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**DIRECT-TO-CONSUMER ADVERTISING AND THE
LEARNED INTERMEDIARY DOCTRINE: UNSETTLING A
SETTLED QUESTION**

Paul F. Strain†
Christina L. Gaarder††

I. INTRODUCTION

The learned intermediary doctrine provides that “a manufacturer of a prescription drug has a duty to warn only physicians, not patients, of potential risks associated with the use of the drug.”¹ This duty, also known as the patient-notice requirement, applies only to physicians because the doctor “is in the best position to understand the patient’s needs and assess the risks and benefits of a particular course of treatment.”² Many states adopted this legal theory,³ and section 6 of the

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1. *Hunt v. Hoffmann-La Roche, Inc.*, 785 F. Supp. 547, 550 (D. Md. 1992). The learned intermediary theory has been applied to medical devices as well as prescription drugs. *Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89, 95 (D. Md. 1989) (holding that, under the learned intermediary doctrine, the manufacturer of a breast prosthesis had no duty to warn the consumer of possible risks associated with the product); see also *infra* notes 8-13 and accompanying text for the definition of the learned intermediary doctrine as it is set forth in the *Restatement (Third) of Torts* (“*Restatement (Third)*”).
2. *Lee*, 721 F. Supp. at 95. A number of other theories have been raised supporting the rationale of the learned intermediary doctrine. In *West v. Searly & Co.*, 806 S.W.2d 608 (Ark. 1991), the Arkansas Supreme Court stated that in many cases it would be almost impossible for a manufacturer to directly warn consumers and, furthermore, a duty to warn would interfere with the doctor-patient relationship. *Id.* at 613. Similarly, in *Brown v. Super. Ct.*, 751 P.2d 470 (Cal. 1988), the Supreme Court of California expressed concern that increasing the liability for manufacturers would drive up the cost of medication making it unaffordable to many patients. *Id.* at 479. See also RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6, cmt. b (1998)

Restatement (Third) of Torts: Products Liability ("Restatement (Third)") provides for it as well.⁴ The *Restatement (Third)*'s adoption of section 6, however, may place the learned intermediary doctrine in peril.⁵ In certain circumstances, section 6 the *Restatement (Third)* imposes the duty to warn patients of the risks associated with medical devices and pharmaceuticals on drug manufacturers, rather than doctors.⁶ This change in the *Restatement* creates an environment more conducive to direct attacks on manufacturers under a duty to warn theory. In the *Restatement (Third)*, the theory promulgated by this expanded patient-notice requirement became an actuality when it was adopted by at least one jurisdiction.⁷

II. PATIENT NOTICE OFFERED BY THE *RESTATEMENT (THIRD)*

The learned intermediary doctrine, as set forth in section 6 of the *Restatement (Third)*, provides that a manufacturer of prescription drugs or medical devices is subject to liability if its product is defective by virtue of a manufacturing defect, a design defect, or a failure to warn.⁸ Section 6 also suggests that the manufacturer may have the duty to warn patients directly in some circumstances.⁹ Section 6, subsection (d) states:

(explaining the rationale behind the learned intermediary doctrine) [hereinafter *RESTATEMENT (THIRD)*]; Teresa Moran Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 *FOOD DRUG COSM. L.J.* 829, 830-31 (1991) (restating court-applied reasoning in support of the learned intermediary doctrine).

3. See *West*, 806 S.W.2d at 613-14 (discussing that applying the learned intermediary doctrine is appropriate in the case of oral contraceptives); *Craft v. Peebles*, 893 P.2d 138, 156 (Haw. 1995) (holding that the trial court properly instructed the jury under the learned intermediary doctrine that the manufacturer of breast implants did not have a duty to warn the consumer); *Leesley v. West*, 518 N.E.2d 758, 763 (Ill. App. Ct. 1988) (concluding that under the learned intermediary doctrine, the manufacturer of Feldene was not strictly liable to the consumer for severe gastrointestinal bleeding caused by the prescription drug); *Humes v. Clinton*, 792 P.2d 1032, 1042-45 (Kan. 1990) (holding that where the manufacturer of intrauterine devices ("IUDs") adequately warns a physician of risks associated with its use, the manufacturer is relieved of a duty to directly warn users of risks associated with its IUDs); *Niemiera v. Schneider*, 555 A.2d 1112, 1117 (N.J. 1989) (ruling that the learned intermediary doctrine relieved the manufacturer of liability from a childhood vaccine's dangerous effects).
4. See *RESTATEMENT (THIRD)* § 6 (1998).
5. See *infra* notes 11-14 and accompanying text.
6. See *RESTATEMENT (THIRD)* § 6(d); see also *infra* note 9 and accompanying text.
7. See *Perez v. Wyeth Lab. Inc.*, 734 A.2d 1245, 1257 (N.J. 1999); see also *infra* notes 18-46 and accompanying text.
8. See *RESTATEMENT (THIRD)* § 6(a)-(b).
9. See *id.* § 6, cmts. a-b. See also *infra* notes 10-15 and accompanying text (discussing the duty to directly warn patients when the physician has a diminished role as a decision-maker).

