections in labeling approved under the 2006 Physician's Labeling Rule.⁷⁴

Providing the fullest possible risk information to consumers could lead to two possible results, both undesirable from a policy standpoint. Presented with a long list of every reported adverse side effect of a drug and unable to determine which are most pertinent to their situations, some consumers might be so concerned about risks that they forgo beneficial medication. Other consumers, again presented with detailed technical warnings that dilute the most important risk and safe usage

⁷⁰ 21 U.S.C. § 353 (b)(1).

⁷¹ See *supra* notes 11, 25 and accompanying text. See generally 21 C.F.R. § 201.56.

⁷² See *supra* notes 22-28 and accompanying text.

⁷³ See *supra* notes 32-33 and accompanying text.

⁷⁴ See *supra* notes 25, 28 and accompanying text.

information, might fail to appreciate pertinent significant risks, an outcome that could encourage inappropriate use.⁷⁵

Neither the *Perez* court nor the *Johnson & Johnson* court considered these potential adverse consequences. Other courts, however, have taken note of the dangers of over-warning. From the patient's standpoint, "a truthful warning of an uncertain or remote danger may mislead the consumer into misjudging the dangers stemming from use of the product, and consequently making a medically unwise decision."⁷⁶ In fact, courts have recognized that even physicians are subject to the risks of over-warning. As one court observed, "if every report of a possible risk, no matter how speculative, conjectural, or tentative imposed an affirmative duty to give some warning, a manufacturer would be required to inundate physicians indiscriminately with notice of any and every hint of danger, thereby inevitably diluting the force of any specific warning given."⁷⁷

As has been discussed, FDA has also expressed concern over the risk of over-warning, explaining that both underutilization of beneficial medicines and inappropriate use or overuse of medicines can result.⁷⁸ It has noted that "defensive labeling" by drug manufacturers could dilute the most serious risks of a medicine and thus "could result in scientifically unsubstantiated warnings and underutilization of beneficial treatments."⁷⁹ It has also observed that over-warning patients runs the risk of "potentially discouraging safe and effective use of approved products or encouraging inappropriate use...."⁸⁰

The continued value of the learned intermediary doctrine today is that it functions in tandem with FDA's regulation of prescription drug labeling and advertising to help avert these undesirable outcomes. The doctrine recognizes that most consumers cannot be expected to understand complex drug risk information that is of necessity couched in technical scientific terms. Thus, it holds manufacturers responsible for providing an accurate and complete warning to physicians, who still today are in the best position to advise patients on the risks and benefits of drugs and provide meaningful warnings.

C. *The Lack of a Workable Standard for Determining an Adequate Warning to Consumers under Perez or Johnson & Johnson*

Closely related to the serious policy concerns that *Perez* and *Johnson & Johnson* raise are the significant practical problems at the trial court level that would arise if the learned intermediary doctrine were disregarded when a drug has been advertised to consumers. Neither *Perez* nor *Johnson & Johnson* offers meaningful guidance to courts and litigants on what the appropriate standard should be for determining whether a warning to consumers in an advertisement is adequate. In part, this is a result of the procedural postures in which the rulings were issued. *Perez* involved a motion for summary judgment, and in *Johnson & Johnson* the court was reviewing the denial of a motion *in limine*. Neither court actually had to consider the adequacy of a warning to a consumer in light of specific facts.

⁷⁵ See *infra* notes 79-80 and accompanying text.

⁷⁶ Dowhal v. SmithKline Beecham Consumer Healthcare, 88 P.3d 1, 14 (2004). See also *supra* note 9.

⁷⁷ *Carlin*, 920 P.2d at 1347 (citations and internal quotation marks omitted).

⁷⁸ See *supra* text accompanying notes 26-28.

⁷⁹ 71 FED. REG., *supra* note 12, 3935.

⁸⁰ *Id.*

In fact, the *Perez* court candidly acknowledged that it did not have all of the facts about the advertising of Norplant before it. And it conceded that the implant device did not “afford the best context in which to address the general question whether direct-to-consumer marketers of pharmaceutical products are unqualifiedly relieved of a duty to warn consumers of the dangerous propensities of a product.”⁸¹

The *Johnson & Johnson* opinion is of even less help to courts and practitioners. The court made the sweeping announcement that “manufacturers of prescription drugs are subject to the same duty to warn consumers about the risks of their products as other manufacturers.”⁸² But the court offered almost no consideration of the practical consequences of its ruling, not only to drug manufacturers,⁸³ but to judges and litigants at the trial court level.

Parties asking a court to impose on drug manufacturers a duty to warn consumers directly about prescription drug risks might ask the court to adopt the standards currently used for deciding whether a warning to *physicians* is adequate or, alternatively, to look to the standards for assessing the reasonableness of warnings to consumers in general products liability cases. Neither standard is appropriate for use when the question is the adequacy of a warning about the risks of a prescription drug.

