

By Christopher Q. Pham

The Learned Intermediary Doctrine and DTC Advertising

Prescription drug manufacturers may face added liability for ads directed at consumers

Today, most people are accustomed to seeing advertisements for prescription drugs during their favorite television shows.¹ These advertisements feature prescription drugs of all types, from allergy medications to pills for erectile dysfunction. According to the U.S. General Accounting Office, an estimated 8.5 million U.S. residents per year receiving prescription drugs asked for them by name from their physicians after seeing an advertisement.² Many people also are aware that prescription drugs may be purchased via the Internet.

Direct-to-consumer (DTC) advertising by drug manufacturers is relatively new and, not surprisingly, has sparked myriad legal issues and lawsuits. Indeed, if a prescription drug or medical device causes personal injury, plaintiffs typically seek a deep pocket and sue the manufacturer, employing a variety of legal theories and claims. These theories most often include the allegation that the manufacturer failed to provide

adequate warnings regarding the use of the product and its risks.

In its defense, a drug manufacturer invariably argues that it is shielded from liability under the learned intermediary doctrine, which is predicated on the cherished physician-patient relationship. Nevertheless, the courts have continued to struggle with the applicability of the learned intermediary doctrine under circumstances in which drug manufacturers advertise directly to the consumer. Who has the duty to adequately warn the consumer—the physician under the learned intermediary doctrine or the drug manufacturer that engages in DTC advertising?

After decades of advertising only to health professionals, drug manufacturers first sought approval from the Food and Drug Administration in 1983 to advertise directly to the consumer through broadcast media, including telecommunications and television.³ A two-year voluntary moratorium on DTC advertising ensued, which the FDA lifted on September 9, 1985, stating that existing laws adequately addressed the legal issues involving DTC advertising.⁴

Federal regulations distinguish print from broadcast advertising.⁵ Under Section 502(n) of the Food, Drug, and Cosmetic Act, print advertisements for prescription drugs and medical devices must include what Section 502(n) terms a

“brief summary” containing a product’s indications, contraindications, and effectiveness.⁶ The brief summary requirement is easily satisfied by placing in an ad the warning language of the inserts found in FDA-approved labeling. In contrast, broadcast advertising (including radio, television, and the Internet) must contain the brief summary and what is termed a “major statement” presenting the results of clinical testing and the product’s major side effects.⁷ Until recent regulatory changes, the disclosure requirements of the brief summary and the major statement made DTC advertising cost-prohibitive for drug manufacturers due to the limited space and time available to fulfill the requirements.

In August 1999, the FDA issued its Guidance for Industry: Consumer-Directed Broadcast Advertisements.⁸ Instead of the brief summary and the major statement, the FDA’s guidance suggests that DTC broadcast advertising, which is product specific, contain an “adequate provision,”⁹ which must include four elements: 1) a toll-free telephone number for consumers to obtain product information, 2) identification of a current publication that contains a summary of FDA-approved labeling for the product, 3) a statement advising consumers to consult with their health care provider, and 4) an Internet Web site address that contains product information.¹⁰ The object of the adequate provision is to ensure that consumers are informed of various resources to which they can refer for information that is required in the brief

summary and major statement.

By complying with the adequate provision prong in the FDA’s guidance, drug manufacturers essentially can satisfy the brief summary and major statement requirements and do so in a cost-effective manner. Thus the adequate provision provided the impetus for drug manufacturers to launch full-scale DTC advertising programs in broadcast media.

Exceptions to the Doctrine

Under the learned intermediary doctrine, a drug manufacturer only has the duty to provide warnings to the physician—not the patient—of foreseeable health risks associated with a drug.¹¹ Clearly a physician is in the best position to understand a patient’s medical needs and to assess the benefits and risks posed by a particular drug.¹² Thus, the physician is the “learned intermediary” between the drug manufacturer and the patient and is responsible for providing the necessary warnings to the patient.¹³ The learned intermediary doctrine and its public policy implications have been adopted by “an overwhelming number of jurisdictions,” including California.¹⁴

With the publication of the *Restatement (Third) of Torts* in 1997, the American Law Institute adopted the learned intermediary doctrine, but with several exceptions.¹⁵ Specifically, the manufacturer may have a duty to warn the consumer directly if there is a “limited therapeutic relationship” between the physician and the patient, such as when “the physician or other

Christopher Q. Pham is an associate in the Products Liability Department of the Los Angeles office of Sedgwick, Detert, Moran & Arnold LLP. Two partners at the firm, Ralph Campillo and Steven Di Saia, assisted with this article.