A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to . . . *the patient when the manufacturer knows or has reason to know that the health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.*¹⁰

The *Restatement (Third)* bases its requirement that the manufacturer provide direct notification to the patient on the belief that the rationale for the learned intermediary doctrine is undercut in certain circumstances.¹¹ These circumstances include those in which there is a "limited therapeutic relationship" and "the physician or other health-care provider has a much-diminished role as an evaluator or decision-maker."¹² The comments note that "[i]n these instances it may be appropriate to impose on the manufacturer the duty to warn the patient directly."¹³

This Article examines one such example, direct-to-consumer advertising, for which the *Restatement (Third)* suggests that courts "should consider" imposing tort liability on drug manufacturers who advertise a prescription drug and its indicated use through the media without providing direct warnings to consumers.¹⁴

The *Restatement (Third)* recognizes that arguments exist both for and against imposing a duty on the manufacturer to warn patients. Proponents favoring imposing a duty state that "manufacturers [who] com-

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10. RESTATEMENT (THIRD) § 6(d) (emphasis added). The comments to subsection (d) further explain this duty by stating that "direct warnings and instructions to patients are warranted for drugs that are dispensed or administered to patients without the personal intervention or evaluation of a health-care provider." *Id.* § 6(d), cmt. e.
 11. *Id.* § 6, cmt. b. The comments to section 6 explain the rationale behind the learned intermediary rule, stating that "only 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." *Id.* See also *supra* notes 1-4 and accompanying text for a discussion of the rationale of the learned intermediary doctrine.
 12. RESTATEMENT (THIRD) § 6, cmt. b.
 13. *Id.*
 14. See *id.* § 6, cmt. e. Comment e also indicates that manufacturers have a duty to warn patients in cases where "vaccines [are] administered en masse at public health clinics." *Id.* See, e.g., *Brazzell v. United States*, 788 F.2d 1352, 1358-59 (8th Cir. 1986) (finding the government liable for failing to warn consumer of swine flu vaccine of prolonged muscle soreness as a possible side effect); *Givens v. Lederle*, 556 F.2d 1341, 1345 (5th Cir. 1977) (holding the manufacturer of a polio vaccine liable for failing to warn consumers about the risk of contracting polio); *Davis v. Wyeth Labs.*, 399 F.2d 121, 130 (9th Cir. 1968) (holding the same as the court in *Givens*). Another example of where a manufacturer may be directly liable to the patient other than in direct-to-consumer advertising includes instances where government regulations so require. See RESTATEMENT (THIRD) § 6, cmt. e. Both of these topics are beyond the scope of this Article.

municate directly with consumers should not escape liability simply because the decision to prescribe the drug was made by the health-care provider."¹⁵ Opponents, those supporting the traditional learned intermediary rule, however, 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 a particular patient."¹⁶

III. COURTS' APPLICATION OF SUBSECTION 6(d)(2) TO DIRECT TO- CONSUMER MARKETING CASES

Several courts have considered whether the manufacturer has a duty and, thus, is liable for failing to warn patients under circumstances where it might seem that the health-care provider is not able to reduce the risk of harm in accordance with the drug's warnings. As provided for in the comments to section 6(d)(2), these courts are split.¹⁷

A. *Adoption of the Patient-Notice Requirement: Perez v. Wyeth Laboratories, Inc.*

Since the *Restatement (Third)*'s publication, at least one court, the Supreme Court of New Jersey, adopted the view that a manufacturer has a duty to warn consumers directly in instances where the manufacturer engaged in direct-to-consumer advertising.¹⁸

