

January 1997

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Recommended Citation

Michael C. Allen, *Medicine Goes Madison Avenue: An Evaluation of the Effect of Direct-to-Consumer Pharmaceutical Advertising on the Learned Intermediary Doctrine*, 20 CAMPBELL L. REV. 113 (1997).

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COMMENTS

MEDICINE GOES MADISON AVENUE: AN EVALUATION OF THE EFFECT OF DIRECT-TO-CONSUMER PHARMACEUTICAL ADVERTISING ON THE LEARNED INTERMEDIARY DOCTRINE

I. INTRODUCTION

Technology touches virtually every aspect of American life. Perhaps nowhere have the benefits of technological advances and development been felt more profoundly than the delivery of health care. Many diseases and problems virtually without treatment twenty years ago, today are remedied with routine procedures and therapies. Cardiac surgery, chemotherapy, and childhood vaccinations are typical of recent medical advancements.

The advances in treatment have been accompanied by significant increases in the cost of health care. It is estimated that in 1996, Americans spent more than \$1 trillion on health care products and services.¹ Health care is the single largest business in the United States, representing 14% of the gross domestic product.² Health care expenses comprise the largest single area of non-government spending.³

Corresponding with the financial burdens attendant to our modern health care system, a fundamental change has taken place in the way Americans pay for their health care.⁴ It is no longer customary for an individual to take personal financial responsibility for the cost of such care.⁵ The majority of Ameri-

1. Beso Sikharulidze, *Product Innovation, Demographic Trends Continue to Push the Health Care Sector Ahead*, SELECT UPDATE, (FIDELITY DIST. CORP., BOSTON, MASS.), Summer 1997, at 3 (on file in the Law Review Office).

2. *Id.*

3. *Id.*

4. Julie Rovner, *United States of America: The Healthcare System Evolves*, LANCET, Oct. 12, 1996, at 1001.

5. Kevin Dunne & Ciara Ryan, *How Management of Medical Costs is Revolutionizing the Drug Industry*, Defense Council J., Apr. 1995, at 177.

cans now depend upon payment of health care costs by a variety of third party providers, including private insurance programs and various state and federal entitlement programs.⁶

These fundamental changes have drastically altered the delivery of health care services. In an attempt to minimize the escalation of costs, "managed care", a heretofore unknown concept emerged. Health care providers, insurers and manufacturers began to actively compete to attempt to optimize services and outcomes while minimizing costs. Such competition has produced both welcome and unwelcome changes. The annual percentage increase in total health benefit costs declined to 2.1% in 1996, down from the late 1980's when health care inflation reached levels of 19%.⁷

The economic shift from an individually funded health care delivery system to a system funded by institutions has profoundly affected the pharmaceutical manufacturing industry. Manufacturers increasingly find it necessary to compete for representation and placement on formularies maintained by hospitals, insurers and Pharmacy Benefit Managers (PBMs).⁸ PBMs attempt to minimize prescription drug costs by negotiation with suppliers in exchange for agreements to purchase specific medications utilized by the group members.⁹

As manufacturers attempt to appropriately position their products in the chain of delivery, new techniques are often employed to supplement traditional marketing efforts which have historically consisted of direct physician education, information provided in medical references, educational seminars, and research grants.¹⁰ The pharmaceutical industry is responding to these challenges through vertical integration. Many U.S. pharmaceutical manufacturers have recently purchased PBMs¹¹ and created alliances with insurers, health maintenance organizations, and various health care providers.

6. Rovner, *supra* note 4, at 1001.

7. Sikharulidze, *supra* note 1, at 1.

8. Dunne, *supra* note 5, at 180.

9. *Id.* at 178.

10. *Id.* at 200.

11. See Anita McGahan, *Industry Structure and Competitive Advantage*, HARV. BUS. REV., Nov.-Dec. 1994, at 115. Merck & Co., the largest U.S. pharmaceutical manufacturer, purchased Medco, a leading PBM for \$6.6 Billion; Smithkline Beecham purchased another PBM, Diversified Pharmaceutical Services, for \$2.3 Billion. *Id.*

Among the most controversial of the new marketing techniques employed by pharmaceutical manufacturers is direct-to-consumer prescription advertising in a variety of formats and media. Pharmaceutical remedies for varied problems such as allergies, nail fungus, hypertension, hair loss, and depression are placed directly before the consumer in magazines, television, and via the Internet.¹² The utilization of direct consumer marketing raises questions and issues addressing manufacturer liability for failure to adequately warn of risks possibly associated with pharmaceutical use. In the past five years, reports indicate that pharmaceutical companies have spent over \$1 billion on direct-to-consumer ads.¹³ John Kamp, senior vice-president of the American Association of Advertising Agencies, has predicted that *annual* expenditures would top \$1.2 billion dollars if the Food and Drug Administration relaxed its consumer advertising policies.¹⁴

On August 8, 1997 the Food & Drug Administration (FDA) in fact announced proposed guidelines that allow a drug manufacturer for the first time to explicitly state its product's purpose in a direct-to-consumer radio or television advertisement.¹⁵ Michael J. Friedman, lead FDA Commissioner, characterizes the new regulations as an attempt to "promote greater consumer awareness about prescription drugs"¹⁶

The new guidelines, which address advertisements on television and radio, require manufacturers to include information about major risks of the product and to provide more detailed information by a toll-free telephone number, Internet site or readily available brochure.¹⁷ Nevertheless, consumer groups are concerned about the ultimate effect of such advertisements. Sidney M. Wolfe, executive director of Public Citizen's Health Research Group, warns that "misleading information can injure and kill."¹⁸

The established medical community also has expressed concerns about the use of direct-to-consumer marketing activities. Susan Winckler, director of policy and legislation for the American Pharmaceutical Association cautions that product-specific ads

12. Michael F. Conlan, *In-Your-Face Pharmacy: Will the Boom in Rx Ads Aimed at Consumers Continue?*, DRUG TOPICS, July 8, 1996, at 92.

