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Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?

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WILL MORE AGGRESSIVE MARKETING PRACTICES LEAD TO GREATER TORT LIABILITY FOR PRESCRIPTION DRUG MANUFACTURERS?

Richard C. Ausness

Manufacturers of prescription drugs have begun to market their products more aggressively than they did in the past. These marketing efforts are not confined to health care professionals alone; pharmaceutical companies now engage in extensive direct-to-consumer advertising on radio and television, in the print media, and even on the Internet. While these promotional efforts no doubt increase sales, they may also lead to greater tort liability for drug-related injuries. The most likely theories of liability are failure to warn and negligent marketing. Liability for inadequate warnings will almost certainly increase if courts abandon the learned intermediary rule and require drug manufacturers to warn consumers instead of physicians when they engage in direct-to-consumer advertising. In addition, injured consumers may make negligent marketing claims in cases where there is evidence that pharmaceutical companies have pressured physicians to over-prescribe their products or where these companies have failed to exercise some control over doctors or pharmacists who facilitate abuse of prescription drugs.

I. INTRODUCTION

At one time, prescription drug manufacturers directed their promotional efforts solely at physicians and other health care providers.¹ They provided information about their products in the *Phy-*

* Ashland Oil Professor of Law, University of Kentucky. B.A., 1966; J.D. 1968, University of Florida; LL.M., 1973, Yale University. This Article grew out of a presentation which I gave as part of program entitled "Current Issues in Toxic Torts & Products Liability." This program was sponsored by the Indiana University School of Law-Indianapolis and Eli Lilly & Co. and was held at the Indiana University School of Law-Indianapolis at Indianapolis, Indiana on October 10, 2001. I would like to thank Professor Andrew R. Klein and Associate Dean Susanah M. Mead for inviting me to speak at the program and for their encouragement and assistance in connection with the writing of this Article.

1. *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245, 1247 (N.J. 1999) (observing that "[p]harmaceutical manufacturers never advertised their products to pa-

sicians' Desk Reference and sometimes placed discreet advertisements in medical journals and other professional publications. Sales representatives also visited doctors' offices on a regular basis and provided them with brochures and product samples.² The tort liability regime of that era reflected the fact that prescription drugs were different from ordinary consumer goods. Thus, while section 402A of the *Restatement (Second) of Torts* prescribed strict liability for most products,³ it classified prescription drugs as "unavoidably unsafe" products and largely exempted the sellers thereof from strict liability.⁴ In addition, courts uniformly applied the learned intermediary rule in products liability cases. This doctrine effectively insulated drug manufacturers from liability for failure to warn as long as they provided adequate warnings to physicians.⁵

Beginning in the late 1980s,⁶ however, drug companies discovered that they could greatly increase the market for their products by advertising directly to consumers instead of limiting their marketing efforts exclusively to physicians.⁷ As a consequence, these companies began to advertise prescription drugs in mainstream newspapers like the *New York Times* and the *Wall Street Journal*, in popular magazines, on radio and television, and on the Internet.⁸ It is estimated that drug manufacturers now spend more than \$1 billion a year on such direct-to-consumer advertising.⁹

These changes in traditional marketing practices have generated calls for increased liability on the theory that prescription

tients, but rather directed all sales efforts at physicians").

2. Donald E. Thompson II, Comment, *The Drug Manufacturer's Duty to Warn—To Whom Does It Extend?*, 13 FLA. ST. U. L. REV. 135, 144 (1985).

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

4. *Id.* cmt. k; see also Richard C. Ausness, *Unavoidably Unsafe Products and Strict Products Liability: What Liability Rule Should Be Applied to the Sellers of Pharmaceutical Products?*, 78 KY. L.J. 705, 707 (1989-90).

5. See Catherine A. Paytash, Note, *The Learned Intermediary Doctrine and Patient Package Inserts: A Balanced Approach to Preventing Drug-Related Injury*, 51 STAN. L. REV. 1343, 1345 (1999).

6. The Upjohn Company became the first drug manufacturer to engage in nationwide direct-to-consumer advertising when it introduced its celebrated anti-baldness product, Rogaine, to an eager public in 1989. See Michelle D. Ehrlich, *Doctors Can "Just Say No": The Constitutionality of Consumer-Directed Advertising of Prescription Drugs*, 12 HASTINGS COMM. & ENT. L.J. 535, 535 (1990); Barbara J. Tyler & Richard A. Cooper, *Blinded by the Hype: Shifting the Burden When Manufacturers Engage in Direct to Consumer Advertising of Prescription Drugs*, 21 VT. L. REV. 1073, 1073 (1997).

7. See Mae Joanne Rosok, Comment, *Direct-to-Consumer Advertising of Prescription Drugs: After a Decade of Speculation, Courts Consider Another Exception to the Learned Intermediary Rule*, 24 SEATTLE U. L. REV. 629, 629 (2000) (declaring that direct-to-consumer advertising "can effectively increase product sales by reaching potential consumers through print and broadcast media").

8. Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 141 (1997).

9. Wayne L. Pines, *A History and Perspective on Direct-to-Consumer Promotion*, 54 FOOD & DRUG L.J. 489, 506-07 (1999).

drugs are now being marketed in the same manner as any other product.¹⁰ One means of increasing liability would be to abolish the learned intermediary rule, either entirely or only in cases where the manufacturer has engaged in direct-to-consumer advertising.¹¹ Another route to enhanced liability is "negligent marketing."¹² This theory would impose liability upon product manufacturers who advertised their products in such a way as to invite misuse by underage or psychologically vulnerable buyers or by criminals; it also would subject manufacturers to liability for failure to control sales to such consumers by careless or unscrupulous retailers.¹³ However, while these approaches merit some consideration, I conclude that subjecting pharmaceutical companies to greater tort liability will not necessarily benefit the consuming public.

Part II of this Article begins with a description of the statutory regime under which the Food and Drug Administration (FDA) regulates prescription drug labeling and advertising.¹⁴ Part III examines the various rationales that are commonly invoked to support the learned intermediary rule. It also identifies some of the accepted exceptions to the learned intermediary rule and considers whether the courts should recognize a new exception in the case of direct-to-consumer advertising. Part IV introduces the concept of negligent marketing. It discusses the development of negligent marketing in the context of handgun litigation and evaluates the application of this concept in prescription drug litigation. Finally, Part V of the Article argues that it is better to discourage unethical and dangerous marketing practices by industry self-regulation, or if necessary by government regulation, than to create new, and potentially open-ended, forms of tort liability.

II. FDA REGULATION OF PRESCRIPTION DRUG LABELING AND ADVERTISING

Unlike ordinary consumer goods, prescription drugs are heavily regulated by the FDA.¹⁵ As part of this statutory scheme, the FDA

10. See generally Teresa Moran Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 FOOD DRUG COSM. L.J. 829, 848 (1991) (concluding that "[a] strong case can be made for recognizing an exception to the learned intermediary rule when prescription drug manufacturers engage in consumer-directed advertising").

11. See *infra* Part III.

12. See *infra* Part IV.

13. *Id.*

14. See *infra* Part II.

15. Ann N. James, Comment, *Warnings and the Pharmaceutical Companies: Legal Status of the Package Insert*, 16 HOUSTON L. REV. 140, 143 (1978) (declaring that virtually all phases of the manufacture and sale of pharmaceutical products are closely regulated by the FDA). For an overview of the FDA's regulatory authority over pharmaceutical products, see Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1758-1835 (1996). The FDA's regulatory authority is derived from the

oversees the labeling and the advertising of prescription drugs.¹⁶ The FDA also regulates the labeling of all medical devices and the advertising of "restricted" medical devices.¹⁷ The FDA regulates the labeling,¹⁸ though not the advertising,¹⁹ of over-the-counter drugs as well.²⁰

A. FDA Labeling Regulations

As part of its licensing process, the FDA requires the manufacturer of a new prescription drug to submit proposed labeling for approval.²¹ The reason the FDA reviews the proposed labeling is to ensure that it will provide the treating physician with all information necessary to use the product safely and appropriately.²² Thus, the FDA requires that such labeling contain dosage information, directions for safe use, conditions for which the drug is effective, contraindications, and warnings about known or suspected side effects or adverse reactions.²³

Once approved, this labeling must accompany the product in the form of a package insert.²⁴ FDA-approved labeling is also published in the *Physicians' Desk Reference*, a book that is readily available to physicians and other health care professionals.²⁵ However, the FDA's regulatory power over labeling is not limited to package inserts, but also extends to "any written material that supplements or explains the product, is disseminated by the manufacturer, and reaches the customer, doctor, or patient, either before, with, or after the product."²⁶ Thus, written materials, such as "brochures, detail

Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301-394 (2000), and the Public Health Service Act, 42 U.S.C. §§ 247b, 262 (2000).

16. 21 C.F.R. pt. 201 (2001) (labeling); *id.* pt. 202 (2001) (advertising).

17. 21 U.S.C. §§ 352, 352(r) (1994). Restricted medical devices are products whose sale is restricted in some way by the FDA. See Nancy K. Plant, *Prescription Drug Promotion on the Internet: Tool for the Inquisitive or Trap for the Unwary?*, 42 ST. LOUIS U. L.J. 89, 91 n.14 (1998).

18. 21 U.S.C. §§ 352(a), (n).

19. The Federal Trade Commission is responsible for overseeing the advertising of over-the-counter products. 15 U.S.C. § 52 (2000).

20. Plant, *supra* note 17, at 91 n.14.

21. Jeffrey N. Gibbs & Bruce F. Mackler, *Food and Drug Administration Regulation and Products Liability: Strong Sword, Weak Shield*, 22 TORT & INS. L.J. 194, 211-12 (1987).

22. *Id.* This information is ordinarily directed at the prescribing physician and not the patient. See Charles J. Walsh et al., *The Learned Intermediary Doctrine: The Correct Prescription for Drug Labeling*, 48 RUTGERS L. REV. 821, 827-28 (1994).

23. James, *supra* note 15, at 301.

24. 21 C.F.R. § 201.100(d) (2001).

25. Gibbs & Mackler, *supra* note 21, at 212.

26. Edward M. Basile et al., *Medical Device Labeling and Advertising: An Overview*, 54 FOOD & DRUG L.J. 519, 519 (1999); see *United States v. 47 Bottles, More or Less, Jenasol RJ Formula "60,"* 320 F.2d 564 (3d Cir.), *cert. denied*, 375 U.S. 953 (1963).

aids, promotional mailings, posters, 'Dear Doctor' letters and scientific journal articles" distributed by pharmaceutical companies are all included within the definition of labeling.²⁷

Manufacturers whose labeling fails to meet FDA requirements risk both criminal and civil liability. A product will be considered misbranded if the manufacturer fails to comply with the FDA's labeling requirements, thereby subjecting the manufacturer to criminal sanctions.²⁸ In addition, most courts will treat a violation of FDA labeling regulations as negligence per se²⁹ in any civil action brought against a manufacturer by an injured consumer.³⁰ Unfortunately, for drug manufacturers, in most cases, compliance with FDA labeling requirements will not necessarily protect them against tort liability based on inadequate warnings.³¹

B. FDA Regulation of Advertising and Promotion

Since 1963,³² the FDA has also regulated advertising for pre-

27. Basile, *supra* note 26, at 519.

28. See Pennington Parker Landen, *Federal Preemption and the Drug Industry: Can Courts Co-Regulate?*, 43 FOOD DRUG COSM. L.J. 85, 104 (1988).

29. When the legislature has established a mandatory standard of conduct in a criminal statute, many courts apply the doctrine of negligence per se in civil cases. Under this principle, the statutory standard establishes the standard of care for negligence so that violation of that standard conclusively establishes that the defendant failed to exercise reasonable care. See *Carter v. William Sommerville & Son, Inc.*, 584 S.W.2d 274, 278 (Tex. 1979) (observing that "[n]egligence per se is a tort concept whereby a legislatively imposed standard of conduct is adopted by the civil courts as defining the conduct of a reasonably prudent person"); see also Richard C. Ausness, *The Case for a "Strong" Regulatory Compliance Defense*, 55 MD. L. REV. 1210, 1239-41 (1996) (discussing the concept of negligence per se and the effect of noncompliance with statutory requirements).

30. See *Orthopedic Equip. Co. v. Eutsler*, 276 F.2d 455, 461 (4th Cir. 1960) (treating surgical nail manufacturer's violation of FDA labeling requirements as negligence per se); *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961, 964-65 (E.D. Wis. 1981) (suggesting that failure to comply with FDA warning requirements for oral contraceptives might be negligence per se).

31. See *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 658 (1st Cir. 1981); *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975); *Chambers v. G.D. Searle & Co.*, 441 F. Supp. 377, 383 (D. Md. 1975), *aff'd*, 567 F.2d 269 (4th Cir. 1977); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973); *Ortho Pharm. Corp. v. Chapman*, 388 N.E.2d 541, 554 (Ind. Ct. App. 1979); *Feldman v. Lederle Labs.*, 592 A.2d 1176, 1197 (N.J. 1991); *McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522, 534-35 (Or. 1974); *Bristol-Meyers Co. v. Gonzales*, 561 S.W.2d 801, 804 (Tex. 1978).

There is an exception to this rule in the case of certain medical devices where tort claims based on failure to warn are expressly preempted. See *Meyer v. Int'l Playtex, Inc.*, 724 F. Supp. 288, 293 (D.N.J. 1988); *Lavetter v. Int'l Playtex, Inc.*, 706 F. Supp. 722, 723 (D. Ariz. 1988); *Rinehart v. Int'l Playtex, Inc.*, 688 F. Supp. 475, 477 (S.D. Ind. 1988); *Edmondson v. Int'l Playtex, Inc.*, 678 F. Supp. 1571, 1571 (N.D. Ga. 1987); *Stewart v. Int'l Playtex, Inc.*, 672 F. Supp. 907, 909 (D.S.C. 1987).