health-care provider has a much-diminished role as an evaluator or decision-maker.”¹⁶ One specifically cited example in the restatement is the “administration of a vaccine in clinics where mass inoculations are performed.”¹⁷ The dilution of the physician-patient relationship when vaccines are dispensed at a clinic “without [the physician providing] the sort of individualized medical balancing of risks to the vaccinee” defeats the objective of the learned intermediary doctrine.¹⁸ However, outside the realm of mass immunizations in clinical settings, when a vaccination is performed by a physician who consults with the patient, the doctrine remains applicable and the drug manufacturer need only warn the physician.¹⁹

Courts also have carved out exceptions to the doctrine. Various courts have refused to apply the learned intermediary doctrine in personal injury actions involving oral contraceptives. The learned intermediary doctrine is inapplicable in that context because 1) the patient, not the physician, chooses to take the contraceptive, 2) minimal physician-patient consultation is required, and 3) oral contraceptives are already federally regulated to a great extent, which ensures that a patient choosing to take oral contraceptives is doing so with informed consent.²⁰

However, courts are split on whether to apply the learned intermediary doctrine to cases involving intrauterine devices (IUDs). The Fourth and Sixth Circuits have held that since IUDs are only available through a doctor’s prescription, the learned intermediary doctrine applies,²¹ but the Eighth Circuit has held that “IUDs, like other forms of birth control, are atypical from most prescription drug products because the treating physician generally does not make an intervening, individualized medical judgment in the birth control decision.”²²

Additionally, when a drug manufacturer engages in excessive marketing of a drug or deemphasizes a drug’s side effects, courts have found that the manufacturer has waived the protection under the learned intermediary doctrine. In *Stevens v. Parke, Davis & Company*, the California Supreme Court held that “an adequate warning to the profession may be eroded or even nullified by over promotion of the drug through a vigorous sales program which may have the effect of persuading the prescribing doctor to disregard the warnings given.”²³ The court found that the drug manufacturer encouraged its sales force to promote the drug by making personal visits to physicians’ offices, during which no verbal warnings were given, although written warnings were included in the brochures that were distributed to the physicians.²⁴

The *Stevens* court further found that the drug manufacturer’s promotional “give-aways”—samples of the drug—also failed to include warnings of the drug’s side effects and contraindications.²⁵ The court held that although a drug manufacturer may be in strict compliance with regulations and directives promulgated by the FDA, this compliance “[is] only minimal in nature and when the manufacturer or supplier knows of, or has reason to know of, greater dangers not included in the warning, its duty to warn may not be fulfilled.”²⁶ The court found that the drug manufacturer “watered down” its warnings by overpromoting its drug with samples that hailed the effectiveness of the drug without mentioning the drug’s side effects.²⁷

The Doctrine and DTC

Is there a DTC exception to the learned intermediary doctrine? One court in one state says that there is: The New Jersey Supreme Court, in *Perez v. Wyeth Laboratories*,²⁸ accepted the invitation of the American Law Institute in the *Restatement (Third) of Torts* to rule on this issue. The restatement first summarizes the arguments for and against applying the learned intermediary doctrine to DTC advertising:

Those who assert the need for adequate warnings directly to consumers contend that manufacturers that communicate directly with the consumers should not escape liability simply because the decision to prescribe the drug was made by the health-care provider. Proponents of the learned intermediary rule argue that, notwithstanding direct communications to the consumer, drugs cannot be dispensed unless a health-care provider makes an individualized decision that a drug is appropriate for a particular patient, and that it is for the health-care provider to decide which risks are relevant to the particular patient.²⁹

The drafters of the *Restatement (Third) of Torts* ultimately refused to take a position on the debate and instead left it to “developing case law” to decide the fate of the learned intermediary doctrine in connection with DTC advertising.³⁰

Shortly after the publication of the *Restatement (Third) of Torts*, the Fifth Circuit Court of Appeals in *In re Norplant Contraceptive Products Liability Litigation* rejected the DTC exception to the learned intermediary rule.³¹ The court was not persuaded by the plaintiffs’ argument that the “physician’s reduced role” in selecting a form of contraceptive for patients “invalidates the rationale of the learned intermediary doctrine because the patient cannot rely on the

physician to provide an adequate warning.”³² The court held:

Although it may be true that physicians may seek to provide greater freedom to their patients in selecting an appropriate form of contraception, Norplant is nevertheless a prescription drug. The record makes it clear that physicians play a significant role in prescribing Norplant and in educating their patients about the benefits and disadvantages to using it. [The plaintiffs’] argument therefore is unavailing.³³

Less than three months after that opinion, in another case involving Norplant implants, the *Perez* court adopted the DTC exception to the learned intermediary doctrine.³⁴ In *Perez*, the New Jersey Supreme Court held that the learned intermediary doctrine is inapplicable when prescription drugs are directly marketed to the consumer. The court found that DTC advertising “alters the calculus of the learned intermediary doctrine.”³⁵ The court held that since Wyeth Laboratories directed its advertising campaign for Norplant—a contraceptive capsule implanted under the skin—at women, rather than physicians, the concept of the traditional physician-patient relationship does not apply.

The *Perez* court held that the justifications for applying the learned intermediary doctrine—the complexity of the product information, the physician’s superior capability to communicate complex information, the manufacturers’ inability to communicate personally with an individual patient in order to understand the patient’s unique medical condition, and judicial reluctance to intrude on physician-patient relations—are eroded when a manufacturer communicates directly with the consumer.³⁶ The court reasoned that the fact that drug manufacturers are choosing to communicate directly with consumers, rather than physicians, invalidates the notion that a physician, not a patient, decides whether a product should be used. Also, the court found that DTC advertising undermines the physician-patient relationship even when the advertising encourages consumers to consult first with a physician.

Lastly, since the FDA requires detailed warnings in the package inserts of prescription drugs, the consumer may reasonably presume that such warnings are adequate.³⁷ Therefore, the *Perez* court reasoned that a drug manufacturer who advertises directly to consumers cannot hide behind the shield of the learned intermediary doctrine if that manufacturer fails to provide adequate warnings to consumers. However, the *Perez* court also held that if the drug manufacturer complied with FDA labeling and advertising require-

DAVID OSTROVE ■ ATTORNEY—CPA

- Expert Witness — 43 years
- Lawyer/Accountant Malpractice
- Forensic Accounting
- Tax Matters
- Business Valuation
- Value of Services
- Computation of Damages
- Mediator, Arbitrator



323/939-3400 dostrove@comcast.net

Judgments Enforced

Law Office of Donald P. Brigham

23232 Peralta Dr., Suite 204, Laguna Hills, CA 92653

P: 949.206.1661

F: 949.206.9718

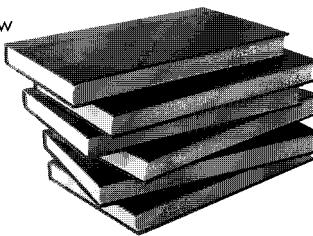
dbrigham@earthlink.net

AV Rated

Results!

Defining the firm of **Cohen, Miskei & Mowrey.**

- Economic Damages
- Fraud Investigations
- Bankruptcy and Reorganization Services
- Business and Professional Practice Valuations
- Expert Witness Services
- Family Law including:
Asset Tracing, Cash Flow
Available for Support,
Lifestyle Analysis and
Post-Separation
Accounting



COHEN, MISKEI & MOWREY LLP.

Certified Public Accountants and
Consultants to Counsel and Management

15303 VENTURA BOULEVARD, SUITE 1150, SHERMAN OAKS, CA 91403
TEL: 818.986.5070 FAX: 818.986.5034

ments, the manufacturer is entitled to a rebuttable presumption that the warning was adequate. The court cautioned that drug manufacturers should not be made the “guarantors against remotely possible, but not scientifically-verifiable, side-effects of prescription drugs, a result that could have a ‘significant anti-utilitarian effect.’” Thus a drug manufacturer’s compliance with FDA standards and regulations is dispositive of any claim of liability.³⁸

While *Perez* was the first court to adopt the DTC exception to the learned intermediary doctrine, it also reinforced the rule that a manufacturer of a prescription drug or medical device is not required to warn a physician of every conceivable risk.³⁹ In *Brown v. Superior Court*, the California Supreme Court adopted the *Restatement (Second) of Torts*, Section 402A, Comment k by holding that manufacturers of prescription drugs or medical devices can only be liable under a products liability theory if they are found to have failed to warn of known dangers or dangers about which the manufacturers should have known.⁴⁰ A product manufacturer is not required to warn of risks that are unknown or risks that are commonly known to the medical community.⁴¹ Additionally, if a physician has specific knowledge of a risk associated with a drug or medical device, there is no liability to the manufacturer for a failure to warn because the manufacturer is not the cause of the injury.⁴² California courts have since extended the *Brown* exception and granted Comment k protection specifically to all implanted medical devices that may only be sold to, or on the order of, physicians.⁴³ As a matter of public policy, unless drug manufacturers are shielded from liability against claims of inadequate warning, the costs of litigating these claims would shift to the consumer and would thus make life-saving and life-improving drugs unaffordable.⁴⁴