13. *Id.*

14. *Id.*

15. *FDA Eases Rules for Televised Drug Ads*, THE NEWS AND OBSERVER (Raleigh, N.C.), August 9, 1997, at 1.

16. *Id.*

17. *Id.*

18. *Id.*

can create a challenge for both the prescriber and the pharmacist.¹⁹ The American Medical Association (AMA) has long maintained a policy in opposition to product-specific prescription ads aimed at consumers.²⁰ A 1992 study by the *Annals of Internal Medicine* reports that a peer review of 109 prescription ads found 92 per cent of the advertisements lacking in some manner.²¹ Nevertheless, Joseph Cranston, director of AMA's drug policy department noted that due to "the thrust on patient empowerment and the consumer's zeal for as much information as possible about health care, including the medications that they take, it's kind of academic."²²

Direct-to-consumer advertising of pharmaceuticals has also attracted the attention of the legal community. Numerous courts and authors have considered the impact of such activities on a manufacturer's potential liability,²³ concluding that products liability doctrines can and must adapt to changes in society's methods and practices. The California Supreme Court, for example, noted that "[t]he manufacturer's obligation to the consumer must keep pace with the changing relationship between them"²⁴

One area specifically affected is the commonly accepted doctrine of the learned intermediary. The learned intermediary doctrine dictates that a pharmaceutical manufacturer's duty to warn the ultimate consumer is satisfied by an accurate and adequate warning to the prescribing physician.²⁵ Suggestions have been made that direct patient marketing is designed to form "consumer preferences", thus undermining the concept of the learned intermediary.²⁶ Most recently, the Oklahoma Supreme Court held that an exception to the learned intermediary doctrine existed in a case involving prescription nicotine patches.²⁷

This comment will attempt to examine and evaluate the learned intermediary doctrine in light of the recent explosion in

19. Conlan, *supra* note 12, at 94.

20. *Id.*

21. *Id.*

22. *Id.*

23. See *Garside v. Osco Drug, Inc.*, 764 F. Supp. 208, 211, n.4 (D. Mass. 1991), *rev'd. on other grounds*, 967 F.2d 77 (1st Cir. 1992); Teresa M. Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 FOOD & DRUG COSM. L.J. 829 (1991).

24. *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 443 (Cal. 1944).

25. *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 811 (5th Cir. 1992).

26. Dunne, *supra* note 5, at 195.

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

direct-to-consumer advertising of pharmaceutical products, focusing on an analysis of product liability principles, including comments from the proposed Restatement (Third) of Torts, as they apply to this subject. This comment will examine the potential ramification of FDA consumer advertising requirements, especially as they relate to potential additional exceptions to the learned intermediary doctrine. This analysis will support the conclusion that the learned intermediary doctrine remains functional and provides the consumer with the best available alternative to ensure the most appropriate use of safe and effective pharmaceuticals.

II. PRINCIPLES OF LIABILITY ASSOCIATED WITH MANUFACTURER'S DUTY TO WARN OF RISKS

A. *General Principles of Product Liability for Failure to Warn*

A manufacturer's potential liability for failure to warn is generally based upon either traditional negligence theory (alleging a breach of a duty to warn of risks) or strict liability.²⁸ Instructions and warnings serve two main functions: to enable consumers to minimize risks through proper use of a product and to allow consumers the opportunity to make informed decisions regarding the choice to encounter risks associated with a product which cannot be eliminated.²⁹ Warnings associated with pharmaceuticals primarily impact the decision whether to encounter the risk at all, as pharmaceutical warnings provided directly to a consumer would have little or no impact on a patient's ability to reduce potential risk by adherence to the warnings.

Pharmaceutical manufacturer liability has been a difficult area of product liability jurisprudence.³⁰ Attempts to balance the risk versus rewards of pharmaceutical products are exceedingly complex. The majority of jurisdictions, including those who have adopted the strict liability position of Restatement (Second) of Torts § 402A,³¹ refuse to impose strict liability on manufacturers and distributors of pharmaceuticals.³² The reluctance to impose

28. W. PAGE KEETON ET. AL., PROSSER AND KEETON ON THE LAW OF TORTS § 95A, at 678 (5th ed. 1984).

29. *Id.* § 96 at 685.

30. Teresa M. Schwartz, *Prescription Products and the Proposed Restatement (Third)*, 61 TENN. L. REV. 1357 (1994).

31. RESTATEMENT (SECOND) OF TORTS § 402A (1965).

32. See *Grundberg v. Upjohn, Co.*, 813 P.2d 89, 98 (Utah 1991) (concluding that "a broad grant of immunity from strict liability claims based on design

such liability is often based upon a recognition of the public benefits provided by the availability of pharmaceuticals,³³ as well as comment k of the Restatement (Second) of Torts § 402A, which states:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended use. These are especially common in the field of drugs The seller of such drugs, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability . . . merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.³⁴

Courts have also specifically declined to apply the product liability theories of express and implied warranties of fitness and merchantability to prescription drugs.³⁵ Such theories, representing a blend of tort and contract concepts are poorly fitted to prescription liability issues. The majority of jurisdictions require reliance upon the warranty in order to impose manufacturer liability.³⁶ Prescription consumer reliance is more appropriately placed upon the medical judgment of the physician, rather than “warranties” allegedly conveyed by the manufacturer.³⁷

Courts have also declined to impose Uniform Commercial Code (U.C.C.) implied warranties of fitness and merchantability to prescription drugs. This issue was well stated by the North Carolina Court of Appeals, rejecting a claim based upon the U.C.C. (codified at N.C.G.S. § 25-2-314), noting “[t]o say that the issuance of a prescription for drugs, which prescription is to be filled by a pharmacist should the patient desire to follow the physician’s suggestion, constitutes the transfer of title to the drugs in the formula in the prescription, is simply too unrealistic for seri-

defects should be extended to FDA-approved prescription drugs”); *Coyle v. Richardson-Merrell Inc.*, 584 A.2d 1383 (Pa. 1991) (declining to extend strict liability to sellers of pharmaceuticals).