In *Perez v. Wyeth Laboratories, Inc.*,¹⁹ the plaintiffs had contraceptive capsules, known as Norplant, implanted under the skin of their upper arms.²⁰ The plaintiffs alleged that the pharmaceutical manufacturer engaged in a "massive advertising campaign" beginning in 1991 which included television commercials and print advertisements in women's magazines.²¹ The plaintiffs complained that while the ads touted the benefits of the product, they did not warn about the side effects, which included weight gain, headaches, and a host of other difficul-

15. RESTATEMENT (THIRD) § 6, cmt. e.

16. *Id.*

17. See *infra* notes 18-62 and accompanying text.

18. See *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245, 1259 (N.J. 1999). Direct-to-consumer advertising is the process by which manufacturers directly solicit end-users of its product. See Bradford B. Lear, *The Learned Intermediary Doctrine in the Age of Direct Consumer Advertising*, 65 Mo. L. Rev. 1101, 1109 (2000).

19. 734 A.2d 1245 (N.J. 1999).

20. *Id.* at 1247.

21. *Id.* at 1248 (listing *Glamour*, *Mademoiselle*, and *Cosmopolitan* as various women's magazines that printed the advertisements).

ties while the product was implanted, and the subsequent pain and scarring accompanying the removal of the product.²²

The trial court dismissed the plaintiffs' claims, holding that the manufacturer was not liable for failing to warn them directly.²³ It found that the plaintiffs failed to rebut New Jersey's statutory presumption that the manufacturer's warnings to the physician were adequate.²⁴

The trial court was persuaded that, although the manufacturer marketed directly to consumers, the learned intermediary doctrine still applied because "a physician is not simply relegated to the role of prescribing the drug according to the woman's wishes."²⁵ Ultimately, the physician was the one responsible for weighing the risks and benefits of the drug before prescribing it to a patient.²⁶ The New Jersey Superior Court, Appellate Division upheld this decision.²⁷

The Supreme Court of New Jersey, however, reversed and remanded the case.²⁸ Describing the rising trend of direct-to-consumer advertising and citing statistics showing a ninety percent increase in

22. *Id.* (enumerating all of the other side effects associated with the contraceptive).

23. *Id.* at 1249 (citing *Perez v. Wyeth Labs., Inc.*, 713 A.2d 588, 595 (N.J. Super. Ct. Law Div. 1997)).

24. *Id.* at 1249. The New Jersey statute provides:

In any product liability action the manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction or, in the case of dangers a manufacturer or seller discovers or reasonably should discover after the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction. An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician. If the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et seq., a rebuttable presumption shall arise that the warning or instruction is adequate. For purposes of this section, the terms "drug", "device", "food", and "food additive" have the meanings defined in the "Federal Food, Drug, and Cosmetic Act."

N.J. STAT. ANN. § 2A:58C-4 (West 2000).

25. *Perez*, 734 A.2d at 1249 (quoting *Perez v. Wyeth Labs., Inc.*, 713 A.2d 588, 594 (N.J. Super. Ct. Law Div. 1997)).

26. *Id.* The trial court did not elaborate further as to why it was persuaded. *See id.*

27. *Id.*

28. *Id.* at 1264.

consumer advertising from 1995 to 1996,²⁹ the court explained that the *Restatement (Third)* left it to "developing case law" to determine whether to create an exception to the learned intermediary rule for direct-to-consumer advertising.³⁰ Therefore, to "develop the case law," the court announced an opinion regarding why the learned intermediary doctrine no longer applied, and why the manufacturer's duty still existed.

1. Inapplicability of the Learned Intermediary Doctrine to Direct-to-Consumer Advertising

Accepting the invitation of the *Restatement (Third)*, the *Perez* court examined the underpinnings of the learned intermediary doctrine and determined that its rationale did not support its application to direct-to-consumer advertising.³¹ The court identified four premises supporting its conclusion, including:

- (1) [R]eluctance to undermine the doctor patient-relationship [*sic*]; (2) absence in the era of "doctor knows best" of need for the patient's informed consent; (3) inability of drug manufacturer to communicate with patients; and (4) complexity of the subject.³²

The court concluded that the era where these rationales applied was passed, noting that the "'Norman Rockwell image of the family doctor no longer exists.'"³³

The court found that "[i]nformed consent requires a patient-based decision rather than the paternalistic approach of the 1970s,"³⁴ and that the patient now has a role in determining whether to use a particular drug.³⁵ The court considered persuasive the fact that, as managed care reduces the amount of time the doctor spends with the patient, "physicians have considerably less time to inform patients of the risks and benefits of a drug."³⁶ Finally, the court found that the enormous amount of money that manufacturers spend on consumer advertising belied both the notion that manufacturers lacked a means

29. *Id.* at 1251 (citing Bob Van Voris, *Drug Ads Could Spell Legal Trouble Consumer Campaigns May Result in Greater Liability*, NAT'L L.J., July 21, 1997, at B1).