32. Noah, *supra* note 8, at 142 (noting that the FDA first promulgated

scription drugs³³ and restricted medical devices.³⁴ The term, "advertising," includes "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communications systems."³⁵ FDA regulations provide that advertisements must be "fairly balanced" and must not promote unapproved uses, omit material information, or make comparative claims about another product unless these claims are supported by substantial evidence from two well-controlled clinical trials.³⁶

Prescription drug manufacturers must include a "brief summary" of the package insert in all advertisements which discuss a drug's effectiveness or identify indications for use.³⁷ This brief summary must describe side effects, contraindications, warnings, and indications for use, but need not provide the sort of dosage and pharmacological information that is typically required by the FDA for product labeling.³⁸ When manufacturers advertise to doctors and other health care professionals, they usually include relevant portions of the physician package insert in the advertisement.³⁹ The brief summary in direct-to-consumer advertisements may be similar to that contained in advertisements directed at health care professionals or it may be written in more simple lay language.⁴⁰ Advertisements that identify a product by name and state that the product is suitable for a specific condition or purpose must satisfy the brief summary requirement;⁴¹ however, so-called reminder and help-seeking advertisements do not have to contain a brief summary.⁴²

In the case of print advertising, drug companies may comply with the FDA's brief summary requirement by reproducing the text of the package insert in the advertisement.⁴³ However, satisfying the brief summary requirement is much more difficult for broadcast advertisers. For this reason, when pharmaceutical companies first began to advertise on radio and television in the mid-1980s, they confined themselves to help-seeking and reminder advertisements, which were exempt from the brief summary requirements. Rogaine advertisements of this period, which suggested that products were available to prevent hair loss but did not identify any of these products by name, exemplified the help-seeking variety of advertise-

regulations with respect to prescription drug advertising in 1963).

33. See 21 U.S.C. § 321(m) (1994).

34. *Id.* § 352(q), (r).

35. 21 C.F.R. § 202.1(l)(1) (2001).

36. *Id.* § 202.1(e)(5)(ii), (6)(i)-(v).

37. *Id.* § 202.1(e)(1).

38. *Id.* § 202.1(e)(3)(i)-(iii).

39. See Plant, *supra* note 17, at 101.

40. *Id.*

41. *Id.*; 21 C.F.R. § 202.1(e)(1) (2001).

42. 21 C.F.R. § 202.1(e)(2)(i)-(iii) (2001).

43. Noah, *supra* note 8, at 149.

ment. The "blue skies" Claritin advertisements of the early 1990s, which mentioned the product by name but failed to mention its medicinal purpose, exemplified the reminder type of advertisement.⁴⁴

Beginning in 1997, the FDA began to relax the brief summary requirement for radio and television advertisements.⁴⁵ Under current regulatory guidelines, which were promulgated in 1999,⁴⁶ drug manufacturers do not have to provide a brief summary on the air, but may simply identify the product's major side effects and contraindications in lay language during the broadcast.⁴⁷ In such cases, however, the manufacturer must comply with an "adequate provision" requirement.⁴⁸ This imposes a duty on the drug manufacturer to disseminate the contents of the approved package label to consumers by: (1) providing a toll-free telephone number where such information can be requested; (2) referring in the broadcast advertisement to a print advertisement or brochures available to the public which contain such information; (3) advising listeners or viewers to ask a pharmacist or doctor for further information about the product; and (4) providing an Internet web site where such information can be obtained.⁴⁹

Recently, the FDA has turned its attention to advertising by drug companies on the Internet.⁵⁰ The FDA traditionally maintained that information published on the Internet was a form of product labeling and could be regulated on this basis.⁵¹ Now, however, the FDA is attempting to develop guidelines to deal with the specialized problems of Internet advertising.⁵²

III. LIABILITY FOR FAILURE TO WARN ULTIMATE CONSUMERS

Sellers are usually required to provide adequate warnings and

44. Pines, *supra* note 9, at 494.

45. In August 1997, the FDA published "Draft Guidance" that allowed drug companies to make "adequate provision" for dissemination of the "brief summary" outside the broadcast itself. See FDA, Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements; Availability, 62 Fed. Reg. 43,171 (1997). This encouraged drug companies to increase advertisements for prescription products on television. See Pines, *supra* note 9, at 497.

46. In 1999, the FDA issued a "Final Guidance" on television advertising that spelled out in detail how drug companies could satisfy the "adequate provision" requirement in their radio and television advertising. See FDA, Guidance for Industry: Consumer-Directed Broadcast Advertisements (Aug. 1999) available at <http://www.fda.gov/cder/guidance/index.htm>.

47. See 21 C.F.R. § 202.1(e)(1) (2001).

48. Marilyn A. Moberg et al., *Surfing the Net in Shallow Waters: Product Liability Concerns and Advertising on the Internet*, 53 FOOD & DRUG L.J. 213, 216-17 (1998).

49. Kelly N. Reeves, *Direct-to-Consumer Broadcast Advertising: Empowering the Consumer or Manipulating a Vulnerable Population?*, 53 FOOD & DRUG L.J. 661, 674 (1998).

50. Noah, *supra* note 8, at 153-55.

51. Basile, *supra* note 26, at 530.

52. Pines, *supra* note 9, at 513-14.

instructions to the ultimate users or consumers of their products. However, under the learned intermediary rule, the sellers of prescription drugs may satisfy their duty to warn by communicating with prescribing physicians and need not attempt to reach consumers. Now that the nature of the physician-patient relationship is changing, it has been suggested that the learned intermediary rule should be done away with, thereby subjecting prescription drug manufacturers to a duty to warn patients as well as doctors.

A. *The Seller's General Duty to Warn*

Manufacturers⁵³ and others in the distributive chain⁵⁴ normally have a duty to provide adequate warnings and instructions to foreseeable users and consumers of their products.⁵⁵ According to the *Restatement (Third) of Torts*, a product may be considered defective when "the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor . . . and the omission of the instructions or warnings renders the product not reasonably safe."⁵⁶

Even if the manufacturer provides a warning, it may still be subject to liability if the court concludes that the warning provided was inadequate. An adequate warning is one that is reasonable under the circumstances.⁵⁷ This usually involves a number of factors.

53. Dix W. Noel, *Products Defective Because of Inadequate Directions or Warnings*, 23 SW. L.J. 256, 281 (1969) ("The duty to warn runs to those the manufacturer should expect to use the chattel, or be endangered by its probable use, and the warning must be reasonably calculated to reach such persons, directly or indirectly.")

54. M. Stuart Madden, *The Duty to Warn in Products Liability: Contours and Criticism*, 89 W. VA. L. REV. 221, 279 (1987) ("Liability for failure to provide adequate warnings may be imposed upon all entities within the chain of distribution, including not only manufacturers, but suppliers, wholesalers, distributors and retailers as well.")

55. Product sellers also may be held liable for failing to provide proper directions or instructions. See, e.g., *Edwards v. Cal. Chem. Co.*, 245 So. 2d 259, 265 (Fla. Dist. Ct. App. 1971) (instructions on insecticide found to be inadequate because they did not advise customers to wear respirator and protective clothing while using product); *Tompkins v. Log Sys., Inc.*, 385 S.E.2d 545, 547-48 (N.C. Ct. App. 1989) (reasonable person could conclude that instructions included in pre-packaged kits for construction of log homes were inadequate because they failed to explain how to make sure that building walls were plumb). In theory, warnings and instructions serve different purposes: warnings provide users or consumers with information about product-related risks, while instructions demonstrate how to use the product properly and safely. See Victor E. Schwartz & Russell W. Driver, *Warnings in the Workplace: The Need for a Synthesis of Law and Communication Theory*, 52 U. CIN. L. REV. 38, 51-52 (1983). Nevertheless, courts and commentators often use the term "warning" to include both warnings and instructions.

56. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(c) (1998).

57. *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 657 (1st Cir. 1981) ("An adequate warning is one reasonable under the circumstances."); *Graham v.*

First, a warning must provide information about all significant risks associated with the product's use⁵⁸ and must reveal the actual likelihood and gravity of such risks when they are known by the manufacturer.⁵⁹ Second, a warning will be considered inadequate if its print size is too small to be noticed by the user⁶⁰ or if the warning is not placed in a prominent position on the label.⁶¹ Third, a warning must be phrased with a degree of intensity that is commensurate with the danger,⁶² and must not be ambiguous, equivocal, or contradictory.⁶³ Fourth, an effective warning must be easily understood by its intended audience;⁶⁴ a warning that uses technical language not

Wyeth Labs., 666 F. Supp. 1483, 1498 (D. Kan. 1987) ("An adequate warning is one that is reasonable under the circumstances."); Ortho Pharm. Corp. v. Chapman, 388 N.E.2d 541, 553 (Ind. Ct. App. 1979) ("To be adequate, a warning must be reasonable under the circumstances.").

58. Little v. Liquid Air Corp., 939 F.2d 1293, 1300 (5th Cir. 1991) ("Because the principal purpose of the warning is to permit the user to make an informed decision whether to expose himself to the risks of the product, however, a manufacturer or distributor 'fulfills its duty to warn in this context only if it warns of all dangers associated with its products of which it has actual or constructive knowledge.") (quoting Jackson v. Johns-Manville Sales Corp., 750 F.2d 1314, 1320 (5th Cir. 1985)); Lindsay v. Ortho Pharm. Corp., 637 F.2d 87, 91 (2d Cir. 1980) ("The manufacturer's duty is to warn of all potential dangers which it knew, or in the exercise of reasonable care should have known, to exist."); Deines v. Vermeer Mfg. Co., 755 F. Supp. 350, 353 (D. Kan. 1990) ("The manufacturer's duty is to warn of all potential dangers which it knew, or in the exercise of reasonable care should have known, to exist.").

59. See Martinkovic v. Wyeth Labs., Inc., 669 F. Supp. 212, 216 (N.D. Ill. 1987) (warning provided to prescribing physician of DTP vaccine could be considered inadequate because it characterized risk of convulsions as "exceedingly rare," when some studies showed the risk to be as high as one in 1,750).

60. See Gardner v. Q.H.S., Inc., 448 F.2d 238, 243 (4th Cir. 1971) (warning about flammability of hair rollers held to be inadequate because it was in the same print size as other material on the product's label); Spruill v. Boyle-Midway, Inc., 308 F.2d 79, 86 (4th Cir. 1962) (warning on furniture polish found to be inadequate because print was too small to attract attention of users).

61. See D'Arienzo v. Clairol, Inc., 310 A.2d 106, 111 (N.J. Super. Ct. Law Div. 1973) (jury issue presented as to adequacy of warning that placed information about risk of allergic reaction to hair dye at the end of instructions on how to apply patch test).

62. Lars Noah, *Constraints on the Off-Label Uses of Prescription Drug Products*, 16 J. PRODS. & TOXICS LIAB. 139, 152 (1994); see also Salmon v. Parke, Davis & Co., 520 F.2d 1359, 1363 (4th Cir. 1975); Martinkovic v. Wyeth Labs., Inc., 669 F. Supp. 212, 215 (N.D. Ill. 1987); Mahr v. G.D. Searle & Co., 390 N.E.2d 1214, 1230 (Ill. Ct. App. 1979); Richards v. Upjohn Co., 625 P.2d 1192, 1196 (N.M. Ct. App. 1980); Seley v. G.D. Searle & Co., 423 N.E.2d 831, 837 (Ohio 1981).

63. See James B. Sales, *The Duty to Warn and Instruct for Safe Use in Strict Tort Liability*, 13 ST. MARY'S L.J. 521, 551-52 (1982); see also Salmon, 520 F.2d at 1363; Martinkovic, 669 F. Supp. at 215; Mahr, 390 N.E.2d at 1230; Richards, 625 P.2d at 1196; Seley, 423 N.E.2d at 837.

64. Bryant v. Technical Research Co., 654 F.2d 1337, 1345-46 (9th Cir. 1981) ("An important factor in evaluating the adequacy of a warning is the clarity of the warning."); Schwartz & Driver, *supra* note 55, at 61.

easily understood by members of the general public may not be adequate.⁶⁵ Finally, an otherwise acceptable warning may be found inadequate if it has not been communicated through the most effective channels.⁶⁶

B. *The Learned Intermediary Rule*

In most cases, the manufacturer of a prescription drug is only required to warn a patient's prescribing physician, and once an adequate warning is given to the physician, the drug manufacturer is relieved of any duty to warn the patient directly.⁶⁷ The exception to

65. See *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 71-72 (Mass. 1985) (warning that oral contraceptive might cause "cerebral thrombosis" did not adequately communicate the risk of a stroke to users). In addition, some courts have concluded that warnings printed solely in English may not be sufficient if they failed to use pictograms or Spanish when the expected users of the product were known to be incapable of understanding a warning written in English. See *Hubbard-Hall Chem. Co. v. Silverman*, 340 F.2d 402, 405 (1st Cir. 1965) ("[T]he jury could reasonably have believed that defendant should have foreseen that its admittedly dangerous product would be used by, among others, persons like plaintiffs' intestates, who were farm laborers, of limited education and reading ability, and that a warning . . . would not, because of its lack of a skull and bones or other comparable symbols or hieroglyphics, be 'adequate.');" *Stanley Indus., Inc. v. W.M. Barr & Co.*, 784 F. Supp. 1570, 1576 (S.D. Fla. 1992) ("In light of the defendants' joint advertising in Miami's Hispanic media and the nature of the product, this court likewise finds that it is for the jury to decide whether the defendant could have reasonably foreseen that the boiled linseed oil would be used by persons such as Gallery's Nicaraguan, Spanish-Speaking unskilled laborers."); *Campos v. Firestone Tire & Rubber Co.*, 485 A.2d 305, 310 (N.J. 1984) ("In view of the unskilled or semi-skilled nature of the work and the existence of many in the work force who do not read English, warnings in the form of symbols might have been appropriate."). But see *Ramirez v. Plough, Inc.*, 863 P.2d 167, 177 (Cal. 1993) ("To preserve . . . uniformity and clarity, to avoid adverse impacts upon the warning requirements mandated by the federal regulatory scheme, and in deference to the superior technical and procedural lawmaking resources of legislative and administrative bodies, we adopt the legislative/regulatory standard of care that mandates nonprescription drug package warnings in English only."); *Thomas v. Clairol, Inc.*, 583 So. 2d 108, 110-11 (La. Ct. App. 1991) ("[P]laintiff . . . had the burden to show the use [of the defendant's hair dye product] was sufficient [among illiterate consumers] that defendant should have foreseen it and provided additional warnings or other safety precautions.").

66. See *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978, 991-92 (4th Cir. 1975) (failure to use sales representatives to warn physicians about risk of vision loss from the use of Aralen rendered warning ineffective); *Yarrow v. Sterling Drug, Inc.*, 263 F. Supp. 159, 163 (D.S.D. 1967), *aff'd*, 408 F.2d 978, 990 (8th Cir. 1969); *Richards v. Upjohn Co.*, 625 P.2d 1192, 1196 (N.M. Ct. App. 1980) (holding that a jury might conclude that changing contraindication for neomycin in package inserts and *Physicians' Desk Reference* might not be sufficient to communicate newly discovered danger of using antibiotic to irrigate open wounds when this use had been recommended for more than ten years).