33. *Grundberg*, 813 P.2d at 95.

34. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

35. *Magrine v. Krasnica*, 227 A.2d 539 (N.J. 1967) *aff’d.*, 250 A.2d 129 (N.J. 1969); *Cheshire v. Southampton Hosp. Ass’n*, 278 N.Y.S.2d 531 (1967); *Foster v. Memorial Hosp. Ass’n of Charleston*, 219 S.E.2d 916 (W. Va. 1975).

36. 63 AM. JUR. 2D *Products Liability* § 455 (1984).

37. *Reaves v. Ortho Pharm. Co.*, 765 F. Supp. 1287, 1288 (E.D. Mich. 1991).

ous consideration.”³⁸ Other jurisdictions have agreed that the prescribing of a medication is a component of the delivery of medical services, rather than the delivery of a product subject to implied U.C.C. warranties.³⁹

Therefore, potential pharmaceutical manufacturer liability for failure to warn would generally have to be determined in accordance with ordinary negligence principles.⁴⁰ The inquiry into pharmaceutical manufacturer warnings generally focuses on two issues; (1) the adequacy of the warnings and (2) to whom the warnings should be made.⁴¹ An analysis of the adequacy of the warning is beyond the scope of this comment and has generated significant litigation in many jurisdictions.⁴² The central issue germane to this inquiry is to whom the warning should be given: health care professional or consumer.

B. Rationale and Development of the Learned Intermediary Doctrine

Drugs dispensed pursuant to a prescription generally carry no manufacturer’s warnings to the ultimate consumer, with the exception of oral contraceptives and nicotine patches.⁴³ This is because of a unique aspect of prescription drug product liability cases: the concept of the prescribing physician as “learned intermediary” who makes an informed, unbiased, and educated decision concerning the appropriateness of medication selection. The doctrine emerged in the mid 1960’s, recognizing that a pharmaceutical manufacturer’s duty to warn is discharged by conveying necessary warnings to physicians. The term “learned intermediary” apparently originated in an opinion from the Eight Circuit Court of Appeals, describing a patient’s doctor as a “learned inter-

38. *Batiste v. American Home Prod. Corp.*, 32 N.C. App. 1, 6, 231 S.E.2d 269, 272 (1977).

39. *Murphy v. E.R. Squibb & Sons, Inc.*, 710 P.2d 247 (Cal. 1985); *Ellsroth v. Johnson & Johnson*, 700 F. Supp. 151 (S.D.N.Y. 1988); *Coyle v. Richardson-Merrill, Inc.*, 584 A.2d 1383 (Pa. 1991).

40. *Feldman v. Lederle Labs.*, 479 A.2d 374, 386 (N.J. 1984); *Johnson v. American Cyanamid Co.*, 718 P.2d 1318, 1324 (Kan. 1986).

41. See Janet Fairchild, Annotation, *Liability of Manufacturer or Seller for Injury or Death Allegedly Caused by Failure to Warn Regarding Danger in Use of Vaccine or Prescription Drug*, 94 A.L.R.3d 748 (1997).

42. *Id.*

43. FDA regulations require manufacturer warnings to accompany these products. See *infra* text accompanying notes 55-65. See 21 C.F.R. § 310.501(a) (1986); *Edwards v. Basel Pharm.*, 933 P.2d 298, 301 (Okla. 1997).

mediary" between the manufacturer and the consumer.⁴⁴ The majority of jurisdictions have adopted this concept and absolve a manufacturer from any requirement to directly warn the patient when the prescribing physician has been adequately warned.⁴⁵

The learned intermediary doctrine is based upon a number of factors including: (1) the physician's training and experience; (2) the physician's evaluation of the patient's needs and wishes; (3) the assumption that the physician is better situated than the manufacturer to convey the appropriate and applicable warnings to the ultimate user; (4) the fact that warnings to consumers might interfere with the traditional physician-patient relationship; and (5) the fact that it is difficult, if not impossible to convey appropriate warnings to the consumer, given the highly technical nature of the information and the variations in needs based upon individual patient characteristics.⁴⁶

The learned intermediary doctrine recognizes that the patient generally relies upon the physician, not the manufacturer, to ensure the appropriate selection and use of pharmaceuticals.⁴⁷ Physician failure to evaluate and communicate the appropriate warnings supplied by the manufacturer to the patient may reasonably result in patient injury as a proximate result of such failure. However, in such cases alleging manufacturer liability, the physician's failure is often viewed as a superseding cause of the patient's injury.⁴⁸ A number of jurisdictions have however, maintained manufacturer liability in conjunction with prescriber negligence, when it can be shown that the manufacturer's warnings to the prescribing physician were in fact inadequate.⁴⁹

44. *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966).