30. *Id.* at 1253 (quoting RESTATEMENT (THIRD) § 6, cmt. b).

31. *Id.* at 1256.

32. *Id.* at 1255.

33. *Id.* (quoting Paul D. Rheingold, *The Expanding Liability of the Drug Manufacturer to the Consumer*, 40 FOOD DRUG COSM. L.J. 135, 136 (1985)).

34. *Id.* at 1255 (citing *Largey v. Rothman*, 540 A.2d 504, 507-08 (N.J. 1988) and discussing *Canterbury v. Spence*, 464 F.2d 772, (D.C. Cir. 1972), *cert. denied*, 409 U.S. 1064 (1972)).

35. *Id.* (citing Teresa Moran Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 FOOD DRUG COSM. L.J. 829, 830-31 (1991)).

36. *Id.* (citing Sheryl Gay Stolberg, *Faulty Warning Labels Add to Risk in Prescription Drugs*, N.Y. TIMES, June 4, 1999, at A27).

of communicating effectively with consumers, and the notion that prescription drugs and medical devices were topics too complex for the consumer to understand.³⁷

First, the fact that manufacturers are advertising their drugs and devices to consumers suggests that consumers are active participants in their health care decisions, invalidating the concept that it is the doctor, not the patient, who decides whether a drug or device should be used. Second, it is illogical that requiring manufacturers to provide direct warnings to a consumer will undermine the patient-physician relationship, when, by its very nature, consumer-directed advertising encroaches on that relationship by encouraging consumers to ask for advertised products by name. Finally, consumer-directed advertising rebuts the notion that prescription drugs and devices and their potential adverse effects are too complex to be effectively communicated to lay consumers. Because the [Food and Drug Administration] requires that prescription drug and device advertising carry warnings, the consumer may reasonably presume that the advertiser guarantees the adequacy of its warnings. Thus, the common law duty to warn [*sic*] the ultimate consumer should apply.³⁸

While rejecting application of the learned intermediary doctrine in cases of direct-to-consumer advertising, the court noted that the Food and Drug Administration (FDA) promulgated guidelines and regulations to address the manufacturer's obligations when advertising pharmaceuticals directly to consumers.³⁹ The court held that "FDA regulations are pertinent in determining the nature and extent of any duty of care that should be imposed on pharmaceutical manufacturers with respect to direct-to-consumer advertising."⁴⁰ The manufacturer will be provided the benefit of a rebuttable presumption that it fulfilled its duty to warn the consumer directly if it complies with FDA advertising, labeling, and warning requirements.⁴¹

37. *Id.* at 1255-56 (citing Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 158 (1997), which stated that drug manufacturers spent \$1.3 billion in 1998 on advertising).

38. *Id.* at 1256. (quoting Susan A. Casey, Comment, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 WM. MITCHELL L. REV. 931, 956 (1993)).

39. *Id.* at 1257-59. The FDA guidelines require that all advertisements for prescription drugs include a brief summary of "side effects, contraindications, and effectiveness as shall be required in regulations" *Id.* at 1258 (quoting 21 U.S.C.A. § 352(n)(3) (West 2000)).

40. *Id.* at 1259.

41. *Id.*

2. Physician Involvement Does Not Relieve the Manufacturer of Liability

The court next considered whether the physician's involvement in prescribing the drug or medical device broke the chain of causation, such that any failure to warn on the part of the manufacturer could not be considered the proximate cause of the plaintiffs' injuries.⁴² While calling this rationale "appealing," the court nonetheless found that the altered patient-physician relationship created by direct-to-consumer advertising warranted a rule of law that enabled the consumer to recover from the manufacturer.⁴³ The court stated that "[o]n balance, we believe that the patient's interest in reliable information predominates over a policy interest that would insulate manufacturers."⁴⁴ The court noted, however, that the manufacturer "may seek contribution, indemnity or exoneration because of the physician's deficient role in prescribing that drug."⁴⁵ The court concluded by saying that:

The direct marketing of drugs to consumers generates a corresponding duty requiring manufacturers to warn of defects in the product Given the presumptive defense that is afforded to pharmaceutical manufacturers that comply with FDA requirements, we believe that it is fair to reinforce the regulatory scheme by allowing, in the case of direct-to-consumer marketing of drugs, patients deprived of reliable medical information to establish that the misinformation was a substantial factor contributing to their use of a defective pharmaceutical product.⁴⁶

42. *Id.* at 1260.

