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NOTES

THE LEARNED INTERMEDIARY DOCTRINE: AN EFFICIENT PROTECTION FOR PATIENTS, PAST AND PRESENT

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INTRODUCTION

The learned intermediary doctrine allows manufacturers of prescription drugs to disclose risks to prescribing physicians rather than to the ultimate users of their products. Pharmaceutical companies that do this properly are immune from liability for failure to warn in the event of drug-related accidents.

Arguments to abandon or change the learned intermediary doctrine have increased recently due to perceived fundamental changes in the healthcare environment. The basic argument for altering or abandoning the rule is that it was adopted in response to a paternalistic style of healthcare that no longer exists. Some argue that the requirement of informed consent made the doctrine irrelevant; there is no longer reason to limit warnings to the prescribing physician if the patient is active in the decision making.[1] This line of reasoning rejects the premise that it is most effective to provide prescription drug warnings to physicians rather than to the ultimate users (patients or consumers).

Others argue that the insufficiency (or irrelevance) of the doctrine is more modern, stemming from the significant pressures placed on the professional judgment and autonomy of physicians by direct-to-consumer advertising and managed care.[2] These commentators believe the learned intermediary can be the

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1. Susan A. Casey, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 WM. MITCHELL L. REV. 931, 934 (1993); Teresa Moran Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 FOOD DRUG COSM. L.J. 829, 829 (1991).

2. *See, e.g.*, Ozlem A. Bordes, *The Learned Intermediary Doctrine and Direct-to-Consumer Advertising: Should the Pharmaceutical Manufacturer Be Shielded from Liability?*, 81 U. DET. MERCY L. REV. 267, 267-68 (2004); Timothy S. Hall, *Reimagining the Learned Intermediary Rule for the New Pharmaceutical Marketplace*, 35 SETON HALL L. REV. 193, 198 (2004); Paul F. Strain & Christina L. Gaarder, *Direct-to-Consumer Advertising and the Learned Intermediary Doctrine:*

most effective source of patient warnings, but only in certain kinds of healthcare contexts.

The debate rages about how best to serve the goals of tort law in relation to those individuals injured by prescription drugs. Proponents of the traditional application of the learned intermediary doctrine argue that efficiency and patient safety remain best served by adhering to the doctrine. Those advocating a change in the doctrine argue that the learned intermediary doctrine protects pharmaceutical manufacturers at the cost of leaving many plaintiffs uncompensated for drug-related injuries. A stalemate between two positions results: either the learned intermediary doctrine is ineffective because its underlying justifications no longer apply or the underlying justifications have continued relevance *despite* massive changes in the delivery of healthcare. What both sides agree on, however, is that there has been a revolutionary change in healthcare delivery.[3] This Note argues, however, that this assumption is exaggerated; healthcare delivery is not the most relevant facet in assessing the continued vitality of the learned intermediary doctrine.

This Note argues that the learned intermediary doctrine was adopted, primarily, because there was a substantial disparity between the knowledge of the physician and that of the patient. In the context of this knowledge disparity, the learned intermediary doctrine is necessary to serve the tort law goal of accident cost avoidance, which requires the consumer warning to be given to the party in the best position to provide that warning.[4] Patient empowerment and the environment of healthcare delivery have changed the doctor-patient relationship in the last forty years. However, the disparity between physician and patient knowledge endures, and arguably grows, making the learned intermediary doctrine as timely as ever.

Part I of this Note discusses the rationale of the learned intermediary doctrine, its history, and its exceptions. Part II describes arguments that the learned intermediary doctrine should be abrogated completely. Part III describes and challenges arguments that the learned intermediary doctrine should be retained, but should be applied in a way that takes into account fact-specific information about the quality of the doctor-patient relationship and healthcare

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Unsettling a Settled Question, 30 U. BALT. L. REV. 377, 382-83 (2001); Sheryl Calabro, Note, *Breaking the Shield of the Learned Intermediary Doctrine: Placing the Blame Where It Belongs*, 25 CARDOZO L. REV. 2241, 2254-56 (2004); Daniel Richardson, Note, *The Lost Child of Products Liability: New Thoughts about Advertising and the Learned Intermediary Doctrine*, 27 VT. L. REV. 1017, 1018 (2003).

3. Richard C. Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?*, 37 WAKE FOREST L. REV. 97, 121 (2002) [hereinafter Ausness, *Aggressive Marketing*]. Even Ausness, a staunch supporter of the traditional application of the doctrine, states, "There is no question that these developments [in pharmaceutical advertising and managed care] have changed the traditional physician-patient relationship." *Id.*

4. Richard C. Ausness, *Learned Intermediaries and Sophisticated Users: Encouraging the Use of Intermediaries to Transmit Product Safety Information*, 46 SYRACUSE L. REV. 1185, 1226-39 (1996) [hereinafter Ausness, *Learned Intermediaries*].

environment. Part IV defends the learned intermediary doctrine in its current form as the most effective way to serve the goal of providing the best warnings to consumers of prescriptions drugs.

I. THE LEARNED INTERMEDIARY DOCTRINE AND ITS EXCEPTIONS

This section discusses the rationale, the application, and the case law history of the learned intermediary doctrine. In addition, it describes a few of the exceptions that have been carved out in particular jurisdictions relating to mass immunizations, birth control, and (in one case) direct-to-consumer advertising (*Perez v. Wyeth Laboratories, Inc.*[5]).

A. Purpose of the Learned Intermediary Doctrine

The learned intermediary doctrine exists to serve the tort goal of accident cost avoidance, which is accomplished by requiring the consumer warning to be given by the party in the best position to provide that warning.[6] This reflects the realities of the prescription drug market. Individuals who use prescription drugs necessarily interact with a prescribing physician.[7] The physician must receive the warnings about the prescription drugs because he or she will use that information, in the context of the individual patient's medical history, to recommend a course of treatment (or alternative courses of treatment).[8] These warnings will be communicated to the patient through the process of obtaining informed consent or by involving the patient in his or her medical decision-making.[9] This method of communicating warnings to the patient is considered to be the most effective means of passing along this information and should result in the best health outcomes for individual patients.[10]

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5. 734 A.2d 1245 (N.J. 1999).