45. *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974); *Hoffman v. Sterling Drug Inc.*, 485 F.2d 132, 142 (3rd Cir. 1973); *Magee v. Wyeth*, 29 Cal. Rptr. 322 (1963); *Ortho Pharm. Co. v. Chapman*, 388 N.E.2d 541 (Ind. 1979); *Whitley v. Cubberly*, 24 N.C. App. 204, 210 S.E.2d 289 (1974) (ruling that pharmaceutical manufacturer was required to provide warnings to the medical profession); *Terhune v. A.H. Robins*, 577 P.2d 975 (Wash. 1978).

46. *Schwartz*, *supra* note 23.

47. *Reaves v. Ortho Pharm. Co.*, 765 F. Supp. 1287, 1288 (E.D. Mich. 1991).

48. *Dyer v. Best Pharmacal*, 577 P.2d 1084 (Ariz. Ct. App. 1978); *Mulder v. Parke Davis & Co.*, 181 N.W.2d 882 (Minn. 1970).

49. *McCue v. Norwich Pharmacal Co.*, 453 F.2d 1033 (1st Cir. 1972) (applying New Hampshire law); *Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919 (8th Cir. 1970); *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966); *Stevens v. Parke Davis & Co.*, 507 P.2d 653 (Cal. 1973); *Love v. Wolf*, 38 Cal. Rptr. 183, (Cal. App. 1964); *Bine v. Sterling Drug, Inc.*, 422 S.W.2d 623 (Mo. 1968).

The United States Court of Appeals for the Eighth Circuit considered the issue of appropriate warnings of risks associated with prescription drugs in *Sterling Drug, Inc. v. Yarrow*,⁵⁰ a case involving the adequacy of warnings conveyed to a physician concerning potential side effects of chloroquine phosphate. The court applied a negligence test (as would the majority of jurisdictions) in considering the adequacy of the warnings. The *Sterling* court noted that “[t]he trial court clearly applied, recognized and expressly enunciated the undisputed standard of a duty to make reasonable efforts to warn the *medical profession* of the side effects of a drug.”⁵¹

Courts have narrowly extended the doctrine of the learned intermediary to require warnings to other selected health care providers. The North Carolina Court of Appeals has extended the duty of a manufacturer to include a duty to warn a nurse anesthesiologist practicing under the supervision of the attending physician anesthesiologist.⁵² The court cited with approval the proposition that warnings are *only* required to be given to members of the medical profession responsible for the patient’s care.⁵³ The use of the term “only” reasonably leads to the conclusion that the duty to warn does not extend to the patient, recognizing that the appropriate medical professionals are responsible for gathering information, evaluating the risks, and ultimately making the appropriate pharmacological selection. This narrow extension of the duty to warn is entirely consistent with the principles of the learned intermediary doctrine.⁵⁴

Because of the learned intermediary doctrine, as a general rule, a patient cannot sue the manufacturer for a failure to warn if the medical profession was adequately warned. Cases such as *Holley* and *Hoffman* demonstrate that the particular members of the medical profession that are to receive the warnings may expand to reflect changes in healthcare delivery.

50. *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978 (8th Cir. 1969).

51. *Id.* at 991 (emphasis added).

52. *Holley v. Burroughs Wellcome Co.*, 74 N.C. App. 736, 330 S.E.2d 228 (1985), *affd.*, 318 N.C. 352, 348 S.E.2d 772 (1986).

53. *Id.* at 747 (citing *Whitley v. Cubberly*, 24 N.C. App. 204, 210 S.E.2d 289 (1974)).

54. *See also Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132 (3d Cir. 1973) (The United States Court of Appeals for the Third Circuit also narrowly extended the duty to warn, noting that the manufacturer had a duty to warn treating, as well as prescribing physicians.).

C. *Exceptions to the Learned Intermediary Doctrine*

Specific exceptions to the learned intermediary doctrine have been recognized, resulting in a duty to warn patients directly, when (1) mass immunizations are given without the traditional physician involvement⁵⁵ and (2) where regulations require that adequate warnings be given to the ultimate user (oral contraceptives and more recently nicotine patches).⁵⁶ The rationale behind the mass immunization exception is that the traditional physician-patient relationship is altered in such a manner that the patient no longer benefits from the physician's diagnostic skills and judgement. During mass immunizations (military, schools, health departments, etc.), the patient is often not individually evaluated by a physician. As such, the physician, if present at all, acts only to oversee the administration and therefore fails to act in the capacity of a learned intermediary who would advise and protect the patient individually.⁵⁷

Several states have also recognized an exception to the learned intermediary doctrine in cases involving medications for which the Food and Drug Administration requires direct-to-consumer warnings.⁵⁸ Although courts have not been uniform in recognition of this exception, this issue is particularly interesting in light of the recent FDA policy on direct-to-consumer advertising.⁵⁹ To date, courts have applied this exception to FDA requirements for consumer warnings associated with oral contraceptives, nicotine patches and non-therapeutic medical devices such as breast implants and intrauterine devices.⁶⁰

Courts recognizing the learned intermediary exception based on FDA required warnings have noted that the traditional physician-patient relationship is often altered, much like the cases

55. *Davis v. Wyeth Labs.*, 399 F.2d 121 (9th Cir. 1968); *Reyes v. Wyeth Labs.*, 498 F.2d 1264 (5th Cir. 1974); *Givens v. Lederle Labs.*, 556 F.2d 1341 (5th Cir. 1977).

56. *Edwards v. Basel Pharms.*, 933 P.2d 298 (Okla. 1997); *Odgers v. Ortho Pharm. Corp.*, 609 F. Supp. 867 (E.D. Mich. 1985).