No other court has adopted the DTC exception recognized in *Perez*, so the influence of this one opinion remains to be seen. Presently, with the exception of New Jersey, 49 states, as well as the District of Columbia and Puerto Rico, have not addressed the applicability of the learned intermediary doctrine to DTC advertising.⁴⁵ As the drafters of the *Restatement (Third) of Torts* noted, whether a DTC exception to the learned intermediary doctrine is adopted should be left in the hands of the courts. To date, most jurisdictions, including California, still support the traditional notion that the physician is the learned intermediary between the manufacturer and the patient, with few exceptions. Manufacturers, doctors, and consumers in California and the other jurisdictions in which courts have been silent about a DTC excep-

tion must continue to wait for judicial guidance on this issue. ■

¹ In a recent survey of television viewers, 30 percent reported that they spoke to their physicians regarding a specific prescription drug they saw in a television advertisement. Among the 30 percent, 44 percent reported that their physicians prescribed the drug they requested. *Kaiser Family Foundation, New Reports Show Impact of Direct-to-Consumer Advertising and Trends in Prescription Drug Spending and Utilization* (Nov. 2001), available at <http://www.kff.org/content/2001/20011129a/> (last visited Mar. 29, 2003).

² Aparna Kumar, *Doctors Split on Usefulness of Drug Advertising*, L.A. TIMES, Jan. 14, 2003, at 12.

³ Lance S. Gilgore, *A Consideration of Direct-to-Consumer Advertising of Prescription Drugs and Potential Legal Problems with the Brief Summary Requirement: Is the FDA's Regulatory Authority Illusory?*, 46 FOOD DRUG COSM. L.J. 849, 851 (1991).

⁴ Direct-to-Consumer Advertising of Prescription Drugs; Withdrawal of Moratorium, 50 Fed. Reg. 36677 (Sept. 9, 1985). The moratorium was the result of the FDA's request for further investigation and discussion of the effects on consumers of DTC advertising as they relate to existing FDA standards and regulations.

⁵ 21 C.F.R. §202.1.

⁶ 21 U.S.C. §352(n); 21 C.F.R. §202.

⁷ 21 C.F.R. §202.1(e) (1).

⁸ Center for Drug Evaluation and Research, Food and Drug Administration, *Guidance for Industry: Consumer-Directed Broadcast Advertisements* (Aug. 1999), available at <http://www.fda.gov>.

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Carlin v. Superior Court of Sutter County*, 13 Cal. 4th 1104, 1126 (1996).

¹² *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 989 (1971).

¹³ See *Sterling Drug, Inc. v. Cornish*, 370 F. 2d 82, 85 (8th Cir. 1966) (in which a court first used the term "learned intermediary" to describe the role of the physician in the tripartite relationship between the drug manufacturer, the physician, and the patient. The court held that the drug manufacturer had a duty to warn the learned intermediary, not the patient, of a drug's side effects.).

¹⁴ *Pumphrey v. C.R. Bard, Inc.*, 906 F. Supp. 334, 338 (N.D. W.Va. 1995); *Carmichael*, 17 Cal. App. 3d at 989.

¹⁵ RESTATEMENT (THIRD) OF TORTS, *Products Liability* §6(d) (1997).

¹⁶ *Id.* at §6, cmt. b.

¹⁷ *Id.* at §6, cmt. e; see, e.g., *Brazzell v. United States*, 788 F. 2d 1352, 1358-59 (8th Cir. 1986) (The government was directly liable to the consumers for failure to warn that prolonged muscle soreness is a possible side effect of swine flu vaccine.); *Davis v. Wyeth Labs.*, 399 F. 2d 121, 130 (9th Cir. 1968) (Manufacturer of polio vaccine was directly liable to consumers for failure to warn that contracting polio is a side effect of polio vaccine.).

¹⁸ *Reyes v. Wyeth Labs.*, 498 F. 2d 1264, 1276 (5th Cir. 1974), cert. denied, 419 U.S. 1096 (1974).