6. For a clear discussion of these goals, see Ausness, *Learned Intermediaries*, *supra* note 4, at 1226-39. There are three primary goals of tort law: "accident cost avoidance, minimization of administrative costs, and compensation of accident victims." *Id*. at 1226. Whether the goal of minimizing administrative costs is being met is evaluated by looking at both the costs incurred by the manufacturer to determine what they must do to be compliant with the law and the amount of money spent (by all parties) on litigation. *Id*. at 1235-36. Third, and perhaps most importantly, tort law exists for the compensation of accident victims. *Id*. at 1237.

7. There are illegal markets for prescription drugs, including those available through the internet. For a discussion of legal and illegal internet pharmacies, see Hall, *supra* note 2, at 198.

8. Ausness, *Aggressive Marketing*, *supra* note 3, at 109.

9. Laurie K. Marshall, Comment, *Keeping the Duty to Warn Patients of the Risks and Side Effects of Mass-Marketed Prescription Drugs Where It Belongs: With Their Physicians*, 26 U. DAYTON L. REV. 95, 111 (2000) (citing Canterbury v. Spence, 464 F.2d 772, 781-82 (D.C. Cir. 1972)).

10. Ausness, *Learned Intermediaries*, *supra* note 4, at 1233.

B. Application of the Learned Intermediary Doctrine

The majority of jurisdictions apply the learned intermediary doctrine as a duty-oriented rule.[11] Manufacturers know what actions are required to receive immunity from failure to warn claims.[12] This approach serves the policy goal of reducing administrative costs because "an original producer will know in advance that it satisfy [sic] its duty to warn by conveying product safety information to the appropriate intermediary. In contrast, a balancing test will impose significant information costs on many of the parties in the distributive chain."[13] A duty-oriented test decreases litigation costs because defendants can prevail at the summary judgment stage of litigation if they can show they provided adequate warnings to the prescribing physician.[14] A general practice of deciding failure to warn claims on summary judgment motions should "discourage plaintiffs from litigating frivolous claims and . . . give the parties an incentive to settle meritorious ones."[15]

C. Case Law Involving the Learned Intermediary Doctrine and Its Exceptions

Since 1948, courts have recognized that physicians necessarily intervene between pharmaceutical manufacturers and consumers of prescription drugs.[16] The term "learned intermediary" was coined in 1966 in *Sterling Drug, Inc. v. Cornish*.[17] A patient suffered retinal degeneration after taking a drug called Aralan (chlorquine phosphate). The court held that manufacturers had a duty to warn prescribing physicians of side effects, including those suffered only by a very small number of individuals taking the drug.[18] It reasoned that when dealing with prescription drugs:

> the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer. If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided.[19]

It is widely accepted that exceptions to the learned intermediary doctrine should exist for prescription drugs that are dispensed (or likely will be dispensed)

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11. Hall, *supra* note 2, at 217.

12. Ausness, *Learned Intermediaries*, *supra* note 4, at 1224.

13. *Id*. at 1235.

14. *Id.* at 1236-37. The reason defendants can prevail at the summary judgment stage of a trial is because the duty can be determined in advance, which minimizes the need for a jury to weigh evidence.

15. *Id*. at 1236.

16. Marcus v. Specific Pharm., Inc., 77 N.Y.S.2d 508, 510 (Sup. Ct. 1948). For a discussion of this case, see Bordes, *supra* note 2, at 268-69.

17. 370 F.2d 82, 85 (8th Cir. 1966).

18. *Id*. at 85.

19. *Id*.

in the absence of a physician.[20] The most obvious examples of this are found in mass immunization clinics. The 1968 case of *Davis v. Wyeth Laboratories*[21] held that the manufacturer of the Sabin polio vaccine was not protected by the learned intermediary doctrine because it actively participated in designing the immunization clinic, and therefore knew that the prescription drug would be dispensed outside the context of the doctor-patient relationship.[22] "It was dispensed to all comers at mass clinics without an individualized balancing by a physician of the risks involved. In such cases . . . warning by the manufacturer to its immediate purchaser will not suffice[,]" and the manufacturer must directly warn the consumer or ensure that he or she receives an adequate warning.[23]

Reyes v. Wyeth Laboratories[24] extended the logic of Davis to cases in which the manufacturer "had ample reason to foresee" that its product would be "dispensed without procedures appropriate for distribution of prescription drugs."[25] Although Wyeth did not actively participate in the immunization program (in contrast to *Davis*), it should have been familiar with "practices and knowledge common in the drug industry as to distribution and administration of pharmaceutical products."[26] Courts split on whether the exception should apply when a physician administers the vaccine in his or her office (not in a clinic situation).[27]

Some jurisdictions recognize an additional exception to the learned intermediary doctrine for contraceptive prescriptions (both for oral contraceptives and for intrauterine devices (IUDs)).[28] The justification for this exception is different, and more controversial, than that for mass immunizations. A physician is present in these cases, but it is alleged that there is a change in the dynamic of the physician-patient relationship sufficient to abrogate the learned intermediary doctrine. The court in *MacDonald v. Ortho Pharmaceutical Corp.* held that a "manufacturer of birth control pills owes a direct duty to the consumer to warn her of the dangers inherent in the use of the pill."[29] The plaintiff had suffered a stroke as a result of blood clots caused by Ortho's Ortho-Novum oral

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20. Richardson, *supra* note 2, at 1030.

21. Davis v. Wyeth Labs., Inc., 399 F.2d 121 (9th Cir. 1968).

22. *Id.* at 131.

23. *Id*.

24. 498 F.2d 1264 (5th Cir. 1974).

25. *Id.* at 1277.

26. *Id*.