57. *Dunne*, *supra* note 5, at 177.

58. *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65 (Mass. 1985); *Odgers*, 609 F. Supp. 867; *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961 (E.D. Wis.), *amended by* 532 F. Supp. 211 (E.D. Wis. 1981).

59. *Reaves v. Ortho Pharm. Corp.*, 765 F. Supp. 1287 (E.D. Mich. 1991); *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142 (D. Or. 1989).

60. *Edwards*, 933 P.2d at 301; *Hill v. Searle Labs.*, 884 F.2d 1064 (8th Cir. 1989).

involving mass immunizations.⁶¹ Much of the litigation involving this exception has involved the prescribing of oral contraceptives. Courts have noted that the decision to use birth control medication frequently involves increased patient input into the decision, as well as less involvement by the physician in monitoring the use of the medication.⁶² Courts have also commented on other factors, including the fact that oral contraceptives are often advertised directly to consumers, the products are typically not used for therapeutic reasons, and the products often involve serious side effects.⁶³ Additionally, courts have noted that the FDA requires patient warnings regarding side effects to accompany the dispensing of the product.⁶⁴ Courts recognizing the duty to directly warn the consumer have also struggled with questions concerning the adequacy of the warnings.⁶⁵

III. EFFECTS OF DIRECT-TO-CONSUMER PHARMACEUTICAL ADVERTISEMENTS

Many of the rationales and factors suggested by courts in opinions declining to recognize the learned intermediary doctrine have likewise been suggested as being applicable to cases involving direct-to-consumer advertisements.⁶⁶ Arguments have been advanced that the advertisements may alter the patient-physician relationship and subsequently affect the judgment of the prescribing physician.⁶⁷ In addition to the requirement to warn associated with the *delivery or dispensing* of certain medications,⁶⁸ legislation exists which addresses the duty to warn in *advertisements* for prescription drugs. The Federal Food Drug and Cosmetic Act requires that all print advertisements for prescription drugs contain information in "brief summary" relating to side effects, contraindications, and effectiveness.⁶⁹ Regulations further require

61. *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379 (E.D.Mich. 1985); *Odgers v. Ortho Pharm. Corp.*, 609 F. Supp. 867 (E.D. Mich. 1985); *Lukaszewicz*, 510 F. Supp. 961.

62. *Hill*, 884 F.2d at 1071.

63. *Stephens*, 602 F. Supp. at 380-81 (E.D. Mich. 1985).

64. 21 C.F.R. § 310.501(a) (1986).

65. As previously noted, analysis of adequacy of warnings is beyond the scope of this comment; See Fairchild, *supra* note 42.

66. Schwartz, *supra* note 23, at 842

67. *Id.* at 839.

68. See *supra* note 43.

69. 21 U.S.C. § 352(n) (1997).

that the "brief summary" disclose all risk-related information contained in a product's approved package labeling.⁷⁰

In contrast to the "brief summary" requirement for print advertisements, the newly articulated FDA guidance addressing advertisements through broadcast media (radio, television and telephone communications) modifies the requirement to an "adequate provision" standard.⁷¹ All such prescription advertisements must include information about the major risks in either audio or audio and visual parts of the presentation.⁷² A sponsor may provide a "major statement" of major risks along with an "adequate provision" for the delivery of the approved package labeling in connection with the broadcast presentation.⁷³

This alternative recognizes the difficulty associated with delivery of the "brief summary" statement in broadcast media. The proposed guidance encourages "product sponsors to provide consumers with non-promotional, consumer-friendly information that is consistent with approved product labeling, in addition to the information currently required by the regulations"⁷⁴ The purpose of the draft guidance is to "provide consumers with adequate communication of the required risk information, while facilitating the process used by sponsors to advertise their products to consumers."⁷⁵ The proposals set forth are not binding on the FDA or the manufacturers, as they are offered only as guidance, but one would expect that the recommendations will quickly become standard industry practice.

What will be the effect of such recommendations on the learned intermediary doctrine? Will or should the courts extend the exceptions often recognized for oral contraceptives and nicotine patches to the issue of direct-to-consumer advertised products in light of mandates and recommendations to provide such warnings with advertisements? Several court decisions indicate that direct-to-consumer advertising is indeed a factor in application of the learned intermediary doctrine.⁷⁶ The newly revised Restatement (Third) of Torts discusses these concerns, stating:

70. § 352(n).

71. Draft Guidance for Industry; Consumer-Direct Broadcast Advertisements, 62 Fed. Reg. 43,171 (1997).

72. *Id.*

73. *Id.*

74. *Id.* at 43,172.

75. *Id.*

76. *Hill v. Searle Lab.*, 884 F.2d 1064 (8th Cir. 1989) (applying Arkansas law); *Garside v. Osco Drug, Inc.*, 764 F. Supp. 208, 211 n.4 (D. Mass. 1991), *rev'd on*

[A]rguments have been advanced that in two other areas courts should consider imposing tort liability on drug manufacturers who fail to provide direct warnings to consumers. In the first, . . . governmental regulatory agencies have mandated that patients be informed In the second, manufacturers have advertised a prescription drug and its intended use in the mass media.⁷⁷

A critical examination of the potential ramifications of direct-to-consumer advertising and direct-to-consumer warnings is appropriate in analyzing suggestions for an additional exception to the learned intermediary doctrine based on direct-to-consumer advertisements.

A. *Potential Effect of Direct-to-Consumer Advertising on the Physician-Patient Relationship*

It has been suggested that direct-to-consumer pharmaceutical advertising may negatively interfere with the critical relationship between a physician and his or her patient.⁷⁸ To the contrary, any potential change in this relationship attendant to consumer advertising is beneficial, rather than negative.