67. Yonni D. Fushman, Comment, *Perez v. Wyeth Labs., Inc.: Toward Creating a Direct-to-Consumer Advertisement Exception to the Learned Intermediary Doctrine*, 80 B.U. L. REV. 1161, 1162 (2000).

the general duty under products liability law to warn the ultimate consumer is known as the learned intermediary rule because the physician is expected to act as an intermediary between the manufacturer and the patient.⁶⁸ Although the learned intermediary rule first arose in connection with prescription drug cases,⁶⁹ courts now routinely apply it to cases involving medical implants⁷⁰ and medical devices as well.⁷¹

When the learned intermediary rule applies, a manufacturer may transmit a warning to a physician by means of a package insert, by placing information about the product in the *Physicians' Desk Reference*, by advertising in medical journals, by sending letters directly to physicians, or by personal visits to physicians' offices by company sales representatives.⁷² The legal sufficiency of a particular method of communication will depend on the circumstances.⁷³ A pharmaceutical company's duty to warn is continuous; therefore, the manufacturer must notify the medical community of any risks or

68. *Reaves v. Ortho Pharm. Corp.*, 765 F. Supp. 1287, 1289 (E.D. Mich. 1991); *West v. Searle & Co.*, 806 S.W.2d 608, 613 (Ark. 1991); *Felix v. Hoffman-LaRoche, Inc.*, 540 So. 2d 102, 104 (Fla. 1989); *Edwards v. Basel Pharms.*, 933 P.2d 298, 300 (Okla. 1997); *Terhune v. A.H. Robins Co.*, 577 P.2d 975, 978 (Wash. 1978).

69. *See, e.g., Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 811 (5th Cir.), *cert. denied*, 112 S. Ct. 2304 (1992) (Accutane acne medicine); *Anderson v. McNeilab, Inc.*, 831 F.2d 92, 93 (5th Cir. 1987) (Zomax sinus remedy); *Plummer v. Lederle Labs.*, 819 F.2d 349, 356 (2d Cir.), *cert. denied*, 484 U.S. 898 (1987) (Orimune oral polio vaccine); *Swayze v. McNeil Labs., Inc.*, 807 F.2d 464, 469 (5th Cir. 1987) (fentanyl narcotic anesthetic); *Givens v. Lederle*, 556 F.2d 1341, 1345 (5th Cir. 1977) (Sabin oral polio vaccine); *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966) (Aralen anti-arthritis medication); *Tracy v. Merrell Dow Pharms., Inc.*, 569 N.E.2d 875, 878 (Ohio 1991) (Nicorette anti-smoking treatment); *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 836 (Ohio 1981) (Ovulen oral contraceptives).

70. *See Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89, 95 (D. Md. 1989), *aff'd*, 898 F.2d 146 (4th Cir. 1990) (silicone gel breast implants); *Desmarais v. Dow Corning Corp.*, 712 F. Supp. 13, 17-18 (D. Conn. 1989) (silicone gel breast implants); *Padgett v. Synthes, Ltd.*, 677 F. Supp. 1329, 1335 (W.D.N.C. 1988) (compression plate attached to tibia bone); *Perfetti v. McGhan Med.*, 662 P.2d 646, 650 (N.M. Ct. App.), *cert. denied*, 662 P.2d 645 (N.M. 1983) (silicone gel breast implants).

71. *See Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1098 (5th Cir. 1991) (artificial heart valve); *Phelps v. Sherwood Med. Indus.*, 836 F.2d 296, 303 (7th Cir. 1987) (heart catheter); *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1232 (4th Cir. 1984) (cardiac pacemaker).

72. *Smith v. E.R. Squibb*, 273 N.W.2d 476, 478-79 (Mich. Ct. App. 1979); *Thompson, supra* note 2, at 144.

73. *See Wyeth Labs., Inc. v. Fortenberry*, 530 So. 2d 688, 692-93 (Miss. 1988) (warning about routine risks communicated by means of package insert held to be adequate as a matter of law). *But see Yarrow v. Sterling Drug, Inc.*, 263 F. Supp. 159, 163 (D.S.D. 1967), *aff'd*, 408 F.2d 978 (8th Cir. 1969) (holding that manufacturer should have used sales representatives to communicate warning to physicians).

side effects that are discovered after the product is first marketed.⁷⁴ However, once the manufacturer informs the physician about drug-related risks, the burden shifts to the physician to disclose this information to the patient.⁷⁵ On the other hand, a prescription product will be regarded as defective if the manufacturer fails to provide an effective warning to the prescribing physician.⁷⁶ Moreover, the patient has a direct cause of action against the manufacturer for any injuries that occur as the result of this breach of duty.⁷⁷

1. *Rationales for the Learned Intermediary Rule*

Over the years, courts and commentators have offered a variety of rationales in support of the learned intermediary rule. One justification for the rule rests on the nature of the physician-patient relationship.⁷⁸ It is assumed that the physician is primarily responsible for deciding what drugs to prescribe, while the patient plays a relatively passive role in the decision-making process.⁷⁹ Because the physician is medically trained and the patient is not, in most cases, the patient must rely on the physician to choose the most appropriate treatment.⁸⁰ Consequently, warnings are best directed at the

74. *Beyette v. Ortho Pharm. Corp.*, 823 F.2d 990, 992 (6th Cir. 1987); *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 91 (2d Cir. 1980); *Stanback v. Parke, Davis & Co.*, 502 F. Supp. 767, 770 (W.D. Va. 1980), *aff'd*, 657 F.2d 642 (4th Cir. 1981).

75. *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1232 (4th Cir. 1984) ("Once adequate warnings are given to the physician, the choice of treatment and the duty to disclose properly fall on the doctor."); *Rosok*, *supra* note 7, at 634-35. The physician's duty to warn his or her patients is derived from the doctrine of informed consent. See Alan R. Sykes, Note, *Prescription Drugs and the Duty to Warn: An Argument for Patient Package Inserts*, 39 CLEV. ST. L. REV. 111, 121 (1991).

76. *Mahr v. G.D. Searle & Co.*, 390 N.E. 2d 1214, 1228 (Ill. App. Ct. 1979) (pointing out that "a prescription drug may be deemed unreasonably dangerous if it is manufactured and distributed without adequate warnings of possible adverse reactions").

77. *Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919, 923 (8th Cir. 1970); *Wooderson v. Ortho Pharm. Corp.*, 681 P.2d 1038, 1050 (Kan. 1984); *McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522, 529 (Or. 1974); *Paytash*, *supra* note 5, at 1346.

78. Lloyd C. Chatfield II, Note, *Medical Implant Litigation and Failure to Warn: A New Extension for the Learned Intermediary Rule?*, 82 KY. L.J. 575, 584-85 (1993-94) (pointing out that "the nature of the physician-patient relationship forms the foundation of the learned intermediary rule").

79. Nancy K. Plant, *The Learned Intermediary Doctrine: Some New Medicine for an Old Ailment*, 81 IOWA L. REV. 1007, 1014 (1996) (stating that "[c]ourts that apply the [learned intermediary] doctrine assume that the physician is the primary decisionmaker regarding whether a particular patient should use a particular prescription drug").

80. *West v. Searle & Co.*, 806 S.W.2d 608, 613 (Ark. 1991) (stating that "the patient relies upon the physician's judgment in selecting the drug, and the patient relies upon the physician's advice in using the drug"); *Seley v. G.D. Searle & Co.*, 423 N.E. 2d 831, 840 (Ohio 1981) (observing that "[t]he patient is expected to place primary reliance upon the physician's judgment, and to follow

physician rather than at the patient.

Another rationale for the learned intermediary doctrine assumes that prescription drugs are complicated and that treatment choices must be based on an individualized assessment of the patient's particular physical condition.⁸¹ In the words of one court, "[p]rescription 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 [the] patient."⁸² Thus, the individualized nature of the treatment process strongly indicates that information about prescription drugs can best be utilized more effectively by physicians than by patients.

The learned intermediary rule may also be justified on the theory that warnings communicated directly to patients by pharmaceutical companies might actually be harmful instead of beneficial to their health.⁸³ Specifically, if information about particular drugs were not screened and interpreted by their doctors, it is feared that some patients might overreact to consumer-oriented warnings and fail to seek proper medical treatment.⁸⁴

Another rationale for the learned intermediary rule rests on more practical considerations. Drug manufacturers traditionally have transmitted warnings and other information to patients by means of a package insert.⁸⁵ However, unlike over-the-counter products, prescription drugs are normally shipped in bulk packages to pharmacies, who repackage them for sale to individual customers.⁸⁶ For this reason, it would be difficult for warnings from manufacturers to reach ultimate consumers of their products.⁸⁷ Further-

his advice and instructions as to the use of the drug"); *McKee v. Moore*, 648 P.2d 21, 24-25 (Okla. 1982) (declaring that "[t]he patient is expected to and, it can be presumed, does place primary reliance upon [the physician's] judgment").

81. *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024, 1031-32 (D.N.J. 1988) (stating that "[b]ecause prescription drugs are often complex in formula and effect, the physician is in the best position to take into account the propensities of the drug and the susceptibilities of the patient, and to give a highly individualized warning to the ultimate user based on the physician's specialized knowledge").

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

83. Susan A. Casey, Comment, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 WM. MITCHELL L. REV. 931, 948 (1993).

84. Plant, *supra* note 79, at 1015.

85. Chester Chuang, Note, *Is There a Doctor in the House? Using Failure-to-Warn Liability to Enhance the Safety of Online Prescribing*, 75 N.Y.U. L. REV. 1452, 1467 (2000).

86. Tyler & Cooper, *supra* note 6, at 1083.

87. *Basko v. Sterling Drugs, Inc.*, 416 F.2d 417, 426 (2d Cir. 1969) (observing that "it is difficult under such circumstances for the manufacturer, by label or direct communication, to reach the consumer with a warning") (quoting *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 130 (9th Cir. 1968)); *West v. Searle & Co.*, 806 S.W.2d 608, 613 (Ark. 1991) (declaring that "it is virtually impossible

more, it would be virtually impossible for manufacturers to produce warnings in lay language that would adequately inform patients of risks that are often varied and related to the physical condition of individual patients.⁸⁸ Physicians, on the other hand, can tailor these warnings to fit the needs of individual patients.⁸⁹

Finally, requiring drug manufacturers to warn ultimate consumers directly might undermine the physician-patient relationship.⁹⁰ As one court observed: "The physician-patient relationship is a fiduciary one based on trust and confidence and obligating the physician to exercise good faith. As a part of this relationship, both parties envision that the patient will rely on the judgment and expertise of the physician."⁹¹ Arguably, this relationship would be seriously compromised if the patient relied upon information from sources other than his or her personal physician.

2. *Exceptions to the Learned Intermediary Rule*

The learned intermediary rule assumes the existence of a physician-patient relationship under which information and advice can be efficiently transmitted from the physician to the patient. Consequently, the courts have been reluctant to apply the rule in situations where there is no physician-patient relationship, where such a relationship is greatly attenuated, or where the patient plays a major role in the medical decision-making process.⁹² As a result, a number of recognized exceptions to the learned intermediary rule have evolved over the years.⁹³

in many cases for a manufacturer to directly warn each patient").

88. Paytash, *supra* note 5, at 1347.

89. Kociemba v. G.D. Searle & Co., 680 F. Supp. 1293, 1305 (D. Minn. 1988) (pointing out that "the physician, as the prescriber of the drug, is in the best position to give a highly individualized warning to a patient based on the physician's knowledge of the patient and the inherent risks of the drug"); Terhune v. A.H. Robins Co., 577 P.2d 975, 978 (Wash. 1978) (observing that "[t]he physician decides what facts should be told to the patient").

90. See Swayze v. McNeil Labs, Inc., 807 F.2d 464, 471 (5th Cir. 1987) (declaring that "[w]hen the physician-patient relationship does exist, as here, we hesitate to encourage, much less require, a drug manufacturer to intervene in it"); Dunkin v. Syntex Labs., Inc., 443 F. Supp. 121, 123 (W.D. Tenn. 1977) (observing that "attempts to give detailed warnings to patients . . . might also tend to interfere with the physician/patient relationship"); West v. Searle & Co., 806 S.W.2d 608, 613 (Ark. 1991) (stating that "imposition of a duty to warn the user directly would interfere with the relationship between the doctor and the patient").

91. Tracy v. Merrell Dow Pharms., Inc., 569 N.E.2d 875, 879 (Ohio 1991) (citations omitted).

92. Plant, *supra* note 79, at 1016 (noting that "[c]ourts have not allowed manufacturers to invoke the Learned Intermediary doctrine in situations in which . . . no true physician-intermediary relationship exists and those in which the patient exercises an unusually significant role in determining whether the drug is an appropriate treatment").

93. See Casey, *supra* note 83, at 939-47; Schwartz, *supra* note 10, at 832-34.

The first exception applies to cases where a patient receives a vaccine administered as part of a mass immunization program.⁹⁴ Since there is rarely any contact between physicians and patients in such programs, it is felt that direct warnings are necessary to allow patients to make informed choices about the risks and benefits of immunization.⁹⁵ The learned intermediary rule has also been rejected in several cases where a vaccine was given in a doctor's office when the court concluded that the plaintiff's physician had not made any individualized balancing of risks and benefits before administering the vaccine.⁹⁶

A second exception involves oral contraceptives.⁹⁷ A few courts have excluded these drugs from the reach of the learned intermediary rule,⁹⁸ reasoning that patients participate more actively in decisions about contraceptive practices than in other types of medical treatment.⁹⁹ These courts also contend that manufacturers of oral contraceptives should be required to provide information about their products to patients directly because users of oral contraceptives do not always maintain an ongoing professional relationship with their doctors and, hence, do not rely upon them for information.¹⁰⁰ It should be pointed out that most courts continue to apply the learned intermediary rule even to oral contraceptives.¹⁰¹ In their view, it is appropriate to apply the learned intermediary rule in such cases because most patients do rely on their physicians for advice about

94. *Petty v. United States*, 740 F.2d 1428, 1440 (8th Cir. 1984) (swine flu vaccine administered in mass immunization program); *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1269 (5th Cir.) (polio vaccine administered through mass immunization program), *cert. denied*, 419 U.S. 1096 (1974); *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 122 (9th Cir. 1968) (same); *Cunningham v. Charles Pfizer & Co.*, 532 P.2d 1377, 1381 (Okla. 1975) (same).

95. *See Williams v. Lederle Labs.*, 591 F. Supp. 381, 389 (S.D. Ohio 1984) (declaring that a direct warning to the patient was required if "the vaccine is typically administered without the individualized balancing that underlies the learned intermediary rule").

96. *Givens v. Lederle*, 556 F.2d 1341, 1345 (5th Cir. 1977); *Williams v. Lederle Labs.*, 591 F. Supp. 381, 389 (S.D. Ohio 1984); *Samuels v. American Cyanamid Co.*, 495 N.Y.S.2d 1006, 1008 (Sup. Ct. 1985).