27. For an example of a case that does not apply the exception, see *Hurley v. Lederle Laboratories Division of American Cyanamid Co.*, 863 F.2d 1173, 1178 (5th Cir. 1989). For cases that do apply the exception in this situation, see, for example, *Givens v. Lederle*, 556 F.2d 1341, 1345 (5th Cir. 1977); *Williams v. Lederle Laboratories*, 591 F. Supp. 381, 389 (S.D. Ohio 1984); *Samuels v. American Cyanamid Co.*, 495 N.Y.S.2d 1006, 1008 (Sup. Ct. 1985).

28. For an example of this exception as applied to oral contraceptives, see *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 68 (Mass. 1985). For examples of this exception as applied to IUDs, see *Hill v. Searle Laboratories*, 884 F.2d 1064 (8th Cir. 1989).

29. *MacDonald*, 475 N.E.2d at 68.

contraceptive. Although the drug manufacturer had adequately warned the physician, it had not mentioned the word "stroke" in its literature provided to the patient.[30] The court's reasons for treating oral contraceptives differently than other prescription drugs include two rationales based on the doctor-patient relationship.[31] First, the physician is relatively passive in directing the use of oral contraception to healthy, young women.[32] Second, a healthy woman will often have only annual visits with her healthcare provider. This means that the "patient may only seldom have the opportunity to explore her questions and concerns about the medication with the prescribing physician[,]" and she may not be able to remember the information given by the physician over the full course of one year.[33] The same kind of reasoning applies in the context of the insertion of an IUD.[34] Although this is an accepted exception in some jurisdictions, it remains a minority approach.[35] Most jurisdictions continue to treat these contraceptive prescriptions like prescriptions for other medical conditions, because physicians do make individualized decisions and advise patients based on their unique risk factors. In the case of IUDs, even more physician involvement is required, as the IUD must be ordered and then fitted.[36]

Another possible exception to the learned intermediary doctrine exists when the Food and Drug Administration (FDA) requires inserts in packaging of prescription drug products that are intended for consumers. The logic of this exception is that the manufacturer is already required to communicate warnings directly to consumers, so the learned intermediary doctrine serves no purpose.[37]

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30. It had, however, described the possibility of "increased risk to pill users that vital organs such as the brain may be damaged by abnormal blood clotting." *Id*. at 67.

31. The court also relied on the fact that the FDA extensively regulates birth control and mandates that end users should have detailed, clear, and readily accessible information of their risks. *Id*. at 70.

32. *Id*. at 69.

33. *Id*.

34. *See* Hill v. Searle Labs., 884 F.2d 1064, 1071 (8th Cir. 1989).

35. For the traditional approach to the learned intermediary doctrine in oral contraceptive cases, see *Reaves v. Ortho Pharmaceutical Corp.*, 765 F. Supp. 1287, 1290-91 (E.D. Mich. 1991); *Goodson v. Searle Laboratories*, 471 F. Supp. 546, 549 (D. Conn. 1978); *West v. Searle & Co.*, 806 S.W.2d 608, 614 (Ark. 1991); *Cobb v. Syntex Laboratories, Inc.*, 444 So. 2d 203, 205 (La. Ct. App. 1983); *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541, 549-50 (Ind. App. 1979); *Taurino v. Ellen*, 579 A.2d 925, 928 (Pa. Super. Ct. 1990). For the traditional approach applied to IUDs, see *Odom 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); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1305-06 (D. Minn. 1988); *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024, 1032 (D. N.J. 1988); *Humes v. Clinton*, 792 P.2d 1032, 1042-43 (Kan. 1990); *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 401 (Del. 1989); *Terhune v. A.H. Robins Co.*, 577 P.2d 975, 979 (Wash. 1978).

36. *See, e.g.*, *West*, 806 S.W.2d at 614 (applying this reasoning to oral contraceptives); *Lacy*, 567 A.2d at 401 (applying this reasoning IUDs).

37. For an example of this reasoning, see *Edwards v. Basel Pharmaceuticals*, 933 P.2d 298, 303 (Okla. 1997) (holding that "when the FDA requires warnings be given directly to the patient

Therefore, the consumer warnings should be assessed according to common law principles. Again, this exception remains a minority position, and most jurisdictions continue to apply the learned intermediary doctrine in these cases.[38]

Perez v. Wyeth Laboratories, Inc. provides an exception to the learned intermediary doctrine for products that have been directly marketed to consumers.[39] In 1998, the Restatement (Third) of Torts emphasized that the learned intermediary doctrine still protects pharmaceutical manufacturers from liability when they have adequately warned prescribing physicians.[40] However, it asserts in section 6(d)(2) that the patient herself must be adequately warned "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."[41] The Restatement declined to elaborate more fully than that, pointing to "developing case law" to determine whether this exception should apply in the context of direct-to-consumer advertising.[42] *Perez* concluded that it should.[43]

A group of bellwether plaintiffs filed suit against Wyeth Laboratories for failure to warn about the side effects of Norplant, a birth control drug/device. Plaintiffs suffered a wide variety of side effects, including weight gain, nausea, high blood pressure and scarring during the removal of the capsules.[44] The superior court determined that the learned intermediary doctrine would apply in this case, despite the fact that Wyeth had directly marketed its product to consumers.[45] "[E]ven when a manufacturer advertises directly to the public, and a woman is influenced by the advertising campaign, 'a physician is not simply relegated to the role of prescribing the drug according to the woman's wishes.'"[46]

The Supreme Court of New Jersey analyzed the issue differently, and reversed the lower court. The court framed the question in light of assumptions about the changed practice of medicine. In its introduction, it stated, "Our medical-legal jurisprudence is based on images of health care that no longer

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with a prescribed drug, an exception to the 'learned intermediary doctrine' has occurred, and the manufacturer is not automatically shielded from liability by properly warning the prescribing physician").

38. *See, e.g.*, Harrison v. Am. Home Prods. Corp. (*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); 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).