The practice of medicine is a noble profession based upon the ideals of learning and service to fellow man. By virtue of the physician's extensive training and abilities, he or she is placed in a unique position accompanied by immense responsibility. No other member of society is similarly situated as an evaluator and advisor of treatment for illnesses, including the evaluation of the complex, confusing array of medications currently available. "[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."⁷⁹

The patient-physician relationship has historically been granted special protection under the law.⁸⁰ Courts and regulatory authorities have closely scrutinized activities which might inappropriately interfere with physician objectivity. The United States Court of Appeals for the Fourth Circuit noted that "[a]

other grounds, 976 F.2d 77 (1st Cir. 1992) (applying Massachusetts law); *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379 (E.D. Mich. 1985) (applying Michigan law).

77. RESTATEMENT (THIRD) OF TORTS § 8 cmt. e (Tentative Draft No. 2, 1995).

78. Schwartz, *supra* note 23, at 839.

79. RESTATEMENT (THIRD) OF TORTS § 8 cmt. e (Tentative Draft No. 2, 1995).

80. *Department of Air Force v. Rose*, 425 U.S. 352 (1976).

manufacturer of an ethical drug must exercise reasonable care, commensurate with the risk, to warn physicians effectively of the drug's inherent dangers."⁸¹ The *Salmon* court, considering a negligence action against a pharmaceutical manufacturer for failure to adequately warn a physician, concluded that evidence of potential over-promotion of the product precluded summary judgment for the manufacturer.⁸² The *Salmon* court stated that the alleged over-promotion may have eroded the effectiveness of the warnings supplied by the manufacturer.

The North Carolina Court of Appeals has likewise discussed the importance of the medical professional's objectivity in the selection and use of prescription drugs. In *Whitley v Cubberly*⁸³ the court commented:

That [defendant] may have fully complied with all applicable Federal laws in its marketing and labeling . . . would not in itself free it of liability for harm caused by use of the drug if it were shown that such use and resulting harm was caused by the Company's negligent acts in over-promoting the drug For example, even though all warnings required by Federal authorities may have been given, such warnings would be insufficient to exonerate Parke, Davis from all liability if over-promotion through a vigorous sales campaign should induce the medical profession . . . to fail adequately to heed the warnings given.⁸⁴

In *Stevens v. Parke, Davis & Co.*,⁸⁵ the California Supreme Court also affirmed the importance of objective physician warnings.⁸⁶ The manufacturer of an antibiotic was held liable for the wrongful death of a patient, even though the manufacturer had provided letters to physicians detailing side effects, including the specific side effect resulting in the plaintiff's death. The court stated:

We are satisfied that the evidence in the record . . . support[s] the implied finding of the jury that [the manufacturer] negligently failed to provide an adequate warning as to the dangers of [the antibiotic] by so "watering down" its warnings and so over-pro-

81. *Salmon v. Parke, Davis & Co.* 520 F.2d 1359, 1362 (4th Cir. 1975).

82. *Id.*

83. *Whitley v. Cubberly*, 24 N.C. App. 204, 210 S.E.2d 289 (1974) (reversing summary judgment verdict for the defendant manufacturer).

84. *Id.* at 207-08, 210 S.E.2d at 292.

85. 507 P.2d 653 (Cal. 1973).

86. *Id.*

moting such drug that members of the medical profession . . . were caused to prescribe it when it was not justified.⁸⁷

Regulatory agencies also monitor the promotional activities of pharmaceutical manufacturers. A 1992 study by the Office of Evaluation and Inspections examined the promotion of pharmaceuticals by manufacturers to physicians involving payments and gifts.⁸⁸ The study recommended further delineation and clarification of appropriate guidelines of such promotional activities. The study also suggested a multi-disciplinary approach to formulating rules defining the distinction between promotional activity and scientific exchange, involving the Pharmaceutical Manufacturer's Association, the American Medical Association, and the Food and Drug Administration.⁸⁹

The intense level of deference afforded to the physician-patient relationship is readily discerned. Courts, regulatory authorities, and professional associations closely monitor the activities surrounding the distribution of information to prescribing physicians. The goal and effect of such monitoring activities is to ensure that the physician receives and relies upon clear, unbiased, accurate information. This approach enforces the rationale of the learned intermediary, in which the physician evaluates complex, but unbiased information concerning appropriate pharmacological alternatives.

B. Potential Effects of Direct-to-consumer Pharmaceutical Advertising on Consumers

Opinions vary regarding the effect of direct pharmaceutical advertising on consumers. A 1991 report by the General Accounting Office (GAO) reviewed 130 studies on prescription consumer advertising.⁹⁰ The report was critical of much of the research done in previous studies; however the GAO did enumerate several potential benefits including consumer education, price reduction and patient involvement in health care.⁹¹ The report also cau-

87. *Id.* at 662.

88. OFFICE OF EVALUATIONS AND INSPECTIONS, PRESCRIPTION DRUG PROMOTION INVOLVING PAYMENTS AND GIFTS (1992) (abstract on file in Law Review Office).

89. *Id.*

90. GENERAL ACCOUNTING OFFICE, PRESCRIPTION DRUGS: LITTLE IS KNOWN ABOUT THE EFFECTS OF DIRECT-TO-CONSUMER ADVERTISING (1991) (abstract on file in Law Review Office).