97. *Chatfield*, *supra* note 78, at 594-602.

98. *Odgers v. Ortho Pharm. Corp.*, 609 F. Supp. 867, 878 (E.D. Mich. 1985); *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379, 381 (E.D. Mich. 1985); *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 68 (Mass.), *cert. denied*, 474 U.S. 920 (1985).

99. *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 69 (Mass.), *cert. denied*, 474 U.S. 920 (1985).

100. *Id.*

101. *See Reaves v. Ortho Pharm. Corp.*, 765 F. Supp. 1287, 1290-91 (E.D. Mich. 1991); *Goodson v. Searle Labs.*, 471 F. Supp. 546, 549 (D. Conn. 1978); *West v. Searle & Co.*, 806 S.W.2d 608, 614 (Ark. 1991); *Ortho Pharm. Corp. v. Chapman*, 388 N.E.2d 541, 549 (Ind. Ct. App. 1979); *Cobb v. Syntex Labs., Inc.*, 444 So. 2d 203, 205 (La. Ct. App. 1983); *Taurino v. Ellen*, 579 A.2d 925, 928 (Pa. Super. Ct. 1990).

birth control.¹⁰²

A third exception has been recognized for intrauterine devices (IUDs). A federal appeals court in *Hill v. Searle Laboratories*¹⁰³ held that IUDs, like other birth control devices, were "atypical from most prescription drug products because the treating physician generally does not make an intervening, individualized medical judgment in the birth control decision."¹⁰⁴ The court offered several reasons for this conclusion. First, the patient, not the physician, makes the decision to practice birth control, and the reasons for this decision are often not medical in nature.¹⁰⁵ Second, once the IUD is inserted, there may be little subsequent contact between the physician and the patient.¹⁰⁶ Finally, IUDs and other birth control devices are often given in clinic-type conditions where there is little personal contact between the patient and the physician who oversees the procedure.¹⁰⁷ Notwithstanding the *Hill* decision, however, most courts have concluded that the learned intermediary rule does apply to IUD cases.¹⁰⁸ According to these courts, even though the patient may choose which form of contraception to use, her doctor still retains significant control over the decision-making process: not only does the physician describe the various options that are available to the patient, but he or she also fits the IUD in place.¹⁰⁹

Finally, a possible exception to the learned intermediary rule may be available when the FDA requires manufacturers to provide patient package inserts for the benefit of ultimate users of the product.¹¹⁰ FDA regulations mandate the use of patient package inserts for oral contraceptives.¹¹¹ These regulations provide that the manufacturer must furnish information about such matters as contraindications, potential side effects or adverse reactions, precautions that patients should take, and instructions for safe use.¹¹² Package inserts are also required for IUDs¹¹³ and certain other medical prod-

102. *West*, 806 S.W.2d at 614; *Taurino*, 579 A.2d at 928.

103. 884 F.2d 1064 (8th Cir. 1989).

104. *Id.* at 1070.

105. *Id.* at 1071.

106. *Id.*

107. *Id.*

108. *See* *Odum v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992); *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1148 (D. Or. 1989); *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024, 1032 (D.N.J. 1988); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1305-06 (D. Minn. 1988); *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 401 (Del. 1989); *Humes v. Clinton*, 792 P.2d 1032, 1042-43 (Kan. 1990); *Terhune v. A.H. Robins Co.*, 577 P.2d 975, 979 (Wash. 1978).

109. *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 401 (Del. 1989) (declaring that "not only must the physician order the IUD for his patient, but the physician must also fit the IUD in place. Thus, the patient is required to rely on her physician's expertise whenever an IUD is used.").

110. *Fushman*, *supra* note 67, at 1167-68.

111. 21 C.F.R. § 310.501 (2000).

112. *Id.* § 310.501(c).

113. *Id.* § 310.502; *id.* § 801.427.

ucts as well.¹¹⁴ A few courts have taken the position that the learned intermediary rule serves no purpose when the FDA requires the manufacturer to communicate directly with the patient by means of package inserts.¹¹⁵ However, most courts that have considered the issue have concluded that the learned intermediary rule should not be displaced by FDA package insert requirements.¹¹⁶

C. *Should There Be a Direct-to-Consumer Advertising Exception to the Learned Intermediary Rule?*

Some legal commentators believe that the learned intermediary rule has outlived its usefulness.¹¹⁷ They contend that the rule is inconsistent with the modern doctrine of informed consent¹¹⁸ and that it does not reflect the fact that patients have a more important role in health care decision-making than they did in the past.¹¹⁹ These critics also claim that traditional physician-patient relationships are increasingly uncommon in today's health care environment.¹²⁰ Nevertheless, the learned intermediary rule continues to be

114. See, e.g., *id.* § 310.515 (requiring package inserts for estrogen).

115. *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961, 965 (E.D. Wis. 1981) (concluding that:

[s]ince 21 C.F.R. § 310.501 was enacted to protect persons like the plaintiff from the harmful side effects associated with oral contraceptives by warning them of such effects so as to enable them to recognize them and to seek qualified medical assistance, . . . the defendant in this case did have a duty to warn the plaintiff Helen Anne Lukaszewicz of the possible side effects of Ortho-Novum);

Edwards v. Basel Pharms., 933 P.2d 298, 301 (Okla. 1997) (declaring that "[w]hen direct warnings to the user of a prescription drug have been mandated by a safety regulation promulgated for the protection of the user, an exception to the learned intermediary doctrine exists").

116. See *In re Norplant Contraceptive Prod. Liab. Litig.*, 165 F.3d 374, 379-80 (5th Cir. 1999); *MacPherson v. Searle & Co.*, 775 F. Supp. 417, 424-25 (D.D.C. 1991); *Zanzuri v. G.D. Searle & Co.*, 748 F. Supp. 1511, 1516 (S.D. Fla. 1990); *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024, 1033 (D.N.J. 1988); *Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352, 356-57 (Ill. 1996).

117. *Casey*, *supra* note 83, at 957 ("[T]he learned intermediary doctrine . . . is a concept that has outlived its erstwhile value.").

118. See Margaret Gilhooly, *Learned Intermediaries, Prescription Drugs and Patient Information*, 30 ST. LOUIS U. L.J. 633, 657-58 (1986) ("The change in the informed consent doctrine makes appropriate a corresponding change in the role that the physician should perform as a 'learned intermediary.'"); *Thompson*, *supra* note 2, at 146 ("By placing the warning into the hands of the physician, who is given sole discretion to determine what risk, if any, will be communicated to the patient, the current system of manufacturer warnings perpetuates paternalism and aggravates the problem of informed consent.").

119. See *Rosok*, *supra* note 7, at 659 (observing that "[t]he practice of medicine in the United States is less paternalistic than in the past because patient involvement in health care decisions has increased"); *Schwartz*, *supra* note 10, at 844 (arguing that "patients are adopting a stronger role in the doctor/patient relationship").

120. See *Chuang*, *supra* note 85, at 1464 (contending that "[t]oday's managed care organizations often prevent patients from establishing long term relationships with physicians and usually provide patients with shorter consulta-

ertheless, the learned intermediary rule continues to be recognized by the vast majority of American courts.¹²¹ Moreover, the new *Restatement of Torts* has also endorsed the traditional learned intermediary rule,¹²² although not without dissent from some legal scholars.¹²³

A number of commentators have called upon courts to recognize an exception to the learned intermediary rule for prescription products that are advertised directly to consumers.¹²⁴ For the most part, the few courts that have addressed this issue have not shown much enthusiasm for creating such an exception. However, a recent decision by the New Jersey Supreme Court, *Perez v. Wyeth Laboratories, Inc.*,¹²⁵ suggests that this may be about to change.

1. Prior Cases

Stephens v. G.D. Searle & Co.,¹²⁶ decided in 1985, was one of the first cases to consider the potential effect of direct-to-consumer advertising on the learned intermediary rule. In that case, the court was to decide whether the manufacturers of oral contraceptives should lose the benefit of the learned intermediary rule because their "zealous marketing practices" caused patients to request certain types of birth control pills and thereby minimized the physician's role in treatment decisions.¹²⁷ Although the court declined to recognize an exception for direct-to-consumer advertising in *Stephens*, it did take the manufacturer's marketing practices into account when it decided to exempt oral contraceptives from the

tions").

121. See Fushman, *supra* note 67, at 1164 n.19 (citing cases in thirty-seven states that adopt this rule).

122. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d)(1) (1998). For a discussion of the learned intermediary rule and the *Restatement (Third)* see Noah, *supra* note 8, at 161-68.

123. George W. Conk, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?*, 109 YALE L.J. 1087, 1132 (2000) (contending that "none of the rationales set forth in the *Restatement (Third)* justifies the bifurcation of products-liability law and the near-immunity from products liability granted to makers of prescription drugs and other medical products").

124. Fushman, *supra* note 67, at 1183 (arguing that "[a] DTC advertising exception [to the learned intermediary rule] makes sense"); Tyler & Cooper, *supra* note 6, at 1095-96 (contending that "[s]ince the effect of DTC promotions and advertisements is to bypass the learned intermediary, the court should be receptive to an argument for another exception to this doctrine"). *But see* Noah, *supra* note 8, at 180 (declaring that "no persuasive case exists for recognizing an advertising exception [to the learned intermediary doctrine]"); Rosok, *supra* note 7, at 660 (asserting that "[n]either case law precedent nor policy arguments support the argument that direct-to-consumer advertising should create an exception to the learned intermediary rule in drug liability actions").

125. 734 A.2d 1245 (N.J. 1999).

126. 602 F. Supp. 379 (E.D. Mich. 1985).

127. *Id.* at 380.

learned intermediary rule.¹²⁸

The question came up again in *Hill v. Searle Laboratories*.¹²⁹ The court in that case held that the manufacturer of CU-7 IUDs was required to warn ultimate users because the manufacturer's advertising did not give consumers a true picture of the risks associated with using the defendant's product.¹³⁰ The court in another case, *Garside v. Osco Drug, Inc.*,¹³¹ declared that an exception to the learned intermediary rule might be appropriate when a drug manufacturer "bypasses the traditional patient-physician relationship" by means of direct-to-consumer advertising.¹³² However, since the defendant in that case had not advertised to patients, the court's remarks in *Garside* were nothing more than dictum.

More recently, *In re Norplant Contraceptive Products Litigation*,¹³³ decided by a federal appeals court in 1999, also refused to recognize an exception for direct-to-consumer advertising. The plaintiffs in *Norplant* alleged that they had all suffered side effects from Norplant contraceptive devices.¹³⁴ The plaintiffs argued that the product's manufacturer should be held liable for failing to warn them directly about the risks of side effects, while the manufacturer insisted that it was only obligated to warn the plaintiffs' physicians.¹³⁵ The trial court agreed with the defendant's position and granted a motion for summary judgment in its favor.¹³⁶ On appeal, the plaintiffs contended, *inter alia*, that the manufacturer had engaged in "aggressive" marketing and, therefore, should be held liable for not providing adequate information about the product's side effects as part of these marketing efforts.¹³⁷

The appeals court rejected this argument because the plaintiffs were unable to prove that they had seen or relied on any of the defendant's advertising or promotional materials.¹³⁸ Therefore, according to the court, the product manufacturer was entitled to summary judgment even if the court recognized the existence of an exception to the learned intermediary rule when the manufacturer had engaged in direct-to-consumer advertising.¹³⁹ Furthermore, the court concluded that Texas law, which was applicable in this case,

128. Fushman, *supra* note 67, at 1169.

129. 884 F.2d 1064 (8th Cir. 1989).

130. *Id.* at 1070.

131. 764 F. Supp. 208 (D. Mass. 1991), *rev'd*, 976 F.2d 77 (1st Cir. 1992).

132. *Id.* at 211 n.4.

133. 165 F.3d 374 (5th Cir. 1999).

134. *Id.* at 376. The Norplant device is designed to provide long-term birth control protection. It consists of six containers of a hormone, progestin, which are inserted in the patient's upper arm just below the skin. *Id.*

135. *Id.* at 376-77.

136. *Id.*

137. *Id.* at 379.

138. *Id.*

139. *Id.*

would apply the learned intermediary rule, even where a manufacturer employed direct-to-consumer advertising, as long as a physician-patient relationship existed between the victim and her physician.¹⁴⁰ Accordingly, the court affirmed the trial court's summary judgment for the defendant.¹⁴¹

2. *Perez v. Wyeth Laboratories, Inc.*

The New Jersey Supreme Court adopted a different view on this issue in *Perez v. Wyeth Laboratories, Inc.*¹⁴² The plaintiffs in this case alleged that the American distributors of Norplant had failed to provide adequate warnings about various side effects associated with the contraceptive device.¹⁴³ After cases involving approximately fifty New Jersey plaintiffs were consolidated in one court, five "bellweather" plaintiffs¹⁴⁴ were selected to litigate the issue of whether the defendant's duty to warn the ultimate users of the Norplant device was limited by the learned intermediary rule.¹⁴⁵ The trial court held that the learned intermediary rule was applicable and dismissed the plaintiffs' case.¹⁴⁶ The intermediate appellate court, relying in part on the *Restatement (Third) of Torts*¹⁴⁷ and in part on a state statute,¹⁴⁸ affirmed the trial court's decision.¹⁴⁹

On appeal, the New Jersey Supreme Court concluded that sellers of prescription drugs who make direct claims to consumers about the efficacy of their products cannot satisfy their duty to warn merely by providing information to physicians.¹⁵⁰ The court noted that the defendant had begun a massive marketing campaign for the Norplant device in 1991, advertising extensively on television and in

140. *Id.* The court cited *Hurley v. Lederle Laboratories*, 863 F.2d 1173, 1178 (5th Cir. 1988), and *Swayze v. McNeil Laboratories*, 807 F.2d 464 (5th Cir. 1987), as authority for this proposition.

141. 165 F.3d at 379-80.

142. 734 A.2d 1245 (N.J. 1999).

143. *Id.* at 1248. These side effects included "weight gain, headaches, dizziness, nausea, diarrhea, acne, vomiting, fatigue, facial hair growth, numbness in the arms and legs, irregular menstruation, hair loss, leg cramps, anxiety and nervousness, vision problems, anemia, mood swings and depression, high blood pressure, and removal complications that resulted in scarring." *Id.*

144. When a large number of claimants have brought suits involving common issues, it will enhance the prospects of a settlement for all parties if a few claimants can first try these issues in "bellweather" trials in order to obtain information about the value of their cases as determined by the size of jury verdicts (if any) in these trials. See *In re Chevron, U.S.A., Inc.*, 109 F.3d 1016, 1019-20 (5th Cir. 1997).