The risk profile of a prescription drug is inherently complex, as even the *Perez* court had to acknowledge.⁸⁴ The standard for determining whether a warning to a physician is adequate would not be appropriate because it necessarily accepts the use of complex scientific language that lay members of the public are unlikely to comprehend fully:

Whether a given warning is legally adequate or presents a factual question for resolution by a jury requires a careful analysis of the warning's language. The court must examine not only the meaning and informational content of the language but also its form and manner of expression. *Always bearing in mind that the warning is to be read and understood by physicians, not laypersons*, the factors to be considered in resolving this question include whether the warning is accurate, clear, consistent on its face, and whether it portrays with sufficient intensity the risk involved in taking the drug.⁸⁵

It would also not be workable to appropriate the standard under general products liability law for determining whether a warning of dangers from a consumer product is adequate. Broadly speaking, manufacturers and product sellers must provide a

⁸¹ *Perez*, 734 A. 2d at 1263.

⁸² *Johnson & Johnson*, 647 S.E.2d at 914.

⁸³ To provide just a few examples, the majority opinion in *Johnson & Johnson* made no real attempt to address how pharmaceutical manufacturers are to warn consumers of the risks of the many prescription drugs that do not have FDA-approved patient labeling and are not advertised, nor did it consider how manufacturers are to warn patients directly about the risks of prescription drugs administered in hospitals. One concurring opinion pointed to the latter situation as an area where a duty to warn end-users directly would not be feasible, and suggested in passing that to fulfill the duty the court was imposing “[l]abels can be placed on bottles, pamphlets tucked into boxes, and brochures packed in with the boxes of drugs and devices....” See *Johnson & Johnson*, 647 S.E.2d at 920 (Maynard, J., concurring) The majority reasoned that what it characterized as a “plethora” of exceptions to the learned intermediary doctrine meant that there was “no benefit in adopting a doctrine that would require the simultaneous adoption of numerous exceptions in order to be justly utilized.” 647 S.E.2d at 913. There is considerable irony in this comment since it is evident that many extremely broad “exceptions” to its own ruling would have to be recognized to make the ruling “justly utilized” or workable at all in the real world.

⁸⁴ *Perez*, 734 A.2d at 1255.

⁸⁵ *Martin*, 628 N.E. 2d at 1312 (emphasis added). See also *supra* note 11 and accompanying text.

warning sufficient to make the product reasonably safe when put to reasonably foreseeable use.⁸⁶ The risk of injury from a piece of equipment that contains a sharp cutting blade does not vary significantly with the individual using the equipment, and it makes sense to ask juries to determine if a standard warning provided with the equipment makes the product reasonably safe. The risk of experiencing an adverse side effect from taking a prescription medicine, by contrast, varies greatly depending on the specific characteristics of the person who takes it, including the individual's medical history and condition and other drug usage. Given that variation, a warning adequate to make a prescription drug reasonably safe for one potential user will differ from the warning adequate to make the medicine reasonably safe for another user.⁸⁷ This is a fundamental reason why the learned intermediary doctrine recognizes that the intervention of the physician is crucial and requires that the manufacturer give a full warning about known adverse side effects to the physician, rather than to the patient. The reasonable user concept that is inherent in the general tort law standard for determining whether a warning is adequate is not a good fit in this situation.⁸⁸

A court inclined to impose a tort duty on pharmaceutical manufacturers to warn consumers directly could mitigate somewhat the problem of the appropriate standard for judging adequacy of a warning by recognizing, as *Perez* did, a rebuttable presumption of adequacy based on compliance with FDA regulations. Such a showing on the part of the manufacturer would be "virtually dispositive" unless the plaintiff were able to show "deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects."⁸⁹ The continued viability of this standard

⁸⁶ RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(c) ("A product...is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor...and the omission of the instructions or warnings renders the product not reasonably safe.")

⁸⁷ Some courts have recognized exceptions to the learned intermediary doctrine that require the fact-finder to evaluate the reasonableness of a standardized warning directed to end-users in the case of mass vaccinations, where a physician may not even be present (*see, e.g., Reyes*, 498 F.2d at 1277), and in the case of oral contraceptives, which are typically prescribed to healthy patients who take them for long periods of time without being seen by a physician, and which are dispensed with direct warnings to patients required by FDA. *See MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 68-70 (Mass. 1985). These exceptions are narrowly drawn and were developed in view of the very specific characteristics of the medical products involved that make them different from most prescription medicines. *See, e.g., MacDonald*, 475 N.E. 2d at 70 ("The oral contraceptive...stands alone from other prescription drugs [.]") They are not universally recognized. In *Norplant Contraceptive Prods. Liab. Litig.*, 955 F. Supp. 700, 704, 707 (E.D. Tex., 1997), the court noted that "[o]nly a single jurisdiction, Massachusetts, recognizes an exception to the doctrine for prescription contraceptives" and rejected the contraceptive exception because "[e]ven if it were true that women play a greater role in selecting among prescription contraceptives, these products are nevertheless available only by prescription from a physician. The fact that the patient plays a role in deciding to use a particular prescription drug does not diminish the physician's role in determining her suitability for different drugs and in counseling with her as to the benefits and potential risks of each." *Id.* at 707. *See also Mazur v. Merck & Co., Inc.*, 742 F. Supp. 239, 253 (E.D. Pa., 1990) (stating that "[a]ll of the vaccine cases recognize the theoretical validity of the 'mass immunization exception' to the learned intermediary rule, but very few have found situations where its application is warranted.").