39. Perez v. Wyeth Labs, Inc., 734 A.2d 1245, 1257 (N.J. 1999).

40. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d)(1) (1998).

41. *Id*. § 6(d)(2).

42. *Id*. § 6 cmt. e.

43. *Perez*, 734 A.2d at 1257-58.

44. *Id.* at 1248.

45. *Id.* at 1249.

46. *Id*. (quoting Perez v. Wyeth Labs., Inc., 713 A.2d 588 (N.J. Super. Ct. Law Div. 1997), *rev'd*, 734 A.2d 1245 (1999)).

exist."[47] According to the court, there was a time in which physicians saw their patients in their offices and made house calls, and patients paid their (small) bills directly to their doctor. The legal profession assumed that the "doctor knows best."[48] In addition, pharmaceutical companies "never advertised their products to patients."[49] This was the "comforting setting" that justified the learned intermediary doctrine.[50] However, the court noted that, "that has all changed."[51]

In contrast to this idyllic vision of the traditional practice of medicine, the court pointed to changes toward corporate medicine, in which managed care organizations provide services, and prescriptions are prepared in grocery stores, and manufacturers advertise their prescription drugs directly to consumers.[52] Therefore, it framed the question of responsibility for the plaintiffs' injuries, in light of its understanding of this revolution, as "whether our law should follow these changes in the marketplace or reflect the images of the past."[53]

The court determined that the learned intermediary doctrine should not shield Wyeth from liability for failure to warn even though Norplant is available only by prescription and the capsules that deliver the active hormone, Levonorgestrel, are placed under the patient's skin by a physician.[54] Rather, it decided that the learned intermediary doctrine should not apply "when mass marketing of prescription drugs seeks to influence a patient's choice of a drug."[55] The court reached this conclusion because it determined that the premises upon which the learned intermediary doctrine is based are "absent in the direct-to-consumer advertising of prescription drugs."[56] The court cited as its first reason for creating this exception that "with rare and wonderful exceptions, the 'Norman Rockwell' image of the family doctor no longer exists."[57] Informed consent requirements are one facet of the doctor-patient relationship the court feels has substantially changed. Second, physicians cannot provide adequate information to patients about prescription drugs because "managed care has reduced the time

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47. *Id*. at 1246.

48. *Id*. at 1247 (citing Logan v. Greenwich Hosp. Ass'n, 465 A.2d 294, 299 (Conn. 1983)).

49. *Id*. at 1249.

50. *Id*. at 1247.

51. *Id.*

52. *Id*. It is difficult to see exactly what the court means here; managed care organizations do not provide care. Physicians still provide care to patients, even if that care is organized through and paid for by managed care organizations. In addition, it is difficult to see the relevance of the fact that prescriptions would be prepared in a supermarket as opposed to a corner pharmacy; pharmacists are employed in both settings. However, it does seem that the court is bothered by its perception that profit-motivated groups are intervening in an intimate relationship between physician and patient.

53. *Id*.

54. *Id*. at 1247, 1268.

55. *Id*. at 1247.

56. *Id*. at 1255.

57. *Id.* (quoting Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 160 n.78 (1997)).

allotted per patient."[58] Finally, direct to consumer advertising and its profits undermine the premise that "drug manufacturers lack effective means to communicate directly with patients."[59] Because the underlying premises are allegedly inapposite, the "common law duty to warn the ultimate consumer should apply."[60]

The direct-to-consumer-advertising exception has not yet been adopted in other jurisdictions,[61] and it is has been questioned by at least one other court in New Jersey. For instance, in a 2003 decision, *New Jersey Citizen Action v. Schering-Plough Corp.*,[62] the court dismissed a claim for fraudulent advertising for the prescription allergy medication, Claritin.[63] In dicta, the court (affirming the lower court's judgment) stated that, regardless of the *Perez* holding, "the intervention by a physician in the decision-making process necessitated by his or her exercise of judgment whether or not to prescribe a particular medication protects consumers in ways respecting efficacy that are lacking in advertising campaigns for other products."[64]

Perez is a substantial expansion in reasoning for exceptions to the learned intermediary doctrine. It does not assume the absence of a physician (like the immunization cases) nor does it look at the relative involvement of the patient and physician in the decision to use a particular prescription drug or device (like the cases involving birth control). Rather, it concludes that the current overall environment in which healthcare is practiced, with managed care and direct-to-consumer pharmaceutical advertising, renders physicians incompetent to act as learned intermediaries. If true, this could warrant a radical reconfiguration of failure-to-warn jurisprudence for prescription drugs.

There are three basic proposals for changing the traditional application of the learned intermediary doctrine. The first option is to follow the courts which have carved out exceptions for certain kinds of cases. These range from creating an exception for mass immunizations in the absence of a physician (widely adopted) to an exception for prescriptions given when there has been direct-to-consumer advertising (adopted only in New Jersey).[65] However, some scholars argue that an extended list of exceptions to a doctrine suggests that the doctrine has become outdated and should be changed. As one scholar states, "[E]ventually, the law must ask whether it would not be more appropriate to revise the rule itself to eliminate the need for the exceptions, rather than continuing to create bright-line

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58. *Id*.

59. *Id*. The court also notes a fourth premise, the "complexity of the subject," which it states may possibly still be relevant. *Id*.

60. *Id*. at 1256.

61. Bernard J. Garbutt III & Melinda E. Hofmann, *Recent Developments in Pharmaceutical Products Liability Law: Failure to Warn, the Learned Intermediary Defense, and Other Issues in the New Millennium*, 58 FOOD & DRUG L.J. 269, 275 (2003).

62. 842 A.2d 174 (N.J. Super. Ct. App. Div. 2003).

63. Claritin is now available as an over-the-counter medication.

64. *N.J. Citizen Action*, 842 A.2d at 177-78.

65. *See* discussion of cases accompanying *supra* notes 17-39.

exceptions to the rule."[66] A discussion of two such revisions follows.