145. See *Perez v. Wyeth Labs., Inc.*, 713 A.2d 588 (N.J. Super. Ct. Law Div. 1997).

146. *Id.* at 594.

147. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) (1998).

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

149. *Perez v. Wyeth Labs., Inc.*, 713 A.2d 520, 524 (N.J. Super. Ct. App. Div. 1998).

150. *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245, 1247 (N.J. 1999).

women's magazines such as *Glamour*, *Mademoiselle*, and *Cosmopolitan*.¹⁵¹ According to the plaintiffs, while these advertisements extolled the simplicity and convenience of the Norplant device, they failed to mention possible side effects, such as pain and permanent scarring that might occur when the implants were removed.¹⁵²

Relying heavily on an article by Professors Hanson and Kysar,¹⁵³ the New Jersey court identified a number of concerns about direct-to-consumer advertising.¹⁵⁴ For example, the court declared that "an integral part of drug manufacturers' marketing strategy" was to exert pressure on consumers to ask for their products.¹⁵⁵ The court also pointed out that manufacturers who engaged in direct-to-consumer advertising seldom informed consumers about the specific risks associated with using prescription products.¹⁵⁶ Instead, the court observed that warnings tended to be general rather than specific in nature and that consumers often interpreted these warnings as assurances that the product was effective, not that it could be dangerous.¹⁵⁷

At this point, the court considered whether creating an exception to the learned intermediary rule was contrary to either the *Restatement (Third) of Torts* or to the New Jersey Products Liability Act.¹⁵⁸ As the court observed, section 6(d)(2) of the new *Restatement* requires a prescription drug manufacturer to provide a warning directly to the patient "when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings."¹⁵⁹ However, after attempts to create an express exception to the learned intermediary rule for direct-to-consumer advertising failed, the drafters of the *Restatement* decided to let "developing case law" determine whether the courts should recognize such an exception under the auspices of section 6(d)(2).¹⁶⁰ The court in *Perez* decided to take the drafters of the *Restatement* up on their offer to create an exception for direct-to-consumer advertising.

The court also concluded that New Jersey's Products Liability Act¹⁶¹ did not foreclose it from creating an additional exception to the learned intermediary rule.¹⁶² A provision of the Act defined an ade-

151. *Id.* at 1248.

152. *Id.*

153. Jon D. Hanson & Douglas A. Kysar, *Taking Behavioralism Seriously: Some Evidence of Market Manipulation*, 112 HARV. L. REV. 1420 (1999).

154. *Perez*, 734 A.2d at 1251-53.

155. *Id.* at 1251.

156. *Id.* at 1252-53.

157. *Id.* at 1253.

158. *Id.* at 1254-55.

159. RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 6(d)(2) (1998).

160. *See Perez*, 734 A.2d at 1253 (citing RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 6 cmt. e).

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

162. *Perez*, 734 A.2d at 1253-54.

quate warning for a prescription drug as one that a reasonably prudent person would have provided, "taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician."¹⁶³ While this language seemed to indicate that prescription drug manufacturers were only required to warn physicians, the *Perez* court insisted that the statute merely set forth the content of physician-directed warnings *when such warnings were required*, leaving the court free to identify the circumstances when such warnings were legally sufficient.¹⁶⁴

Having disposed of these issues to its satisfaction, the *Perez* court then discussed some of the rationales that had been invoked to support the learned intermediary rule in the past and concluded that, due to significant changes in the nature of the physician-patient relationship, most of these rationales were no longer persuasive when drug companies engaged in direct-to-consumer advertising.¹⁶⁵ For example, the court declared that the doctrine of informed consent, along with the development of managed health care systems, had significantly reduced the role of the physician as the primary decision-maker and source of information about medical treatment.¹⁶⁶ According to the court, the advent of the doctrine of informed consent effectively destroyed the paternalism of the past and gave patients a legal right to participate in treatment decisions.¹⁶⁷ However, since physicians who practiced in a managed health care environment often did not have time to inform patients adequately about the risks and benefits of various prescription drugs, patients would have to look elsewhere for information about the medications they consumed.¹⁶⁸ In the court's view, pharmaceutical companies were a potential source of information about the products they manufactured. At least when they engaged in direct-to-consumer advertising, drug companies could communicate effectively with consumers and, therefore, it made sense to require them to do so.¹⁶⁹ The court also suggested that an enhanced duty to warn was particularly appropriate for so-called "life-style" drugs, such as Rogaine or contraceptives, because they carried the risk of significant side effects, but were not medically necessary.¹⁷⁰

After concluding that drug companies who advertised prescription drugs directly to consumers must also provide them with adequate warnings about drug-related risks, the court in *Perez* considered whether compliance with FDA labeling requirements provided

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

164. *Perez*, 734 A.2d. at 1254.

165. *Id.* at 1255.

166. *Id.*

167. *Id.*

168. *Id.*

169. *Id.* at 1255-56.

170. *Id.* at 1257.

any sort of safe harbor.¹⁷¹ Unfortunately, the court's analysis of this issue was not very enlightening.¹⁷² After describing the FDA's regulatory scheme, the court declared that the manufacturer's duty to warn *physicians* was presumptively satisfied by compliance with FDA labeling requirements.¹⁷³ It then applied this same rebuttable presumption to warnings directed at *consumers*.¹⁷⁴

The court gave two reasons for adopting this position. First, the court seemed to think that there was some value in subjecting physician-directed and consumer-directed warnings to the same rule as far as regulatory compliance was concerned.¹⁷⁵ Second, giving presumptive effect to compliance with FDA labeling regulations would help to prevent over-deterrence by protecting pharmaceutical companies against liability for "remotely possible, but not scientifically-verifiable, side-effects of prescription drugs."¹⁷⁶ However, in a later part of its opinion, the court seemed to withdraw much of the protection it had previously extended to drug manufacturers by declaring that compliance with FDA standards would be "virtually dispositive" of failure to warn claims "absent deliberate concealment or *nondisclosure* of after-acquired knowledge of harmful effects."¹⁷⁷ As one commentator concluded, this language seems to mean that "[a] failure to warn claim can be rebutted by a showing of compliance with FDA regulations, unless, of course, it is a failure to warn claim."¹⁷⁸

Finally, the *Perez* court held that a physician would not necessarily break the chain of causation when he or she acted as a learned intermediary.¹⁷⁹ The court pointed out that while physicians still exercised considerable influence over treatment decisions, nowadays patients participated in this process to such a degree that it was difficult to characterize the physician's role as sufficient to cut off liability for drug companies if they breached their duty to warn.¹⁸⁰ More importantly, the court concluded as a matter of public policy that the patient's right to complete and accurate information about drug-related risks would be best safeguarded if both drug manufacturers and physicians were subject to tort liability for failing to disclose this information.¹⁸¹

At the present time, it is too soon to tell whether other courts will follow the lead of the *Perez* court and also recognize an exception to the learned intermediary rule when the sellers of prescrip-

171. *Id.* at 1257-59.

172. See Fushman, *supra* note 67, at 1179.

173. *Perez*, 734 A.2d at 1259.

174. *Id.*

175. *Id.*

176. *Id.*

177. *Id.* (emphasis added).

178. Fushman, *supra* note 67, at 1179.

179. *Perez*, 734 A.2d at 1262-63.

180. *Id.* at 1260.

181. *Id.* at 1262-63.

tion drugs engage in direct-to-consumer advertising. To be sure, the New Jersey Supreme Court has been responsible for many innovations in American products liability law.¹⁸² But not all such decisions of this court have been followed by other courts,¹⁸³ and there is reason to think that *Perez* falls into this latter category. The exception advocated by the *Perez* court is hard to justify in terms of either doctrine or policy.

D. *Arguments for a Direct-to-Consumer Advertising Exception*

Critics of the learned intermediary rule have made a number of arguments for refusing to apply the rule in cases where drug manufacturers engage in direct-to-consumer advertising. For example, these critics contend that direct-to-consumer advertising and other marketing practices have changed the nature of the physician-patient relationship in a way that largely obviates the need for a learned intermediary rule.¹⁸⁴ In addition, critics of the rule argue that drug manufacturers who engage in mass marketing should be held to the same duty to warn as the sellers of other consumer goods.

1. *Erosion of the Traditional Physician-Patient Relationship*

Critics of the traditional learned intermediary rule contend that consumers no longer passively defer to their physicians, but instead actively participate in medical decisions that affect their health and well-being.¹⁸⁵ One reason for this increased involvement in medical decision-making is that marketing practices by prescription drug companies have given consumers better access to information about treatment options.¹⁸⁶ For example, drug manufacturers frequently

182. See, e.g., *Bexiga v. Havir Mfg. Corp.*, 290 A.2d 281, 285 (N.J. 1972) (refusing to allow manufacturer to delegate responsibility for installing safety features on punch press); *Cintrone v. Hertz Truck Leasing & Rental Serv.*, 212 A.2d 769, 781 (N.J. 1965) (extending strict liability principles to bailments); *Schipper v. Levitt & Sons, Inc.*, 207 A.2d 314, 325-26 (N.J. 1965) (extending strict liability principles to mass-produced housing); *Henningsen v. Bloomfield Motors, Inc.*, 161 A.2d 69, 73-75 (N.J. 1960) (limiting privity of contract and disclaimer defenses in consumer sales).

183. See *O'Brien v. Muskin Corp.*, 463 A.2d 298, 306 (N.J. 1983) (allowing a jury to find a product to be defectively designed even though no safer alternative design existed); *Beshada v. Johns-Manville Prods. Corp.*, 447 A.2d 539, 547-49 (N.J. 1982) (upholding liability for failure to warn of risks that were scientifically unknowable at the time the product was manufactured); *Santor v. A & M Karagheusian, Inc.*, 207 A.2d 305, 312 (N.J. 1965) (applying strict liability principles to pure economic losses).

184. See Schwartz, *supra* note 10, at 840 (arguing that the "[p]romotion of prescription drugs has changed, and the premises on which the learned intermediary rule is based do not necessarily reflect the reality of new marketing practices").

185. *Id.* at 844 (stating that "patients are adopting a stronger role in the doctor/patient relationship").

186. Noah, *supra* note 8, at 178 (declaring that "[d]irect advertising encour-

offer "video tapes, brochures and information packets" about their products and also provide toll-free telephone numbers where consumers can obtain package inserts and other detailed information.¹⁸⁷ In addition, information about specific prescription drugs is often available on the drug company Internet sites, as well as those maintained by health organizations, independent chat rooms and news groups.¹⁸⁸

The sale of prescription drugs over the Internet has also undermined the classic physician-patient relationship. Today consumers can log on to an online pharmacy and purchase prescription drugs without any physical personal contact with a physician.¹⁸⁹ Instead, consumers participate in an "online consultation," which often involves nothing more than filling out a brief questionnaire about general health information and other medication the individual may be taking.¹⁹⁰ The questionnaire is reviewed by a physician employed by the online pharmacy who issues a prescription for the drug that the consumer has requested.¹⁹¹

Finally, the emergence of HMOs and similar managed health care plans has also reduced the power of prescribing physicians. These organizations often obtain substantial price concessions from pharmaceutical companies by agreeing to exclude competing products.¹⁹² However, this means that physicians who are affiliated with these managed health care plans have less discretion when it comes to prescription drugs.¹⁹³ In addition, patients may pressure physicians who are associated with managed health care plans to prescribe specific prescription products because these patients may go elsewhere for medical treatment if physicians do not accede to their demands.¹⁹⁴

There is no question that these developments have changed the traditional physician-patient relationship. However, that does not necessarily mean that the learned intermediary rule should be limited or abolished. In the first place, despite increased involvement by patients in treatment decisions, in most cases they still rely upon physicians to provide them with information about the risks and benefits of various treatment options and to exercise their profes-

ages active participation by consumers in prescribing decisions").

187. Schwartz, *supra* note 10, at 838.

188. See Plant, *supra* note 17, at 104-07.

189. Rebecca Porter, *Internet Pharmacies: Who's Minding the Store?*, TRIAL, May 2000, at 12, Kerry Toth Rost, Note, *Policing the "Wild West" World of Internet Pharmacies*, 76 CHI.-KENT L. REV. 1333, 1333-34 (2000).

190. Chuang, *supra* note 85, at 1455.

191. *Id.*

192. See Walsh et al., *supra* note 22, at 876.

193. *Id.* at 876-77.

194. Fushman, *supra* note 67, at 1172 (suggesting that "[p]hysicians assent to patients demands for specific drugs because they cannot afford to lose patients in the modern managed care regime").

sional judgment in selecting the most appropriate one.¹⁹⁵ Furthermore, because consumers cannot legally obtain prescription products without a physician's consent, he or she continues to have the last word about treatment decisions. Therefore, the most efficient and effective way to transmit information about prescription drugs is to direct this information primarily to physicians and to rely upon them to convey what is needed to their patients. The learned intermediary rule does just that.

2. *Drug Companies Who Advertise to the Public Should Not Receive Special Treatment*

Critics of the learned intermediary rule sometimes suggest that drug companies that engage in direct-to-consumer advertising should be held to the same duty to warn as other sellers. These critics also point out that the advertising techniques employed for prescription drugs resemble the techniques that are used to promote commonplace consumer goods.¹⁹⁶ Specifically, prescription drug advertising, particularly for life-style drugs, often plays upon the personal insecurities and vanities of listeners or viewers.¹⁹⁷ Having chosen to market their products like toothpaste or laundry soap, the critics would argue, pharmaceutical companies should be excluded from the protection of a rule that governs a highly-specialized marketing regime.

This is a powerful argument if one believes that the primary purpose of the learned intermediary rule is to benefit pharmaceutical companies at the expense of consumers. Under this view of the learned intermediary rule, one might justifiably conclude that drug companies should lose the benefit of the rule because direct-to-consumer advertising amounts to a waiver or estoppel on their part. However, this argument collapses if one believes that the learned intermediary rule is primarily intended to ensure that information about prescription drugs is transmitted to the ultimate consumer in the most efficient manner. In other words, if the primary beneficiaries of the learned intermediary rule are consumers, and not drug companies, then the conduct of drug companies should not necessarily determine whether the rule should be retained or not. Instead, the determining factor should be whether or not manufacturers can transmit information more efficiently by communicating solely with prescribing physicians or whether the benefits of direct communica-

195. Noah, *supra* note 8, at 173 (observing that "advocates of an advertising exception fail to appreciate the fact that a medical professional will continue to intervene in the decision to prescribe a drug and make the final judgment about its relative risks and benefits for a particular patient"); Paytash, *supra* note 5, at 1356 (declaring that "while advertisements may induce patients to ask their doctors for particular medications, the physician remains the decisionmaker and the principal source of information about the product").