91. *Id.*

tioned against the potential detriments of increased costs and inadequate risk information.⁹²

An analysis of the potential benefits of direct-to-consumer pharmaceutical advertising indicates that such advertising can often be the first source of information on newly available treatments. Consumer advertising may also increase awareness of established treatments and procedures. An example of the educational benefits of consumer advertising is the ability to trigger consumer recognition of symptoms of various illnesses and diseases. Specific examples might include information on symptoms such as excessive thirst as a potential warning sign of diabetes and unexplained weight loss and insomnia as potential indicators of depression.

Direct-to-consumer advertisements may also encourage consumers who may have previously discontinued treatment due to side effects to consult the appropriate health professional concerning new treatment alternatives. For example, many commonly prescribed anti-hypertensive medications may cause impotence in male patients often resulting in patient self-termination of treatment.⁹³ Information on the availability of potential alternative medications with a lower incidence of side effects may encourage such patients to seek additional treatment.⁹⁴

In addition, as consumers participate in health care decisions they are likely to be better informed and able to convey appropriate information to the prescribing physician. Patients may recognize important risk factors and warning signs that could contribute to more effective and appropriate treatment, pharmacological or otherwise. "Consumer advertising plays an important role in health care by making valuable medical information—such as symptoms that should be checked out with a physician and symptomless conditions for which at-risk groups should be tested—readily available to consumers"⁹⁵ Consumer advertisements also enable patients to become more active partners in the delivery of healthcare. "A properly educated, properly motivated patient-partner is the best bet the physician has for getting

92. *Id.*

93. DRUG FACTS AND COMPARISONS, at 161b (Facts and Comparisons Inc. 1996) (on file in Law Review Office).

94. James G. Dickinson, *Kessler's Marketing War Meets Resistance*; David A. Kesler, *MEDICAL MARKETING & MEDIA*, Feb. 1992, at 48.

95. Conlan, *supra* note 12, at 94 (quoting Richard Samp, Chief Legal Counsel for the Washington Legal Foundation).

a good outcome for the patient overall . . . [a]nd direct-to-consumer ads play a part in that.”⁹⁶ The opportunity to convey such beneficial consumer information should be encouraged, not discouraged by the threat of increased potential manufacturer liability.

C. *Difficulty of Conveying an Adequate Warning to the Consumer*

As previously suggested, the use of consumer directed advertisements may contribute to a more informed consumer and hence result in more desirable health care outcomes. It might be suggested that the imposition of a legally recognized duty for manufacturers to directly warn consumers would further facilitate these desired outcomes. This would create an exception to the learned intermediary doctrine, which generally allows a manufacturer to escape liability for failing to warn a consumer if the physician was adequately warned instead. However, a close analysis of this potential exception to the doctrine reveals several serious obstacles.

The simple act by a physician to prescribe a medication, to pen a few obscure words and symbols on a 4 inch x 6 inch paper, represents the culmination of a complex process representing multiple decisions. The physician must initially correctly diagnose the condition, then subsequently select the appropriate therapeutic category from such options as surgery, physical therapy, counseling, prescription medications, as well as no treatment at all. If medication use is deemed appropriate, the physician must further select the single most appropriate drug based on a myriad of factors, many related directly to the patient's individual characteristics. Factors include patient sensitivity, drug efficacy, duration of treatment, potential for side effects, drug interactions with other therapy the patient may be utilizing, as well as patient preferences. Patient preferences may include taste, mode of use (oral, rectal, injection), cost, previous experience, as well as previous exposure to consumer advertising.

All of these factors are subsequently considered in the physician's ultimate choice of medication. Thus, attempts in a direct-to-consumer ad to adequately convey sufficient information to enable a consumer to make a reasonably informed and educated

96. *Id.* at 94 (quoting Peter Seaver, Vice President for Health-Care Policy and Professional Relations at Pharmacia & Upjohn).

decision would be prohibitively lengthy and difficult to convey.⁹⁷ As an example, the Food and Drug Administration's mandated physician information required for a popular oral contraceptive contains over eight hundred lines of text.⁹⁸ Additionally, serious difficulties are present in attempting to translate the complexities and subtleties of medical terminology into consumer useable information.

Even assuming that adequate information could be conveyed to effectively educate consumers of potential risks, such information may ultimately be counterproductive. Consumers, lacking the training and understanding to properly evaluate risks of treatment as opposed to risks associated with failure to treat, may needlessly discontinue or fail to initiate necessary treatment. This may be particularly significant in the treatment of "silent" conditions such as hypertension, high cholesterol, and diabetes.

D. Potential "Chilling Effect" on the Pharmaceutical Industry

Imposition of legal liability for failure to warn the consumer of risks would likely have a "chilling effect" on the use of direct-to-consumer advertisements. Pharmaceutical manufacturers provide many needed products which have immensely improved the quality and duration of life. However, we must also realize that pharmaceutical manufacturers must respond to appropriate business concerns. Manufacturers owe a duty to owners and shareholders to operate the business in a manner which would reflect sound business judgment. The potential liability associated with abandoning the learned intermediary doctrine in advertising cases would most assuredly minimize the use of this potentially beneficial activity.