II. ABOLISHING THE LEARNED INTERMEDIARY DOCTRINE

One proposal is to abolish the learned intermediary doctrine completely so that prescription drugs are treated like any other product.[67] In traditional products liability, manufacturers are responsible for warning the end users of their products of foreseeable dangers.[68] An exception was created for prescription drugs because of the difficulties associated with effectively reaching the intended, nonmedical audience with adequate warnings.[69] There are two basic arguments for abolishing the learned intermediary doctrine and requiring prescription drug manufacturers to warn consumers directly. First, patients are educated and empowered and no longer need a learned intermediary. Second, direct-to-consumer advertising itself undercuts assumptions upon which the doctrine arguably rests, including the inability to reach consumers, the need for the physician to be the sole source of patient information, and the desire courts have not to intrude on the doctor-patient relationship.[70]

A. Patients Are Educated and Empowered

The first rationale for abrogating the learned intermediary doctrine is that consumers are capable of understanding information directly from manufacturers and do not need the intervention of a physician to understand warnings. One version of this argument is that the concept of informed consent itself renders the learned intermediary doctrine irrelevant. Susan A. Casey asserts that "[t]he single most important argument in favor of direct-to-patient warnings is the notion of informed consent."[71] Informed consent requires physicians to "respect . . . the patient's right of self-determination," which requires a disclosure of risks and benefits that a reasonable person would need to know to make a choice based upon his or her own values.[72] Casey argues that "in the case of drugs and devices, both the physician and the manufacturer are qualified to disclose material information regarding risks and adverse effects."[73] If this is true, then a patient can arrive at informed consent to take a prescription drug merely by reading the warnings provided by the manufacturer. The physician's involvement is a vestige of medical paternalism,[74] and the patient should not be

66. Hall, *supra* note 2, at 240.

67. Bordes, *supra* note 2, at 268; Casey, *supra* note 1, at 959.

68. RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (1965).

69. *Id*. § 402A cmt. k.

70. There are minor variations in different summaries of justifications for the learned intermediary doctrine. This list is consistent with the analysis in *Perez*, which, in turn, bases its reasoning on the arguments that follow in this section.

71. Casey, *supra* note 1, at 958.

72. *Id.* (quoting Canterbury v. Spence, 464 F.2d 772, 784 (D.C. Cir. 1972)).

73. *Id.* at 959.

74. *Id*. at 958.

"needlessly subjected to the physician's or the courts' discretion."[75]

Another version of this argument rests on the assumption that patients are adequately educated to understand direct warnings because they receive information from drug companies via advertising and because they learn about medicine via the internet and other sources. The court in *Perez* relied on an early formulation of this argument that asserted that advertising had changed the relative roles of the physician and patient in medication decisions.[76] By directly providing consumers with information about their products, manufacturers "enabl[ed] consumers to be more actively involved in making decisions about prescription drugs."[77] The physician's role is diminished, although it is still vital because a prescription remains necessary to purchase these drugs. Therefore, the "legal principles applicable to other product sellers should apply equally to prescription drug manufacturers who advertise their products."[78] This argument implies that the direct-to-consumer advertising for pharmaceutical products is capable of providing effective education and information to consumers, and that the pharmaceutical manufacturer displaces the physician as the best person to warn.

These arguments are flawed because they mischaracterize the role of the educated patient in a healthcare encounter. The "root premise" for the legal concept of informed consent in healthcare has existed in the United States since 1914, when the court in *Schloendorff v. Society of New York Hospital*[79] declared that "every human being of adult years and sound mind has a right to determine what shall be done with his own body."[80] The doctrine was entrenched as "almost axiomatic" by the time *Canterbury v. Spence* was decided in 1972.[81] The court in *Canterbury* states,

> True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each. The average patient has little or no understanding of the medical arts, and ordinarily has only his physician to whom he can look for enlightenment with which to reach an intelligent decision.[82]

The physician is therefore obligated to disclose to the patient the material risks and benefits that would enable a reasonable person to make an educated decision.[83] Material information includes "inherent and potential hazards of the

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75. *Id.* at 959.

76. Schwartz, *supra* note 1, at 844. The *Perez* court relies on her argument in its decision. *See* Perez v. Wyeth Labs, Inc., 734 A.2d 1245, 1255 (N.J. 1999).

77. Schwartz, *supra* note 1, at 844.

78. *Id*. at 845.

79. 105 N.E. 92, 93 (N.Y. 1914).

80. *Id.* (quoted in Canterbury v. Spence, 464 F.2d 772, 780 (D.C. Cir. 1972)).

81. *Canterbury*, 464 F.2d at 780.

82. *Id.*

83. *Id.* at 787. This is the more rigorous standard. Another legal standard is based on

proposed treatment, the alternatives to that treatment, if any, and the results likely if the patient remains untreated."[84]

Informed consent depends on a partnership between the doctor and the patient. That partnership is unequal in terms of medical expertise, but equal in terms of moral authority. The doctor brings to the healthcare encounter his or her expertise, acquired through a decade or more of classroom education and clinical training, which requires the application of "textbook" knowledge to each individual patient. Very rarely is there equality of medical knowledge between the doctor and the patient.[85]

The context of healthcare decision making, then, is one in which the doctor describes the options and likely results of therapeutic options (or of doing nothing), and then the patient chooses based on his or her own values. For instance, a patient with prostate cancer can choose between medical management and different types of surgical techniques. To make an informed decision, the patient needs to know rates of success and which complications potentially accompany which treatments. One patient, based on his particular life circumstances, may choose a surgery that has a very high likelihood of eradicating the cancer completely, but carries with it a higher chance of impotency. Another patient with the exact same disease may, for other reasons, choose medical management, with a lower rate of success. Physicians are not paternalistic as long as they do not substitute their value judgments for those of their patients.[86]

Therefore, informed consent diminishes neither the need for medical expertise nor for the learned intermediary doctrine. The court in *Terhune v. A.H. Robins Co*.[87] makes it clear that requiring the patient to make an informed decision does not invalidate the learned intermediary doctrine, because "[i]n any such situation which may come to mind, the patient is expected to look to the physician for guidance and not to the manufacturer of the products which he may use or prescribe in the course of treatment."[88]

The argument, therefore, that the doctrine of informed consent somehow

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professional custom. *Id.* at 783. The court in *Canterbury* found this standard insufficiently strong and susceptible to manipulation by physician witnesses. *Id*. at 783-84.