196. Schwartz, *supra* note 10, at 836-37.

197. *Id.*

tions with consumers outweigh the costs.

IV. NEGLIGENT MARKETING

A second source of potential liability for pharmaceutical companies is a relatively new legal theory known as "negligent marketing." The concept of negligent marketing is based on the notion that manufacturers should be required to market their products in a way that minimizes the risk that consumers will injure themselves or others. The advantage of negligent marketing over more conventional product liability theories is that a claimant who relies on negligent marketing does not prove that the product in question is defective. So far, virtually all reported negligent marketing cases have involved handguns. However, plaintiffs' attorneys have recently invoked this theory at the trial level in a few high-profile prescription drug cases.¹⁹⁸ If they are successful, one would expect negligent marketing claims to proliferate significantly in the years ahead.

A. *Types of Negligent Marketing*

Litigation against handgun manufacturers has given rise to two distinct forms of negligent marketing. The first type of negligent marketing is based upon a product seller's advertising and promotional activities, and the second is based upon its failure to supervise adequately the conduct of distributors and retail sellers.¹⁹⁹ In addition, it is possible that the courts may eventually recognize other forms of negligent marketing in the future. One evolving form of negligent marketing of particular interest to the pharmaceutical industry is "overpromotion."

1. *Targeting Vulnerable or Unsuitable Consumers*

The first type of negligent marketing claim focuses on advertising or promotional efforts that are intended to induce unsuitable persons to purchase products that are dangerous to themselves or others. For example, anti-smoking advocates contend that the infamous cartoon character, Joe Camel, was introduced to create a favorable impression of smoking in the minds of young children and thus to encourage them to become smokers at some time in the future.²⁰⁰ Another cigarette company was forced to withdraw its men-

198. See *In re: Rezulin Prods. Liab. Litig.*, No. 1348, 2001 U.S. Dist. LEXIS 16624, at *21-22 (S.D.N.Y. Oct. 17, 2001); *Brumley v. Pfizer, Inc.*, 149 F. Supp. 2d 305, 307 (S.D. Tex. 2001).

199. See generally Andrew Jay McClurg, *The Tortious Marketing of Handguns: Strict Liability Is Dead, Long Live Negligence*, 19 SETON HALL LEGIS. J. 777, 800-05 (1995) (discussing various categories of negligent marketing).

200. Erica Swecker, Note, *Joe Camel: Will "Old Joe" Survive?*, 36 WM. & MARY L. REV. 1519, 1519 (1995) (declaring that "[c]igarette advertisements featuring a 'sunglass-sporting, phallic-nosed,' camel named Joe, surrounded by his 'cool, jazz-playing, pool-hustling, poker-playing, cigarette-smoking' crowd of

thol cigarette, "Uptown," because the product was deliberately targeted at African-American consumers.²⁰¹ Another instance of arguably inappropriate targeting involved "Crazy Horse Malt Liquor," an alcoholic beverage that was allegedly developed for sale to Native Americans, a population that is afflicted by a very high level of alcoholism.²⁰² While none of these examples involved litigation, they illustrate the type of exploitation that might constitute negligent marketing.

Negligent marketing also covers advertising and other promotional efforts directed at groups who are likely to harm others.²⁰³ Advertising handguns or assault weapons to "criminal consumers" is illustrative of this type of negligent marketing.²⁰⁴ In one case, for example, the defendant allegedly advertised its product in *Soldier of Fortune* and survivalist-type magazines, emphasized its firearm's high volume of firepower and paramilitary appearance, and touted the weapon's resistance to fingerprints.²⁰⁵ The court concluded that these practices increased the risk of product misuse by criminals and, therefore, could form the basis for civil liability.²⁰⁶

2. Failure to Supervise Retail Sellers

Another type of negligent marketing would subject manufacturers to liability when they distribute their products in a way that enables unauthorized users to obtain access to them from unscrupulous retail sellers. For example, in one case,²⁰⁷ the plaintiffs alleged that gun manufacturers had distributed large numbers of handguns to southeastern states, where gun regulations were relatively lax, knowing that many of these firearms would be shipped to urban centers in the northeast where they would be sold illegally to felons and others who were not legally entitled to possess them.²⁰⁸ The

camel-friends, have been accused of enticing children to smoke"); see also Daniel Hays Lowenstein, *Too Much Puff: Persuasion, Paternalism, and Commercial Speech*, 56 U. CIN. L. REV. 1205, 1213 (1988) (suggesting that cigarette company advertising deliberately targets minors); Frank J. Vandall, *Reallocating the Costs of Smoking: The Application of Absolute Liability to Cigarette Manufacturers*, 52 OHIO ST. L.J. 405, 420 (1991) (making a similar argument).

201. Kathryn A. Kelly, *The Target Marketing of Alcohol and Tobacco Billboards to Minority Communities*, 5 U. FLA. J.L. & PUB. POL'Y 33, 56-57 (1992); Vernellia R. Randall, *Smoking, the African-American Community, and the Proposed National Tobacco Settlement*, 29 U. TOL. L. REV. 677, 684 (1998).

202. Celeste J. Taylor, *Know When to Say When: An Examination of the Tax Deduction for Alcohol Advertising that Targets Minorities*, 12 LAW & INEQ. 573, 585 (1994).

203. McClurg, *supra* note 199, at 806.

204. *Id.*

205. *Merrill v. Navegar, Inc.* 89 Cal. Rptr. 2d 146, 156-57 (Cal. Ct. App. 1999), *rev'd*, 26 Cal. 4th 465 (2001).

206. *Id.* at 172.

207. *Hamilton v. Accu-Tek*, 62 F. Supp. 2d 802 (E.D.N.Y. 1999).

208. *Id.* at 830-31.

trial court agreed with the plaintiffs that the defendants had a duty to exercise reasonable measures to prevent their products from being used to supply illegal gun markets in other states.²⁰⁹ Recently, a number of cities and counties have made similar allegations in their suits against gun manufacturers.²¹⁰

3. Overpromotion

The term "overpromotion" traditionally referred to advertising that diluted the effects of product warnings.²¹¹ However, it can be argued that efforts by manufacturers to induce intermediaries to distribute their product in a way that increases the risk of injury can also be described as overpromotion. Although this form of overpromotion has not yet been invoked in handgun litigation, it has been raised, at least implicitly, in the prescription drug context. Specifically, some claimants have alleged that prescription drug sales representatives have encouraged or pressured physicians to overprescribe certain drugs such as antidepressants and painkillers.²¹²

B. Negligent Marketing in Firearms Litigation

So far, all reported cases in which a negligent marketing claim was made involved firearms. An examination of these cases indicates that courts are currently reluctant to accept this new, and potentially expansive, theory of liability. Negligent marketing claims, which were first raised in the 1980s, were uniformly unsuccessful,²¹³ as were later claims brought in the 1990s.²¹⁴ The first breakthrough

209. *Id.* at 832.

210. Winifred Weitsen Boyle, Comment, *There's No Smoking Gun: Cities Should Not Sue the Firearms Industry*, 25 U. DAYTON L. REV. 215, 224 (2000); Doug Morgan, Comment, *What in the Wide, Wide World of Torts Is Going On? First Tobacco, Now Guns: An Examination of Hamilton v. Accu-Tek and the Cities' Lawsuits Against the Gun Industry*, 69 MISS. L.J. 521, 533 (1999). In many of these suits, the negligent marketing claim is characterized as a "public nuisance" claim. Scott Preston, Comment, *Targeting the Gun Industry: Municipalities Aim to Hold Manufacturers Liable for Their Products and Actions*, 24 S. ILL. U. L.J. 595, 603-05 (2000).

211. Anne G. Kimball & Sarah L. Olson, *When All Else Fails, Blame Madison Avenue: Negligent Marketing Claims in Firearm Litigation*, 36 TORT & INSUR. L.J. 981, 1001 (2001).

212. See *infra*, Part C.1.

213. See *Riordan v. Int'l Armament Corp.*, 477 N.E.2d 1293, 1296 (Ill. Ct. App. 1985); *Linton v. Smith & Wesson*, 469 N.E.2d 339, 340 (Ill. Ct. App. 1984); *Knott v. Liberty Jewelry & Loan, Inc.*, 748 P.2d 661, 664 (Wash. Ct. App. 1988).

214. See *Leslie v. United States*, 986 F. Supp. 900, 912-13 (D.N.J. 1997); *McCarthy v. Sturm, Ruger & Co.*, 916 F. Supp. 366, 372 (S.D.N.Y. 1996), *aff'd sub nom. McCarthy v. Olin Corp.*, 119 F.3d 148, 157 (2d Cir. 1997); *First Commercial Trust Co. v. Lorcin Eng'g, Inc.*, 900 S.W.2d 202, 204-05 (Ark. 1995); *Resteiner v. Sturm, Ruger & Co.*, 566 N.W.2d 53, 56 (Mich. Ct. App. 1997); *Forni v. Ferguson*, 648 N.Y.S.2d 73, 74 (N.Y. App. Div. 1996).

occurred in 1999 with the *Hamilton* and *Merrill* decisions.²¹⁵

1. *Hamilton v. Accu-Tek*

In *Hamilton v. Accu-Tek*,²¹⁶ a group of plaintiffs successfully brought negligent marketing claims in a New York federal district court against twenty-five handgun manufacturers. The plaintiffs argued that the defendants had a duty to market and distribute their products in a manner that would minimize the chances that they would fall into the hands of persons who were likely to use them in the commission of criminal acts.²¹⁷ The plaintiffs alleged that the defendants shipped large numbers of firearms to southeastern states, where gun regulations were less stringent, knowing that these guns would eventually be transported to northeastern states and sold illegally.²¹⁸ The defendants, on the other hand, maintained that they sold their products to federally licensed dealers and had no duty to protect shooting victims from the criminal acts of third parties.²¹⁹ They also denied that their marketing practices were negligent and further contended that the plaintiffs had failed to provide satisfactory proof of cause-in-fact.²²⁰

The trial judge, Jack Weinstein, a distinguished jurist, concluded that the defendants had a duty to market their products in a reasonable and prudent manner.²²¹ In addition, he relieved the plaintiffs of the burden of showing which specific product caused which injury and instead allowed them to establish causation through the use of a market share liability approach.²²² Judge Weinstein's opinion discussed a variety of legal issues associated with the plaintiffs' claims, including: (1) whether gun manufacturers owed any legal duty to bystanders who might be injured by firearms; (2) whether the defendants failed to exercise due care with respect to their marketing activities; (3) whether the marketing practices of the defendants caused the victims' injuries; (4) whether the criminal acts of third persons amounted to a superseding cause, thereby relieving the defendants of any responsibility for shooting victims' injuries; and (5) whether gun manufacturers could be held collectively

215. *Hamilton v. Accu-Tek*, 62 F. Supp. 2d 802 (E.D.N.Y. 1999); *Merrill v. Navegar, Inc.*, 89 Cal. Rptr. 146 (Cal. Ct. App. 1999).

216. 62 F. Supp. 2d 802 (E.D.N.Y. 1999).

217. *Id.* at 825.

218. *Id.* at 829-30.

219. *Id.* at 832.

220. *Id.* at 817-18.

221. *Id.* at 827.

222. *Id.* at 843-44. For an analysis of market share liability, see David A. Fischer, *Products Liability—An Analysis of Market Share Liability*, 34 VAND. L. REV. 1623 (1981); Andrew R. Klein, *Beyond DES: Rejecting the Application of Market Share Liability in Blood Products Litigation*, 68 TUL. L. REV. 883 (1994); Note, *Market Share Liability: An Answer to the DES Causation Problem*, 94 HARV. L. REV. 668 (1981).

liable for damages on a market share basis.²²³

The first issue in *Hamilton* was whether the defendants were obliged to protect casual bystanders from injuries caused by non-defective products. While admitting that New York law subjected a manufacturer to strict liability only when it placed a *defective* product into the stream of commerce,²²⁴ the trial court concluded that negligence principles were broad enough to support a duty of due care toward bystanders even when a product was not defective.²²⁵ The court also determined that the manufacturers had breached this duty of care.²²⁶ The court observed that the risk of injury was very great if handguns fell into the hands of those who were likely to use them to commit crimes.²²⁷ Moreover, most guns used in crimes were not stolen, but were purchased, often illegally, from federally licensed firearms dealers.²²⁸ In the court's view, the defendants could have reduced these illegal sales by refusing to do business with careless or unscrupulous gun dealers, by limiting sales at unregulated gun shows, and by requiring that handguns be sold to the public only in responsibly-operated retail stores.²²⁹ The court also found that the defendants were fully aware that their marketing practices were facilitating the movement of guns from the southeast into the underground markets in the northeastern part of the country.²³⁰

Another issue was whether the defendants' negligent marketing practices were a cause-in-fact of shooting deaths generally and whether there was some causal connection between these practices and the specific injuries suffered by the plaintiffs.²³¹ In this case, the court found that the defendants' marketing practices had indeed facilitated an influx of illegal firearms into New York City,²³² thereby making them more readily available to the sorts of person who had injured the plaintiffs.²³³ The fourth issue before the court involved proximate cause. The defendants argued for the traditional position that the criminal actions of third parties should be treated as unforeseeable superseding events that broke the chain of causation and relieved them of any liability.²³⁴ However, the court pointed out that an intervening act would not be sufficient to insulate a defendant from liability if it were a natural and foreseeable consequence

223. *Hamilton*, 62 F. Supp. 2d at 818-35.

224. *Id.* at 823.

225. *Id.* at 823-24.

226. *Id.* at 827-29.

227. *Id.* at 825-26; *see also* *Hamilton v. Accu-Tek*, 935 F. Supp. 1307, 1313-14 (E.D.N.Y. 1996) (reviewing data and supporting sources).

228. *Hamilton v. Accu-Tek*, 62 F. Supp. 2d 802, 825-26 (E.D.N.Y. 1999).

229. *Id.* at 826.

230. *Id.* at 832.

231. *Id.* at 834-35.

232. *Id.* at 836-37.

233. *Id.* at 837-38.