An illustrative example of the potential of this concept is the near crisis in the childhood vaccine market in the mid 1980's. Fearful of potential civil tort liability, the number of private pharmaceutical companies producing the diphtheria-tetanus-pertussis

97. 44 Fed. Reg. 40,020 (1979). In the 1970's, the Food and Drug Administration conducted studies which indicated that most patients did not receive information concerning medication from their physician, and those who did receive information often did not understand it or forgot it before leaving the office. *Id.*

98. ORTHO PHARMACEUTICAL CORP., ORTHO-CYCLEN ORTHO TRI-CYCLEN, (1994) (on file in Law Review Office).

(DPT) vaccine decreased from eight manufacturers to two manufacturers between 1980 and 1986.⁹⁹

Congress responded with the National Childhood Vaccine Injury Act of 1986.¹⁰⁰ The statute provides a no-fault compensation scheme for injured parties, requiring the plaintiff to initially file any potential claim with the Secretary of Health and Human Services rather than against the manufacturer.¹⁰¹ If an injured party is dissatisfied with the statutory compensation award, the Vaccine Act does allow victims to proceed under state product liability laws. However, Congress limited the available legal theories.¹⁰²

The history and necessity of the Vaccine Act demonstrate the potential impact of manufacturer liability on the availability of pharmaceuticals. It would be reasonable to infer that imposition of increased potential liability for products advertised directly to consumers would likewise limit or eliminate the use of such advertisements. As a result, consumers would be deprived of the numerous potential benefits discussed previously.

V. CONCLUSIONS

Unmistakably the power of advertising can generate consumer interest in and awareness of consumer products including prescription drugs. This is evidenced by the significant growth in sales of various medications which have been advertised directly to consumers.¹⁰³ However, consumer interest alone does not result in the actual use of any particular prescription medication. Our current health delivery system allows only physicians to initiate and facilitate the use of such medications. Although physicians no doubt respond to patient requests, ideas and suggestions concerning medication choice, it is unreasonable to assume that any medication would be prescribed based solely or even primarily upon patient responses to direct-to-consumer advertisements.

Certainly, it is possible that given two equally appropriate choices, the physician may choose to prescribe a medication sug-

99. H.R. REP. No. 908, 99th Cong., 2d Sess., at 4 (1986).

100. 42 U.S.C. § 300aa-10 to -33 (Supp. 1986).

101. 42 U.S.C. § 300aa-12(b)(1) (1988 & Supp. V 1993).

102. Daniel Cantor, *Striking a Balance Between Product Availability and Product Safety: Lessons from the Vaccine Act*, 44 AM. U.L. REV. 1853 (1995).

103. Marilyn L. Castaldi, *FDA Writing for Tougher Rx for Pharmaceutical Marketing*, PUBLIC RELATIONS J., Aug. 1991, at 14; *When the Prostate Swells*, CONSUMER REPORTS, July, 1993 at 460.

gested by the consumer. However, the overriding physician responsibility is to ensure that the choice of medication is therapeutically appropriate. Simply because a patient inquired about an advertised product and subsequently received that product does not suggest that the physician acted in a manner inconsistent with the doctrine of the "learned intermediary". Physician failure to adequately assess the patient's needs accompanied by a decision on a particular course of treatment which was based solely on a patient's requesting medication he or she had seen in a direct solicitation would almost certainly constitute medical malpractice. The physician would fail to function at the "standard of care" appropriate to his or her position in the health care system. Any subsequent harm suffered by the patient due to this form of professional negligence could and should be redressed by an action directly against the physician.

The availability of effective prescription therapies is critical to maintenance of public health. It is entirely reasonable and proper to create a social and legal environment which encourages manufacturers to continue to develop life-saving and life-improving pharmaceuticals. Certainly all parties involved, including pharmaceutical manufacturers, want to ensure that the public health is protected. The Food and Drug Administration is legislatively mandated to protect the public by ensuring compliance with a standard of safe and effective pharmaceuticals.¹⁰⁴ The proposed Restatement (Third) of Torts makes notice of the significance of FDA regulation, stating the assumption that "governmental regulatory agencies adequately review new prescription drugs and devices, keeping unreasonably dangerous devices off the market."¹⁰⁵

Dean Prosser stated the dichotomy well:

The argument that industries producing potentially dangerous products should make good the harm, distribute it by liability insurance, and add the cost to the price of the product, encounters reason for pause, when we consider that two of the greatest medical boons to the human race, penicillin and cortisone, both have their dangerous side effects, and that drug companies might well have been deterred from producing and selling them.¹⁰⁶

104. See the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355 (1988).

105. RESTATEMENT (THIRD) OF TORTS § 8 cmt. b (Tentative Draft No. 2, 1995).

106. JOHN W. WADE ET. AL., PROSSER, WADE AND SCHWARTZ'S CASES AND MATERIALS ON TORTS at 749 (9th ed. 1994).

Recognition of the public interest in pharmaceutical development has led various state legislatures to adopt specific statutes limiting product liability actions against manufacturers and sellers of pharmaceuticals.¹⁰⁷ However, in the absence of legislative direction, the doctrine of the learned intermediary still represents the most reasonable and effective method of ensuring access to safe and effective medications. Rather than undermining appropriate medication use, the increased utilization of direct-to-consumer pharmaceutical advertising supports this objective. Through increased awareness of alternatives and potential therapies, consumers are better able to benefit from the knowledge and expertise of the prescribing physician. The imposition of a legal liability to warn consumers of potential risks associated with advertised products, however, would force manufacturers to reevaluate and likely decrease the utilization of this potentially valuable form of consumer information.

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107. N.C. GEN. STAT. § 99B-5(c) (1996). ([N]o manufacturer or seller of a prescription drug shall be liable for failing to provide a warning or instruction directly to a consumer if an adequate warning or instruction has been provided to the physician . . . less the United States Food and Drug Administration requires such direct consumer warning or instruction to accompany the product.). See also ARIZ. REV. STAT. ANN. § 12-701 (West 1992); N.J. STAT. ANN. § 2A: 58C-4 (West 1987); OHIO REV. CODE ANN. § 2307.80(c) (Anderson 1995); OR. REV. STAT. § 30.927 (1995); UTAH CODE ANN. § 78-18-2 (1992).