84. *Id.* at 787-88.

85. A reasonable argument can be made that doctors and patients are equal in knowledge in certain limited situations, such as a decision for a healthy, young woman to take birth control pills. Both the physician and the patient (by reading literature provided by the manufacturer) may be able to understand the risks equally well. This is the argument that the court advances in *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 69-70 (Mass. 1985).

86. JAMES F. CHILDRESS, WHO SHOULD DECIDE? PATERNALISM IN HEALTH CARE 13 (1982) (stating that paternalism is a "refusal to accept or to acquiesce in another person's wishes, choices, and actions for that person's own benefit").

87. 577 P.2d 975 (Wash. 1978).

88. *Id.* at 978. The court states, "The fact that the patient makes the final choice among suggested contraceptives (or decides not to use any at all) does not constitute a distinction which makes the general rule inapplicable." *Id*.

renders the learned intermediary doctrine irrelevant must fail. An informed patient judgment is possible only after a physician discloses the material medical information. If the physician was required to do this for pharmaceutical products in 1966, it remains necessary today.

B. Direct-to-Consumer Advertising Undercuts Rationales for the Learned Intermediary Doctrine

Serious problems also plague the argument that direct-to-consumer advertising destroys the presumptions upon which the learned intermediary doctrine is based.

1. Pharmaceutical Manufacturers Can Reach Consumers.—Commentators argue that the learned intermediary doctrine was adopted because pharmaceutical manufacturers were incapable of reaching consumers and that direct-to-consumer advertising has changed that assessment. Some scholars have suggested that drug companies can effectively reach patients because their advertising campaigns are so successful. For example, the court in *Perez* argued that, "having spent $1.3 billion on advertising in 1998, drug manufacturers can hardly be said to 'lack effective means to communicate directly with patients,' when their advertising campaigns can pay off in close to billions in dividends."[89] The court in *Perez* relied on Lars Noah's assessment when refusing to apply the learned intermediary doctrine in its groundbreaking decision.[90]

Although advertising may increase sales, it remains true that it is virtually impossible for pharmaceutical manufacturers to provide a warning to specific patients based on their unique medical history and condition and the constellation of other drugs they may be taking.[91] The near impossibility of providing specific warnings remains even though these manufacturers clearly "reach" consumers. The ability to "reach" consumers in the sense of providing them with prescription drug information sufficient to entice them to request a product does not guarantee that the information is tailored to their physiological needs. Direct-to-consumer advertising therefore does not abrogate the need for the learned intermediary doctrine solely because it provides an effective channel for reaching patients.

2. Physician Must Be Sole Source of Information.—At least one commentator contends that the learned intermediary doctrine is only valid if the physician is the sole source of patient information.[92] It is therefore invalid if the

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89. Perez v. Wyeth Labs., Inc., 734 A.2d 1245, 1255 (N.J. 1999) (quoting Noah, *supra* note 57, at 158) (internal citations omitted).

90. *Id.* at 1255-56.

91. Ausness, *Aggressive Marketing*, *supra* note 3, at 108-10. It is "virtually impossible for a manufacturer to test a new chemical entity with every other medication that might create an adverse interaction." For this reason, warnings are added after adverse, unforeseen drug interactions. Barbara A. Noah, *Adverse Drug Reactions: Harnessing Experiential Data to Promote Patient Welfare*, 49 CATH. U. L. REV. 449, 491 (2000).

92. *See, e.g.*, Schwartz, *supra* note 1, at 842. Schwartz states, "The learned intermediary rule is based on the notion that the doctor should be the sole source of information about prescription

consumer has been exposed to any direct-to-consumer-advertising (or other forms of information, including word of mouth), whether or not that information effectively conveys warnings.

However, there is nothing in the doctrine itself that suggests that a physician can act as a learned intermediary only when he or she is the sole source of patient information. Courts do not require this when they apply the learned intermediary doctrine.[93] In *Davis v. Wyeth*,[94] for instance, the court held that the decision to prescribe a particular drug is essentially a medical one, but it does not state that the patient cannot be influenced by any other sources.[95] In *Thomas v. Hoffman-La Roche, Inc.*,[96] the court held that "the physician through education, experience, and specialized training is in the best position to make a benefit/risk analysis in making the determination to prescribe a particular drug for a specific patient."[97] Also, in *Terhune v. A.H. Robins Co.*,[98] the court held that "[t]he patient is expected to and, it can be presumed, does place primary reliance upon [the physician's] judgment."[99] The physician's expertise is still needed, even if there are other sources of patient information. The underlying fact that physicians tailor manufacturer warnings to individual patients does not change, regardless of how many other sources of information a patient may have.

3. Direct-to-Consumer Advertising ("DTCA") Purposefully Interferes with the Doctor-Patient Relationship.—A third argument is that the learned intermediary doctrine should be eliminated because it exists in part to preserve the doctor-patient relationship, but pharmaceutical companies intentionally intrude on this relationship through their aggressive advertising campaigns. Fairness should therefore prevent those companies from relying on the learned intermediary doctrine as a shield against failure to warn liability.[100] This argument has common sense appeal and "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."[101] However, it fails to relate to the purpose of the learned intermediary doctrine, which is to protect consumers at the lowest cost. "[I]f the primary beneficiaries of the learned intermediary rule are consumers, and not drug companies, then the conduct of

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drugs. Consumer-directed advertising, however, completely undercuts that notion." *Id*. at 842.