234. *Id.* at 810-11.

of a condition created by the defendant.²³⁵ Having already determined that the defendants had a duty to anticipate and guard against misuse of its products by third parties, the court had no difficulty concluding that such misuse, when it did occur, would not be regarded as a superseding cause.²³⁶ The final issue before the court involved apportionment of damages among the various defendants. Rather than requiring the plaintiffs to establish what each defendant's share should be, the trial court approved instructions that allowed the jury to apportion damages among the various gun manufacturers according to their respective shares of the handgun market.²³⁷

At the end of the trial, the jury returned a verdict against fifteen of the defendants and in favor of one of the plaintiffs.²³⁸ On appeal, the Second Circuit Court of Appeals determined that it was necessary to certify two questions to the New York Court of Appeals: (1) Did New York recognize a duty on the part of gun manufacturers to exercise due care with respect to the marketing and distribution of firearms; and (2) can damages in negligent marketing cases be apportioned according to principles of market share liability?²³⁹ The New York state court agreed to answer these questions, and eventually ruled that handgun manufacturers did not owe a duty to market their products in such a way as to reduce the risk of injury to third parties from criminals.²⁴⁰ The New York court also concluded that it was inappropriate to apply the concept of market share liability to handgun manufacturers.²⁴¹

In its discussion of the duty issue, the New York court pointed out that tort law did not impose a duty on someone simply because his or her conduct might cause harm to others.²⁴² According to the court, foreseeability does not determine whether a duty exists or not; it merely determines the scope of the duty once it is found to exist.²⁴³ In addition, it is not enough for an injured party to show that the defendant owed a general duty of due care to society; rather, the plaintiff must establish that the defendant owed a specific duty to him or her.²⁴⁴

This usually involves the existence of a special relationship between the defendant and either the victim or the wrongdoer.²⁴⁵ Thus, a duty to protect another might arise when a special relation-

235. *Id.* at 833 (quoting *Kush v. Buffalo*, 449 N.E.2d 725, 729 (N.Y. 1983)).

236. *Id.* at 834.

237. *Id.* at 846-47.

238. *Id.* at 808.

239. *Hamilton v. Beretta U.S.A. Corp.*, 222 F.3d 36, 46 (2d Cir. 2000).

240. *Hamilton v. Beretta U.S.A. Corp.*, 750 N.E.2d 1055, 1066 (N.Y. 2001).

241. *Id.* at 1068.

242. *Id.* at 1060.

243. *Id.*

244. *Id.*

245. *Id.* at 1061.

ship, such as employer-employee or parent-child, exists between the defendant and a third-party tortfeasor.²⁴⁶ Because of the relationship in these cases, however, the defendant is in the best position to prevent the harm and, moreover, the risk of unlimited liability is reduced because the class of people to whom a duty is owed is circumscribed by the relationship.²⁴⁷ In this case, as the court pointed out, the pool of potential victims was extremely large and no relationship existed that would give gun manufacturers the power to control the actions of criminals.²⁴⁸ Finally, the court rejected the plaintiff's argument that market share liability should be applied with respect to claims against handgun manufacturers.²⁴⁹

2. Merrill v. Navegar, Inc.

*Merrill v. Navegar, Inc.*²⁵⁰ involved a suit against the manufacturer of two semiautomatic assault weapons, the TEC-9 and the TEC-DC9 (hereinafter referred to collectively as the "TEC-DC9"), which were used by one Gian Ferri to kill eight persons and to wound six others before he killed himself.²⁵¹ It appears that Ferri purchased the guns from properly licensed dealers; however, he violated the law by transporting the weapons from Nevada, where they were legal, to California, where they were not.²⁵² The plaintiffs argued, *inter alia*, that even though the sale of the guns was legal, the defendant, Navegar, should be held liable because it had promoted and marketed its products in a way that increased their appeal to those likely to commit criminal acts.²⁵³ The trial court granted the defendant's motion for summary judgment and the plaintiffs appealed.²⁵⁴

The California intermediate appellate court determined that both the physical characteristics of the weapons and the manner in which they were marketed greatly increased the risk that they would be acquired and used for criminal purposes.²⁵⁵ The court observed that the weapons were designed to accept large capacity 50-round magazines; they were equipped with "barrel shrouds" which allowed the user to hold the weapon with both hands in order to

246. *Id.*

247. *Id.*

248. *Id.* at 1061-62.

249. *Id.* at 1066-68. Upon receipt of the New York court's opinion, the federal appeals court ordered the trial court to dismiss the plaintiff's lawsuit. *Hamilton v. Beretta U.S.A. Corp.*, 264 F.3d 21, 32 (2d Cir. 2001).

250. 89 Cal. Rptr. 2d 146 (Cal. Ct. App. 1999), *rev'd*, 28 P.3d 116 (Cal. 2001).

251. *Id.* at 152.

252. *Id.* at 153-54.

253. *Id.* at 156. The plaintiffs also claimed that the manufacture and sale of the TEC-DC9 semi-automatic pistol was an ultra-hazardous activity. *Id.* at 152. The court affirmed the lower court's dismissal of that claim. *Id.* at 192.

254. *Id.* at 192.

255. *Id.* at 167.

spray fire; the barrels were threaded to allow the attachment of silencers or flash suppressors; they were fitted with a sling device that enabled them to be fired rapidly from the hip; they were compact and were capable of being broken down for better concealment; and they were compatible with a "Hell Fire" trigger system that permitted the weapon to be fired at a much faster rate than a normal semiautomatic weapon.²⁵⁶ Moreover, a TEC-DC9 equipped with such a trigger mechanism could easily be modified to perform like a fully automatic weapon.²⁵⁷ These features not only made the TEC-DC9 function like a military-style submachine gun, they also substantially reduced the weapon's utility for legitimate purposes such as hunting, sport shooting, or self-defense.²⁵⁸

The court also pointed out that Navegar seemed to have deliberately targeted the marketing of the TEC-DC9 toward persons, like the killer, who were attracted to or associated with violence.²⁵⁹ First of all, the defendant advertised its products in magazines, such as *Soldier of Fortune*, *SWAT*, *Combat Handguns*, *Guns*, *Firepower*, and *Heavy Metal Weapons*, which were widely read by militarists and survivalists.²⁶⁰ Moreover, this advertising emphasized the paramilitary character of the weapons by referring to their non-glare finish and combat-type sights.²⁶¹ In addition, Navegar's promotional materials called attention to certain features of the TEC-DC9 that would make it particularly suitable for criminal use. For example, these materials mentioned that the weapons came with a combat sling and a threaded barrel, which permitted the attachment of a silencer, flash suppressor, or a barrel extension.²⁶² They also extolled the fact that the TEC-DC9's surface had "excellent resistance to fingerprints."²⁶³ Furthermore, Navegar displayed its weapons at the sort of gun shows that such persons often attended.²⁶⁴ Finally, Navegar provided TEC-DC9s for use in violent films and television programs, such as *Robocop*, *Freejack*, and *Miami Vice* in order to create an association in the public eye between its products and acts of violence.²⁶⁵

The trial court granted the defendant's motion for summary

256. *Id.* at 154.

257. *Id.* at 157.

258. *Id.* at 154-55.

259. *Id.* at 156.

260. *Id.*

261. *Id.*

262. *Id.* at 157.

263. *Id.* As Navegar correctly pointed out, this claim merely meant that the surface was resistant to damage from oil or sweat when handled. *Id.* at 159. However, the court concluded that some purchasers would interpret Navegar's claim as an assurance that they could use the TEC without fear of leaving behind fingerprints that might identify them to the police. *Id.* at 157.

264. *Id.* at 156.

265. *Id.* at 157.

judgment.²⁶⁶ In deciding whether the lower court should have allowed the plaintiffs' claims against Navegar to go to trial, the intermediate appellate court examined the issues of duty and causation.²⁶⁷ In its discussion of the duty issue, the court found that the risk associated with the defendant's conduct was foreseeable.²⁶⁸ Although Navegar denied that it could have foreseen that its products would be used in a killing spree, the court found the manufacturer was well aware that the TEC-DC9 was often used in criminal assaults and that many of its features were designed to appeal to criminal users.²⁶⁹ Second, the court determined that Navegar's conduct was "morally blameworthy."²⁷⁰ Evidence of blameworthy conduct included: (1) Navegar's marketing of the TEC-DC9 in a way that was calculated to bring it to the attention of those who were likely to use it for criminal purposes; (2) the indifference of Navegar's management to the fact that their product was commonly used for criminal purposes; and (3) the furnishing by Navegar's marketing director of manuals and videotapes which demonstrated how to convert illegally the TEC-DC9 into a fully automatic weapon.²⁷¹

The third factor to be considered in determining whether to impose a duty on the defendant was the public interest in preventing future harm.²⁷² The court in *Merrill* observed that the direct costs of gunshot-related injuries amounted to \$2.3 billion annually.²⁷³ Other costs included such things as lost wages, pain and suffering, police resources, and "the psychological insecurity we all suffer from living in a gun-infested society."²⁷⁴ The court pointed out that public policy, as expressed by courts and legislative institutions, strongly supported the reduction of these social costs.²⁷⁵ The final factor was the burden that such a duty would impose on the defendant and on the community.²⁷⁶ In this case, the gun manufacturer would simply have to refrain from marketing its products to high-risk consumers.²⁷⁷

Having concluded that Navegar owed a duty to market its products in a reasonable manner, the *Merrill* court proceeded to consider whether the defendant's marketing practices caused the plaintiffs'

266. *Id.* at 152.

267. *Id.* at 161.

268. *Id.* at 167.

269. *Id.* at 166.

270. *Id.* at 169.

271. *Id.*

272. *Id.*

273. *Id.* at 169-70 (citing Philip J. Cook et al., *The Medical Costs of Gunshot Injuries in the United States*, 282 J. AM. MED. ASS'N 447, 454 (1999)).

274. *Id.* at 170 (quoting Andrew Jay McClurg, *The Tortious Marketing of Handguns: Strict Liability Is Dead, Long Live Negligence*, 19 SETON HALL LEGIS. J. 777, 792 (1995)).

275. *Id.*

276. *Id.* (citing *Parsons v. Crown Disposal Co.*, 936 P.2d 70 (Cal. 1997)).

277. *Id.* at 171.

injuries.²⁷⁸ Not surprisingly, Navegar argued that there was no causal connection between its marketing efforts and the killer's criminal behavior.²⁷⁹ In particular, the gun manufacturer contended that the plaintiffs had produced no evidence that the killer, Ferri, ever saw any of the company's advertisements or promotions.²⁸⁰ The court held that the plaintiffs did not have to prove that Navegar's conduct was the sole cause of their injuries; rather, the causation requirement could be satisfied by showing that Navegar's conduct was a "substantial factor" in bringing about these injuries.²⁸¹ The court also declared that a defendant's conduct could be characterized as a contributing cause if it created or increased the risk of negligent or criminal behavior even though the defendant did not exercise any control over the party that actually caused the harm.²⁸²

On appeal, the California Supreme Court reversed the intermediate appellate court's decision and reinstated the trial court's judgment for the defendant.²⁸³ The principal ground for this reversal was the court's characterization of the plaintiffs' case as a "products liability action" within the purview of California Civil Code section 1714.4(a).²⁸⁴ This statutory provision declared that "[i]n a products liability action, no firearm or ammunition shall be deemed defective in design on the basis that the benefits of the product do not outweigh the risk of injury posed by its potential to cause serious injury, damage, or death when discharged."²⁸⁵ The court rejected the plaintiffs' assertion that they were seeking to hold Navegar liable because it "negligently designed, distributed, and marketed" the TEC-DC9.²⁸⁶ Instead, the court concluded that the plaintiffs' real claim was that the weapon was "defective in design because the risks of making it unavailable to the general public outweighed the benefits of that conduct."²⁸⁷

Furthermore, the court concluded, even if Navegar's marketing activities would support an independent negligence claim, the plaintiffs had failed to prove cause-in-fact because they offered no evidence to show that the killer, Gian Ferri, was influenced by, or had even seen, the defendant's promotional materials.²⁸⁸ According to the court, Ferri apparently purchased the defendant's products from a retail seller on the basis of price and information supplied by the seller about the weapons' firepower and other performance charac-

278. *Id.* at 185.

279. *Id.*

280. *Id.* at 185-86.

281. *Id.* at 186.

282. *Id.*

283. *Merrill v. Navegar, Inc.*, 28 P.3d 119 (Cal. 2001).

284. CAL. CIV. CODE § 1714.4(a) (Deering 1994).

285. *Id.*

286. *Merrill*, 28 P.3d at 124-25.

287. *Id.* at 126.

288. *Id.* at 132.

teristics.²⁸⁹

C. *Potential Negligent Marketing Claims Against Pharmaceutical Companies*

Negligent marketing that involves advertising that targets vulnerable or dangerous users does not seem relevant to the promotion and sale of prescription drugs. However, the two remaining types of negligent marketing, overpromotion and negligent failure to supervise retail sellers, may be applicable to prescription drug sales and, therefore, will be discussed in more detail below.

1. *Overpromotion*

One type of negligent marketing involves the efforts of manufacturers to pressure or bribe doctors to prescribe certain prescription drugs, such as painkillers or anti-depressants, in excessive dosages or to persons who do not really need them. Recent experience involving the painkiller OxyContin illustrates the potential applicability of this form of negligent marketing to prescription drug sellers.

OxyContin is the brand name of oxycodone hydrochloride, a synthetic opiate, which chemically resembles other opiates such as heroin, morphine, codeine, fentanyl, or methadone.²⁹⁰ It is a slow-release painkiller that is designed to last twelve hours and is intended for use by persons who suffer moderate to severe chronic pain from such diseases as arthritis, back trouble, or cancer.²⁹¹ Unfortunately, when OxyContin pills are crushed, users can achieve a quick, heroin-like high.²⁹² OxyContin abuse started in the rural areas of Kentucky, West Virginia, Virginia, Tennessee, and Maine, but quickly spread to urban areas such as Boston and Miami.²⁹³ At least thirteen lawsuits have already been filed by OxyContin users against the drug's manufacturer, Purdue Pharma.²⁹⁴

Although Purdue Pharma did not advertise OxyContin to the general public, some plaintiffs have alleged conduct on its part that could be described as negligent marketing.²⁹⁵ For example, one vic-

289. *Id.* at 133.

290. Paul Tough, *The Alchemy of OxyContin*, N.Y. TIMES, July 29, 2001, (Magazine), at 32.

291. *Maker of Painkiller OxyContin Faces Lawsuits Alleging the Drug Caused Addictions, Deaths; Company Says Plaintiffs Used Drug Improperly or Illegally*, ST. LOUIS POST-DISPATCH, July 29, 2001, at A11.

292. *Id.*

293. *Suits Claim OxyContin Addiction*, BATON ROUGE ADVOC., July 27, 2001, at 8A.

294. *Maker of Painkiller OxyContin Faces Lawsuits*, *supra* note 291.