¹⁹ *Plummer v. Lederle Labs.*, 819 F. 2d 349, 356-7 (2d Cir. 1987), cert. denied, 484 U.S. 898 (1987).

²⁰ *Stephens v. G.D. Searle*, 602 F. Supp. 379, 380-81 (E.D. Mich. 1985); *Odgers v. Ortho Pharm. Corp.*, 609 F. Supp. 867, 874-75, 878-79 (E.D. Mich. 1985).

²¹ *Odom v. G. D. Searle & Co.*, 979 F. 2d 1001 (4th Cir. 1992); *Beyette v. Ortho Pharm. Corp.*, 823 F. 2d 990 (6th Cir. 1987).

²² *Hill v. Searle Labs.*, 884 F. 2d 1064, 1070 (8th Cir. 1989).

²³ *Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51, 65 (1973).

²⁴ *Id.* at 58.

²⁵ *Id.*

²⁶ *Id.* at 65.

²⁷ *Id.* at 66.

²⁸ *Perez v. Wyeth Labs.*, 734 A. 2d 1245, 1248-49 (N.J. 1999).

²⁹ RESTATEMENT (THIRD) OF TORTS, *Products Liability* §6, cmt. e (1997).

³⁰ *Id.*

³¹ *In re Norplant Contraceptive Prods. Liab. Litig.*, 165 F. 3d 374, 378-79 (5th Cir. 1999).

³² *Id.* at 379.

³³ *Id.*

³⁴ *Perez v. Wyeth Labs.*, 734 A. 2d 1245, 1248-49 (N.J. 1999).

³⁵ *Id.* at 1254.

³⁶ *Id.* at 1255.

³⁷ *Id.* at 1256.

³⁸ *Id.* at 1259.

³⁹ *Plenger v. Alza Corp.*, 11 Cal. App. 4th 349, 362 (1992).

⁴⁰ *Brown v. Superior Court*, 44 Cal. 3d 1049, 1068-69 (1989).

⁴¹ *Carlin v. Superior Court of Sutter County*, 13 Cal. 4th 1104, 1116 (1996).

⁴² *Plenger*, 11 Cal. App. 4th at 362.

⁴³ See, e.g., *Artiglio v. Superior Court*, 22 Cal. App. 4th 1388, 1396-97 (1994) (breast implants); *Hufft v. Horowitz*, 4 Cal. App. 4th 8, 16-17 (1992) (penile implants); *Plenger*, 11 Cal. App. 4th at 362 (IUDs).

⁴⁴ *Brown*, 44 Cal. 3d at 1065-66.

⁴⁵ *Allen Wong, Recent Developments in Health Law: Harvard Law & Health Care Society: Products Liability: The Fate of the Learned Intermediary Doctrine*, 30 J.L. MED. & ETHICS 471 (Fall 2002).

■ IMMIGRATION LAW ■

■ CONSULAR PROCESSING

■ EMPLOYER SANCTIONS (I-9)

■ DESIGN CORPORATE IMMIGRATION POLICIES

■ EXPERT TESTIMONIAL SERVICES

■ TEMPORARY WORK VISAS

■ Intra-Company Transfers

■ Entertainers & Sports Professionals

■ NAFTA (North American Free Trade Agreement) Visas

■ Professionals & Investors

■ Blue/White Collar Employee Immigration Assistance

■ LABOR CERTIFICATIONS

■ FAMILY RELATED PETITIONS

■ OUTBOUND VISA CAPABILITY

■ IMMIGRATION RELATED DUE DILIGENCE in Mergers & Acquisitions & Corporate Restructuring

DON'T PLAY AROUND WHEN IT COMES TO IMMIGRATION LAW

Newport Beach
4685 MacArthur Court, Suite 400
Newport Beach, CA 92660
phone 949-251-8844
fax 949-251-1545
email hirson@hirson.com



HIRSON WEXLER PERL

ATTORNEYS AT LAW

AV Rated

Los Angeles
6310 San Vicente Blvd., Suite 415
Los Angeles, CA 90048
phone 323-936-0200
fax 323-936-4488
email hirson-la@hirson.com

www.hirson.com • also in San Diego, CA • Phoenix, AZ • Las Vegas, NV • New York, NY • Wilton, CT • Toronto, Canada

David Hirson and Mitchell L. Wexler are certified by the State Bar of California Board of Legal Specialization as specialists in Immigration and Nationality Law. All matters of California state law are provided by active members and/or under the supervision of active members of the California State Bar.