43. *Id.* at 1262-63.

44. *Id.* at 1262.

45. *Id.* at 1263.

46. *Id.* This quote infers that the failure to warn creates the defect. *See id.* The *Restatement (Third)*, however, lists the duty to warn, a manufacturing defect, and a design defect as three independent causes for a tort action in negligence and strict liability. *See* RESTATEMENT (THIRD) at *Forward*. *See also, e.g.*, N.J. STAT. ANN. § 2A-58C-2 (West 2000); W. PAGE KEETON, ET AL., PROSSER AND KEETON ON THE LAW OF TORTS 685-89 (5th ed. 1984). Many courts, however, also consider the failure to warn to be a type of design defect. *See generally* Reed v. Sears, Roebuck & Co., 934 F. Supp. 713, 718 (D. Md. 1996) ("[F]ailure to warn' or 'inadequate warning,' conveniently overlooks the fact that 'failure to warn' liability is merely a type of design defect."); Gosewisch v. Am. Honda Motor Co., 737 P.2d 376, 379 (Ariz. 1987) ("[T]o establish a *prima facie* case of strict products liability based on informational defect [failure to warn], [plaintiff] had the burden of proving that . . . lack of an adequate warning made [the product] defective and unreasonably dangerous . . .") (emphasis in original); Canifax v. Hercules Powder Co., 237 Cal. App. 2d 44, 53 (Cal. Ct. App. 1965) ("In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use.") (quoting RESTATEMENT (SECOND) § 402A, cmt. j).

B. The Patient-Notice Requirement Rejected: Polley and Presto

In contrast to *Perez*, other courts have declined to impose liability on drug manufacturers in cases where the manufacturer engaged in direct-to-consumer advertising. For instance, in *Polley v. Ciba-Geigy Corp.*,⁴⁷ the plaintiff/consumer received a brochure from the manufacturer regarding his prescription drug, Clozaril.⁴⁸ In discussing the learned intermediary doctrine and the role of the manufacturer, the United States District Court for the District of Alaska stated:

The learned intermediary rule carefully allocates the duties of educating physicians, on the one hand, and warning patients, on the other, of the risks inherent in prescription medicines How the physician communicates the medicine's dangers to the patient is the physician's own decision, and his or her independent duty. There is no legal support for imposing upon a drug manufacturer an "advisory" role in that decision.⁴⁹

While the *Perez* court rejected the notion that a patient could not understand the complexities of a drug or device, and no longer required the paternalistic role of the physician, the *Polley* court maintained that:

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 The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.⁵⁰

Similar to *Polley*, the Court of Appeals of Georgia, in *Presto v. Sandoz Pharmaceutical Corp.*,⁵¹ held that a drug manufacturer is not liable under a failure to warn theory so long as the warnings provided to the physician were adequate.⁵² In *Presto*, the plaintiffs brought an action for failure to warn as a result of the suicide of their adult son, Greg Presto.⁵³ His physician, Dr. Warren, prescribed Clozaril to Presto to treat his mental illness.⁵⁴ The drug manufacturer, Sandoz

47. 658 F. Supp. 420 (D. Alaska 1987).

48. *Id.* at 421 (applying Alaska law). Clozaril is a prescription medicine intended "for the management of severely ill patients who fail to respond adequately to standard antipsychotic drug treatment." PHYSICIANS' DESK REFERENCE 2155 (55th ed. 2001). The drug should be used only in severe cases because of the significant risk of seizures associated with its use. *Id.*

49. *Polley*, 658 F. Supp. at 421.

50. *Id.* at 421-22 (quoting *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974)).

51. 487 S.E.2d 70 (Ga. Ct. App. 1997).

52. *Id.* at 73.

53. *Id.* at 72.