93. This is true even in the cases Schwartz uses to present her argument. *Id*. at 830 n.5.

94. Davis v. Wyeth Labs., Inc., 399 F.2d 121 (9th Cir. 1968).

95. *Id.* at 130 (holding that "the choice involved is essentially a medical one involving an assessment of medical risks in the light of the physician's knowledge of his patient's needs and susceptibilities. Further it is difficult under such circumstances for the manufacturer, by label or direct communication, to reach the consumer with a warning." Therefore, the physician's warning "is in such cases the only effective means by which a warning could help the patient.")

96. Thomas v. Hoffman-La Roche, Inc., 731 F. Supp. 224 (N.D. Miss. 1989).

97. *Id.* at 229.

98. Terhune v. A.H. Robins Co., 577 P.2d 975 (Wash. 1978).

99. *Id.* at 978-79.

100. *See, e.g.*, Bordes, *supra* note 2, at 268.

101. Ausness, *Aggressive Marketing*, *supra* note 3, at 122.

drug companies should not necessarily determine whether the rule should be retained or not."[102]

III. APPLYING THE LEARNED INTERMEDIARY DOCTRINE AS A FACT-BASED INQUIRY

Rather than arguing that it is more effective in terms of the tort law goal of accident cost avoidance to warn consumers directly (as the first set of proposals did), the proposals in this section assume that warnings to physicians can be the most efficient way to protect consumers, but only in cases where the physician is not overly constrained by pressures of the modern healthcare environment. Therefore, a fact-based inquiry into the context of the provision of the prescription medication is required to determine whether the learned intermediary doctrine should be available to pharmaceutical manufacturers as a defense to liability. The logic, in part, is that pharmaceutical companies are not exempt from failure to warn liability when they have reason to believe the physician will not be in a position to reduce risk.

The main implication for litigation of this kind of fact-based inquiry is that it would be more difficult for defendants to win at the summary judgment stage of litigation because evidence regarding specific advertising, a patient's contact with that advertising, and the relationship of the patient and physician would be factual matters best evaluated by a jury. In addition, a factor-balancing approach opens up the number of potential defendants available to suit; it "extends liability to parties farther down the distributive chain without necessarily relieving parties who are farther up the chain."[103] Therefore, this approach might compensate victims better, but the costs of accident avoidance and administration would increase.[104]

Proposals that depend upon skepticism about the doctor-patient relationship vary in their details, although common themes include a loss of the paternalistic, dyadic doctor-patient relationship and negative effects of direct-to-consumer advertising and managed care. This section will examine two of these proposals and their assumptions. It will then turn in more detail to widespread concerns about the effects of direct-to-consumer advertising and managed care on physicians' ability to function effectively as learned intermediaries.

A. Proposals for and Assumptions of Fact-Based Analyses

Timothy S. Hall offers an alternative to the learned intermediary doctrine which "bring the law's presumptions into line with the modern health care marketplace."[105] Hall suggests that the text of the learned intermediary doctrine should itself be changed, and courts should apply it by weighing various

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102. *Id.*

103. Ausness, *Learned Intermediaries*, *supra* note 4, at 1239.

104. *Id*. at 1237.

105. Hall, *supra* note 2, at 199.

factors.[106] The doctrine he suggests is:

> A manufacturer has the duty to warn the ultimate user of an unavoidably unsafe product, notwithstanding the fact that the product is sold to an intermediary or that the product is legally unobtainable without recourse to an intermediary. A manufacturer may discharge its duty to warn by warning only the intermediary when it knows or has reason to know that the intermediary is in a position to minimize the risk posed by the product.[107]

The factors Hall proposes that the courts weigh when making the determination of the doctor's ability to minimize risk encompass all of the exceptions adopted by jurisdictions throughout the country and others that arguably influence the prescription process now and in the future.[108] He includes: (1) the absence or presence of a prescribing physician; (2) whether the patient "specifically requested" a particular drug; (3) the ability (or inability) for the patient to regularly and frequently discuss the drug's efficacy; (4) whether the drug treats a medical condition or is cosmetic or used for convenience; and (5) whether regulations insist that the consumer be directly warned about side effects and adverse reactions.[109]

Hall believes the learned intermediary doctrine should be changed because of "the change (some would say the decline) from the fee-for-service health care system of that time [circa 1966] with its emphasis on the dyadic, paternalistic physician-patient relationship, to the modern, twenty-first century health care system with its triadic managed care relationships and uncertain authority structure."[110] Hall describes his vision of what the healthcare world was like in 1966 when the learned intermediary doctrine was adopted.[111] "President Lyndon Johnson was in the White House and Dr. Kildare was on television. Dr. Kildare, like Marcus Welby, who followed him, remains an icon of the traditional American health system: a primary care physician devoted to his patients."[112] The learned intermediary doctrine should be changed because the fee-for-service payment and "dyadic, paternalistic physician-patient relationship" has been replaced.[113]

Sheryl Calabro's proposal is that the learned intermediary doctrine should remain essentially unchanged, but that it should be applied in a fact-based way, requiring the court to assess the context of the doctor-patient relationship.[114] Calabro's proposal is that the Rule should apply when the "root justifications for

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106. *Id.*
107. *Id.* at 242.
108. *Id.* at 243.
109. *Id.*
110. *Id.* at 195.
111. *Id.*
112. *Id*.
113. *Id.*
114. Calabro, *supra* note 2, at 2308.

the learned intermediary doctrine are present,"[115] but that it should not be used when there are significant conflicts of interest due to pharmaceutical advertising and managed care that "undermine the ability of the physician to make independent determinations concerning the patient's well-being and to function as a learned intermediary."[116] The court would need to determine this by applying a "flexible framework."[117] There would be four major factors to consider, and the list would not be exhaustive. Those four factors are:

> (1) whether and to what extent the pharmaceutical company has engaged in direct-to-consumer advertisement and the breadth and nature of that advertising; (2) whether the pharmaceutical company has repeatedly encouraged physicians to prescribe their products through gifting and other aggressive marketing practices; (3) whether and how the pharmaceutical company has made its products available through Internet pharmacies; and (4) whether the traditional physician-patient relationship exists.[118]