295. FDA regulations prohibited the manufacturer from advertising narcotic drugs to the public. However, Purdue Pharma did engage in a public education program, Partners Against Pain, which promoted greater use of pain-relief therapy in connection with the treatment of cancer and other diseases. Tough,

tim alleged that the manufacturer "conspired and knowingly promoted and sold OxyContin by enticing doctors to prescribe the drug using free airline tickets, motel stays, vacations, seminars and other means without regard as to the safety of the drug, and without warning these physicians as to the true dangers it possessed."²⁹⁶ In addition, the Attorney General of West Virginia charged Purdue Pharma with "highly coercive and inappropriate tactics to attempt to get physicians and pharmacists to prescribe OxyContin and to fill prescriptions for OxyContin, often when it was not called for."²⁹⁷ Arguably, these allegations, if they could be proven, might support a negligent marketing claim against the drug's manufacturer.

The recent experience with the diet drug, Fen-Phen, illustrates another aspect of negligent marketing, the promotion of "off-label" uses by product manufacturers. An off-label use is a use that is not described or authorized on a prescription drug's FDA-approved labeling.²⁹⁸ It is common and acceptable medical practice for physicians to prescribe off-label uses of prescription drugs.²⁹⁹ However, the FDA prohibits attempts by manufacturers to "promote" unapproved or off-label uses of prescription drugs.³⁰⁰ Of course, manufacturers have a strong economic incentive to encourage off-label uses since these uses increase the sales of their products.³⁰¹ Consequently, manufacturers disseminate information about off-label uses indirectly by funding research, sponsoring educational programs and symposia, and distributing journal articles about such uses.³⁰² Unfortunately, off-label uses sometimes turn out to be dangerous or inappropriate.³⁰³ When this occurs, *sub rosa* marketing efforts by manufacturers may give rise to liability if they encourage doctors to prescribe prescription drugs for off-label uses that prove to be harmful.

Fen-Phen is a combination of two distinct pharmaceutical products, fenfluramine and phentermine. These drugs were approved by the FDA more than twenty years ago for use individually and on a short-term basis by medically diagnosed obese patients.³⁰⁴ When a

supra note 290, at 52.

296. *Raleigh Man Suing OxyContin Makers; Beaver Resident Claims that he was Harmed by Drug*, CHARLESTON GAZETTE & DAILY MAIL (W. Va.), July 21, 2001, at 2A.

297. Tough, *supra* note 290, at 52.

298. Kaspar J. Stoffelmayr, Comment, *Products Liability and "Off-Label" Uses of Prescription Drugs*, 63 U. CHI. L. REV. 275, 275 (1996).

299. David A. Kessler, *Regulating the Prescribing of Human Drugs for Non-approved Uses Under the Food, Drug, and Cosmetic Act*, 15 HARV. J. ON LEGIS. 693, 695 (1978); Merrill, *supra* note 15, at 1854; Noah, *supra* note 62, at 141.

300. 21 C.F.R. § 202.1(e)(4)(i)(a) (2001).

301. Stoffelmayr, *supra* note 298, at 279.

302. See J. Howard Beales, III, *Economic Analysis and the Regulation of Pharmaceutical Advertising*, 24 SETON HALL L. REV. 1370, 1394-96 (1994).

303. Moberg, *supra* note 48, at 221-22.

304. Caren A. Crisanti, Comment, *Product Liability and Prescription Diet*

1992 study indicated that fenfluramine and phentermine were more effective when used in combination, doctors began prescribing these drugs on a large scale for weight-loss purposes.³⁰⁵ As many as six million people are thought to have used the Fen-Phen combination.³⁰⁶ However, medical studies began to show a connection between fenfluramine use and serious heart valve damage.³⁰⁷ This led the FDA to take fenfluramine, known commercially as Redux, off the market in September 1997.³⁰⁸ Litigation against American Home Products, the manufacturer of Redux, soon followed.³⁰⁹ After several cases resulted in substantial damage awards, American Home Products offered to settle most of the remaining cases for \$3.75 billion.³¹⁰

Redux labeling contained warnings about known side effects, such as brain damage and hypertension, but nothing was said about heart valve damage because there was no evidence to suggest that this was a danger at the time the drug's labeling was approved by the FDA.³¹¹ Nevertheless, if there is further litigation, plaintiffs are likely to argue that the manufacturers of Fen-Phen encouraged doctors to prescribe these drugs for mildly overweight people when little was known about the possible effects of long-term use or use of these drugs in combination with each other.

2. *Negligent Failure to Supervise Retail Sellers*

A second type of negligent marketing involves a manufacturer's failure to supervise the activities of retail sellers. Once again, the OxyContin litigation illustrates how a negligent marketing claim might be made. Plaintiffs in one of these suits, a class action suit recently filed in Ohio, have claimed the manufacturer and others "were and are facilitating the inappropriate use of OxyContin by supplying pharmacies in Mexico with OxyContin because they are aware that members of the public can obtain OxyContin from these pharmacies without a prescription."³¹² This allegation, which has been vigorously disputed by OxyContin's manufacturer, resembles one of the negligent marketing claims brought against handgun manufacturers in *Hamilton v. Accu-Tek*.

Drug Cocktail, Fen-Phen: A Hard Combination to Swallow, 15 J. CONTEMP. HEALTH L. & POL'Y 207, 211 (1998).

305. *Id.* at 207, 211-12.

306. Patrick Strawbridge, *Diet-Drug Trial Set in Bluffs*, OMAHA WORLD-HERALD, April 16, 2000, at 1A.

307. Crisanti, *supra* note 304, at 210-11.

308. *Id.* at 211; Strawbridge, *supra* note 306.

309. Strawbridge, *supra* note 306.

310. Richard B. Schmitt & Robert Langreth, *AHP To Pay \$ 3.75 Billion in Diet Suits*, WALL ST. J., Oct. 8, 1999, at A3.

311. Crisanti, *supra* note 304, at 222-23.

312. Rob Modic, *Oxycontin Class-Action Suit Filed*, DAYTON DAILY NEWS, July 20, 2001, at 2, available at LEXIS, News Library, Bglobe File.

Internet pharmacies may turn out to be another source of negligent marketing liability. As the name implies, an Internet pharmacy sells pharmaceutical products to consumers through its website.³¹³ These sites offer lower prices, around-the-clock availability, increased privacy, and better access to prescription drugs for the elderly and those who live in rural areas.³¹⁴ Internet sites can be categorized as pharmacy-based or prescribing-based.³¹⁵ "Pharmacy-based" sites are state-licensed and require the patient to obtain an off-site doctor's prescription.³¹⁶ However, "prescribing-based" sites typically sell prescription drugs on the basis of a perfunctory "online consultation" between the customer and a physician employed by the Internet pharmacy.³¹⁷ Furthermore, some of these prescribing-based sites are located outside the United States and do not require any sort of prescription to order medicine.³¹⁸ Sooner or later, plaintiffs will begin to argue that drug companies have a duty to exercise some degree of supervision over the operations of Internet pharmacies³¹⁹ and that their failure to do so should give rise to liability under the theory of negligent marketing.

V. INCREASED LIABILITY FOR PRESCRIPTION DRUG MANUFACTURERS

One can argue that aggressive marketing practices justify the creation of additional duties with respect to those who may be subjected to increased risks. This Article has described two doctrinal changes by which the obligations of drug companies might be expanded. Abolishing the learned intermediary rule would require manufacturers of prescription drugs to formulate warnings for consumers as well as for physicians, while recognizing the concept of negligent marketing would require drug manufacturers to exercise more restraint in their dealings with physicians and to show more interest in the activities of retail sellers. Of course, failure to satisfy these additional duties would result in tort liability for product sellers.

A. *Abolishing or Restricting the Learned Intermediary Rule*

A number of legal commentators believe that the current scheme of physician-directed warnings does not provide sufficient

313. Rost, *supra* note 189, at 1333.

314. Nicole A. Rothstein, Comment, *Protecting Privacy and Enabling Pharmaceutical Sales on the Internet: A Comparative Analysis of the United States and Canada*, 53 FED. COMM. L.J. 343, 350 (2001).

315. Chuang, *supra* note 85, at 1455.

316. *Id.*

317. *Id.*

318. *Id.* at 1456. It is illegal for foreign Internet pharmacies to ship prescription drugs into the United States, but these regulations are often difficult to enforce. *See also* Porter, *supra* note 189, at 13.

319. *See* Chuang, *supra* note 85, at 1483-88.

protection for consumers. Presumably, if drug companies warned consumers directly, they would read these warnings and would refrain from taking prescription drugs that were dangerous or unsuitable for them. This, in theory, would cause the number of injuries associated with prescription drug use to decline. Of course, direct-to-consumer warnings might also scare off some consumers or discourage them from seeking professional help for treatable medical conditions. Thus, it is difficult to determine, *a priori*, whether direct-to-consumer warnings would actually reduce public health costs or not.

What is clear, however, is that drug companies will have to defend many more failure-to-warn claims. As mentioned earlier, the requirements for direct-to-consumer warnings are not easy to satisfy. Warnings directed at ordinary consumers must be complete and accurate; they must be sufficiently prominent that consumers will see them; they cannot be ambiguous or equivocal; they must be easy for ordinary consumers to understand; and they must be communicated effectively to their intended audience.

It is difficult to see how drug manufacturers can provide consumers with complete and understandable information about product-related risks through direct communication. The general warnings provided in radio or television broadcasts are much too short to satisfy the requirements for an adequate warning.³²⁰ Print advertisements are also problematic because information about product-related risks and contraindications is seldom found in the front page of such ads, but rather appears (often in small print) on the back page.³²¹ Moreover, the FDA-approved "brief summary," typically contained therein, is often impossible for the average consumer to understand.³²² Nor are brochures, Internet sites, or references to toll-free numbers likely to satisfy a manufacturer's duty to warn since many consumers will not utilize these sources of information. Although drug manufacturers might try to satisfy their duty to warn by providing patient package inserts (distributed by pharmacists when a prescription is filled), they would have considerable difficulty explaining such matters as side effects, contraindications, and related matters in terms that ordinary consumers could appreciate. Moreover, even if pharmaceutical companies were able to provide adequate warnings by means of package inserts, plaintiffs' lawyers might still argue that direct-to-consumer advertising amounted to "overpromotion" of the drug, thereby diluting the effect of the warn-

320. 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, 129-30 (1997) (stating that "attempts in direct-to-consumer ad to adequately convey sufficient information to enable a consumer to make a reasonably informed and educated decision would be prohibitively lengthy and difficult to convey").

321. Schwartz, *supra* note 10, at 846.

322. *Id.* at 847.

ing's effectiveness.³²³

B. *Negligent Marketing*

Negligent marketing is a bonanza for plaintiffs and a nightmare for defendants. First, a plaintiff does not have to prove that a product was defective in order to bring a negligent marketing claim. In addition, since negligent marketing and failure to warn are different legal concepts, a pharmaceutical company cannot invoke the learned intermediary rule to defeat liability when a negligent marketing claim is brought. Another disadvantage from the defendant's point of view is that the liability standard for negligent marketing is essentially meaningless. There is no objective way to determine when a particular marketing practice is appropriate and when it can be characterized as negligent. Furthermore, in a negligent marketing case, the primary focus is on the conduct of the product manufacturer, making it easier for plaintiffs' lawyers to prejudice the jury by portraying the defendant as irresponsible or unethical. Finally, negligent marketing claims are predominantly factual in nature and, therefore, will ultimately be determined by lay juries.

C. *Tort Litigation in the Twenty-first Century*

Recent developments in tort litigation practice virtually ensure that the imposition of new duties will have a significant, and decidedly negative, impact on the financial well-being of prescription drug companies. Many courts have relaxed the traditional causation requirements, effectively relieving plaintiffs of their duty to prove cause-in-fact. For example, in negligent marketing cases, courts have enabled plaintiffs to overcome serious causation problems by allowing plaintiffs to satisfy proof of causation by relying on such concepts as the substantial factor test³²⁴ and market share liability.³²⁵ The ability to aggregate claims through the use of class actions and other techniques also benefits plaintiffs. By pooling their resources, large groups of plaintiffs can afford to hire the very best legal talent and to spend large sums on litigation. Moreover, aggregation of claims raises the stakes for defendants. Losing a class action is a far more serious matter than losing an individual case. Finally, the availability of punitive damages greatly affects the dynamics of litigation.

With the benefit of these advantages, it is not surprising that plaintiffs' lawyers love to sue pharmaceutical companies. These companies, on the other hand, are sufficiently concerned about the consequences of losing high-profile class action cases that they will

323. See *Incollingo v. Ewing*, 282 A.2d 206, 220 (Pa. 1971) (holding that promotional efforts of drug manufacturer's sales representatives diluted the effectiveness of warning in physician package insert).

324. *Merrill v. Navegar, Inc.*, 89 Cal. Rptr. 2d 146, 186 (Cal. Ct. App. 1999).

325. *Hamilton v. Accu-Tek*, 62 F. Supp. 2d 802, 843 (E.D.N.Y. 1999).

sometimes choose to settle a case even when the plaintiffs' claims are groundless. *In re Dow Corning*³²⁶ is a case in point. When a class action was brought against Dow Corning, the company settled the suit for more than \$3 billion even though there was no scientific evidence to support the plaintiffs' claim that the defendant's breast implants caused their injuries.³²⁷ Even when drug companies refuse to settle, the high costs of litigation may eventually force them to cut their losses by removing a product from the market.

All of this suggests that increased liability, even if it reduces injuries, imposes costs on society. In the case of prescription drugs, abolishing the learned intermediary rule or recognizing the concept of negligent marketing, will impose higher liability costs on pharmaceutical companies. At some point, this increased financial burden may begin to adversely affect the availability and price of prescription drugs. For this reason, courts should be cautious about recognizing new theories of liability, particularly if the increased risks to consumers attributable to aggressive marketing can be dealt with by other regulatory mechanisms. Since prescription drug labeling and advertising are already regulated by the FDA, it seems reasonable to allow this agency to formulate additional regulations, if necessary, than to try to control the marketing practices of drug manufacturers by increasing the scope of tort liability.

VI. CONCLUSION

Pharmaceutical companies have added new forms of marketing, such as direct-to-consumer advertising, to supplement more traditional physician-directed efforts. While these newer marketing techniques appear to be quite effective, it is possible that they may also lead to new forms of tort liability. In particular, courts may refuse to apply the learned intermediary rule to manufacturers who engage in direct-to-consumer advertising or they may impose liability on pharmaceutical companies for negligent marketing. Perhaps, it may become necessary to regulate the marketing activities of drug companies more extensively. If that becomes necessary, however, the FDA, not the courts, should exercise this responsibility.

326. 255 B.R. 445 (E.D. Mich. 2000).

327. *District Judge Affirms Confirmation Order in Dow Corning Settlement*, MEALEY'S LITIG. REP. INS. 5, Nov. 21, 2000.