54. *Id.*

Pharmaceuticals, sent Presto a "pamphlet entitled 'Understanding Clozaril (clozapine) Therapy: A Guide for Patients and Their Families.'"⁵⁵ The pamphlet provided general information and answered some common questions about the drug, but failed to warn that abrupt discontinuation of the drug could cause a recurrence of psychotic symptoms.⁵⁶ Although, the medication helped control Presto's mental illness, his doctor stopped prescribing Clozaril because of its undesired side effects.⁵⁷ Presto committed suicide soon after.⁵⁸

The plaintiffs alleged that the manufacturer, having informed the consumer about its drug through the pamphlet, had a duty to warn of the dangers associated with the drug.⁵⁹ The court applied the learned intermediary rule and held that the manufacturer had no duty to warn the consumer directly.⁶⁰ Moreover, the court elaborated that the brochure did not alter the application of the intermediary rule because "the pamphlet covers only general issues concerning the drug, and as the [plaintiffs] relied on Dr. Warren to prescribe and supervise Presto's use of the drug, this theory of liability is without merit."⁶¹ Again, as in *Polley*, the *Presto* court found the physician's paternalistic role paramount in deciding whether the learned intermediary doctrine applied.⁶²

IV. FORESHADOWING THE FUTURE: ADOPTION OF EXCEPTIONS TO THE LEARNED INTERMEDIARY DOCTRINE

Maryland appellate courts have never squarely addressed the learned intermediary doctrine, although federal courts, applying Maryland law, have consistently presumed that the doctrine is viable in Maryland.⁶³ While the weight of authority strongly supports applica-

55. *Id.* at 73.

56. *Id.* at 73-74.

57. *Id.* at 72-73 (explaining that the doctor agreed to the Prestos' request that Clozaril be replaced with another drug because of its undesirable side effects).

58. *Id.* at 72.

59. *Id.* at 73-74.

60. *Id.* at 73.

61. *Id.* at 74.

62. *Id.* at 73.

63. The legal authority cited in federal cases for the proposition that Maryland law subscribes to the learned intermediary doctrine are traced to *Nolan v. Dillon*, 261 Md. 516, 520, 276 A.2d 36, 39 (1971). In *Nolan*, the plaintiff brought a negligence action against a physician for injecting her intravenously with Sparine, or promazine hydrochloride, in a quantity so large that it should have been injected in her muscle. *Id.* at 518, 276 A.2d at 38. Gangrene set into the plaintiff's fingertips, resulting in their amputation. *Id.* In deciding whether the warnings given by the manufacturer regarding use of Sparine were sufficient to grant a directed verdict, the Court of Appeals of Maryland noted that the instructions on the label and on an insert inside the package "fully discharged its duty to warn. The duty is to give a

tion of the learned intermediary theory in cases of direct-to-consumer advertising, any case to reach the Maryland appellate courts will present an issue of first impression.

Whether other courts addressing the issue will uphold the learned intermediary doctrine or create exceptions remains to be seen. The Second Circuit recently certified a question regarding the learned intermediary theory to the Connecticut Supreme Court, raising a similar issue to that raised in *Perez*.⁶⁴ At this time, however, the New Jersey court's decision in *Perez* is an outlier in the abundant case law upholding the learned intermediary doctrine's use in manufacturer-failure to warn cases. As such, it seems unlikely to gain general acceptance in Maryland or in other jurisdictions in the near future.

reasonable warning, not the best possible one." *Id.* at 520, 523, 276 A.2d at 38, 40 (citations omitted). "Even in jurisdictions which have espoused the doctrine of strict liability, and Maryland has not, [the manufacturer's] warning would have protected it." *Id.* at 523, 276 A.2d at 40 (citations omitted). *See generally* *Doe v. Am. Nat'l Red Cross*, 866 F. Supp. 242, 248 (D. Md. 1994) ("Under the learned intermediary doctrine, recognized under Maryland law, the Red Cross had no obligation to warn . . .") (citations omitted); *Hunt v. Hoffmann-La Roche, Inc.*, 785 F. Supp. 547, 550 (D. Md. 1992) ("Maryland courts have adopted the 'learned intermediary' rule under which a manufacturer of a prescription drug has a duty to warn only physicians, not patients, of potential risks associated with the use of the drug.") (citations omitted); *Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89, 94-95 (D. Md. 1989) ("Under Maryland law, manufacturers of prescription drugs need only warn the prescribing physician and not the patient of risks . . . associated with a prescription drug") (citations omitted).

64. *See Vitanza v. Upjohn Co.*, 214 F.3d 73, 74 (2d Cir. 2000) (certifying the question of whether a manufacturer has a duty to warn consumers directly when it provides prescription drug samples, in this case Ansaïd, an anti-inflammatory drug, to physicians).