⁸⁸ *See McKee v. American Home Products Corp.*, 782 P.2d 1045, 1050-51 (Wash., 1989) ("The foreseeability of injury to an individual consumer in the absence of any particular warning...varies greatly depending on the medical history and condition of the individual."); *Leesley v. West*, 518 N.E.2d 758, 762 (Ill. App. 2 Dist., 1988 (same; also noting that "[t]he fact that manufacturers of a prescription drug cannot adequately evaluate the effect of the drug on any particular patient is one of the predominant reasons that courts have adopted the learned intermediary doctrine exempting those manufacturers from the duty to directly warn consumers").

⁸⁹ *Perez*, 734 A.2d at 1259.

for rebutting the presumption of adequacy, however, is uncertain.⁹⁰ Moreover, courts in states that do not have statutes similar to the New Jersey statute providing for a presumption of adequacy based on compliance with applicable regulatory requirements might be reluctant to create such a presumption by judicial decision.⁹¹

VI. CONCLUSION

DTC advertising of prescription drugs has made consumers more aware of prescription medicines and medical devices that are available, but it has not changed the fundamental role that the physician plays in the decision whether a patient should use a prescription drug or device. Patients understand this, and they still look to their physicians as the primary source of guidance on whether to take prescription medicines. There is little evidence to suggest that physicians no longer consider the unique needs of their patients in choosing drugs to prescribe or that they passively acquiesce when patients request specific medicines without considering the drug's benefits and risks.

Far from being outmoded in the current environment, the learned intermediary remains viable because it is consistent with the fundamental premises of the prescription requirement and FDA's regulation of prescription drug labeling and advertising. It also helps to ensure a uniform, workable standard of conduct for pharmaceutical manufacturers who sell their products in a national market. Courts should decline to recognize an exception to the doctrine for drugs marketed directly to consumers or to abrogate the doctrine altogether.

⁹⁰ *Perez* held that the presumption that a warning that complied with FDA requirements was adequate could be rebutted by showing that the manufacturer deliberately withheld safety information from FDA that, if disclosed, would have changed what FDA required to be included in labeling or advertising. *Perez*, 734 A.2d at 1259. In the authors' view, claims of "fraud on FDA" in this context are foreclosed by the Supreme Court's ruling in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In *Buckman*, the Court held that state tort claims directly asserting that a pharmaceutical manufacturer deliberately concealed information from FDA are preempted because allowing such claims would interfere with FDA's ability to police compliance with its own regulatory requirements. *Buckman*, 531 U.S. at 350. Courts have split on whether similar misrepresentations or concealment claims made in order to rebut the presumption of an adequate warning are also pre-empted under the rationale of *Buckman*. This issue was before the Court earlier this year in *Warner-Lambert v. Kent*, but the Court's disposition of the case did not resolve the issue because the decision was a 4-4 split after Chief Justice Roberts recused himself from the case. See *Warner-Lambert Co., LLC v. Kent*, 128 S.Ct. 1168 (Mem) (Mar. 3, 2008).

The broader issue whether FDA's approval of a drug and its determination of what should be included in the drug labeling information impliedly preempt state law failure-to-warn claims is presented in *Wyeth v. Levine*, 128 S. Ct. 1118 (Mem) (2008) (No. 06-1249), which the Supreme Court will hear in the fall of 2008.

⁹¹ Only a minority of jurisdictions recognize a rebuttable presumption of adequacy based on compliance with FDA requirements or on compliance with applicable governmental regulatory requirements in general. See COLO. REV. STAT. ANN. § 13-21-403(1)(b) (2007); FLA. STAT. ANN. § 768.1256(1) (2007); IND. CODE ANN. §34-20-5-1(2)(2007); KAN. STAT. ANN. § 60-3304(a)(2007); MICH. COMP. LAWS 600.2946(4)(2007); N.J. STAT. ANN. § 2A: 58C-4 (2007); N.D. CENT. CODE § 28-01.3-09 (2007); TEX. CIV. PRAC. & REM. CODE § 82.007(a) (2007); UTAH CODE ANN. § 78-15-6(3)(2007).