After evaluating these factors, the "courts should then balance the equities."[119]

Like Hall, Calabro notes a change in the doctor-patient relationship. She states, "When the learned intermediary doctrine developed, the physician and patient had a professional relationship guided by ethical and fiduciary responsibilities. The physician, driven by the Hippocratic Oath, did not encounter the countervailing pressures that exist today, nor was the consumer inundated with information communicated directly from the pharmaceutical manufacturer."[120]

1. Questioning the Assumptions.—Taken together, these two proposals suggest three features of modern medicine that could adversely affect the physician's ability to serve as a learned intermediary. The first is that physicians are more distant from their patients and arguably less motivated by altruism than they were in the 1960s (and before). The second is that managed care makes physicians less trustworthy than they were under fee-for-service payment arrangements due to certain payment incentive structures. The third is that direct-to-consumer advertising creates conflicts between the physician and the patient that diminish the quality of the physician's care. These arguments deserve careful scrutiny. Which, if any, are true? If they are true, would the alteration of the learned intermediary ameliorate any of the problems?

a. Changes in the doctor-patient relationship.—There is some general truth to Hall's depiction of the traditional doctor-patient relationship, although major changes in that relationship were well underway before the adoption of the learned intermediary doctrine. Although Norman Rockwell's depictions of

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115. *Id*. at 2306.
116. *Id.* at 2259.
117. *Id.* at 2306.
118. *Id.*
119. *Id.* at 2309.
120. *Id.* at 2253.

physicians were nostalgic, the old-fashioned family doctor was the norm rather than the exception before World War II. Seventy percent of physicians were still family practitioners in 1940.[121] Physicians lived in the communities where they worked, and shared the religion and worldview of their patients. "The critical elements in building a practice were not degrees, specialty certification, hospital affiliation, or special skills."[122] Rather, one's reputation in the neighborhood attracted patients.[123] In addition, case history was the main component of diagnosis, because there were few other diagnostic tools. Physician practice was improved by knowing the patient well.[124] Therefore, people had closer relationships with their physicians, and physicians "were comfortable making decisions on behalf of the patients."[125]

However, this relationship changed drastically after World War II. Twenty percent of physicians were general practitioners, house calls virtually disappeared, and specialty practice ensured that physicians obtained patients based on technical expertise rather than people skills.[126] In fact, "specialization meant that patients and doctors were not likely to have met before the onset of the illness, let alone to have developed a relationship."[127] Physicians' incomes increased, which "helped foster belief that doctors had become more concerned with their pocketbooks than their patients."[128] More important, however, was the increased distance between physicians and their patients caused by their extended training.[129]

Physicians, therefore, became less paternalistic. This took place before the adoption of the learned intermediary doctrine and was the result of specialization as opposed to physicians caring less about their patients. The courts that recognized and coined the "learned intermediary" doctrine would have been aware of this massive change in the doctor-patient relationship, so it is unlikely that the learned intermediary doctrine depends on such the paternalistic relationship. When the doctor-patient relationship was paternalistic, the doctor could substitute his or her value judgments for those of the patient because they knew each other well and shared the same value system. This Note argues, however, that the learned intermediary doctrine does not depend on paternalism for its relevancy; instead, it depends on expertise.[130] The changes since the

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121. DAVID J. ROTHMAN, STRANGERS AT THE BEDSIDE: A HISTORY OF HOW LAW AND BIOETHICS TRANSFORMED MEDICAL DECISION MAKING 114 (1991).

122. *Id.* at 117.

123. *Id.*

124. *Id.*

125. *Id.* at 123.

126. *Id.* at 128-29.

127. *Id.* at 129.

128. *Id.* at 108.

129. *Id.* at 134. "[W]hen physicians earn the requisite degrees and pass the national and specialty board exams, they have spent some fifteen years since high school on the training track, most of this time, segregated in a medical world."

130. See the discussion on informed consent, *supra* Part II.A.

doctrine was adopted only increase physician expertise and make the doctrine's justification stronger.

What about the claim that physicians are no longer altruistic and cannot be trusted to put their patients' concerns over their own? First, it is highly simplistic to say that physicians were once bound by the Hippocratic Oath, but currently are not. The Hippocratic Oath has many admirable suggestions, such as to "come for the benefit of the sick" and to guard confidences.[131] It also, however, has problematic counsel (as we would expect from a Greek, cultic group from 4 B.C.E.), such as the prohibition against surgery and abortion.[132] The Hippocratic Oath is only one possible oath that could be said to influence physician ideals.[133] American physician (and signer of the Declaration of Independence) Benjamin Rush counseled heroicism for physicians in 1801.[134] "Rush's ideal physician . . . would never refuse to treat patients because of poverty, or exploit their vulnerability. Indeed, the virtuous physician was heroic: should a plague strike a community, the physician was obliged to stay and treat the ill, even at the risk of death."[135] However, being human beings, one can safely assume that all doctors were not heroes, and much of the professional ethics literature written by physicians during this "golden age" of the doctor-patient relationship focused on physician interests. For example, in the mid-1920s, Richard Cabot was analyzing the ethical aspects of fee-splitting, and in the 1930s the American Medical Association was busy lobbying against "national health insurance, group practice, and physician advertising."[136]

From a historical perspective, it is inaccurate to argue that the learned intermediary doctrine was adopted because physicians were perfectly virtuous in the 1960s. There has been a decrease in the intimacy between physicians and patients, but physicians were and are not perfectly virtuous. Luckily, the learned intermediary doctrine never depended on perfect virtue; instead, it depended on physician expertise.

b. Direct-to-consumer advertising.—Direct-to-consumer advertising increased dramatically in the 1990s, rising "from a meager $55 million in 1991 to $2.5 billion in 2000."[137] A widely cited yearly survey in *Prevention*

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131. *The Oath of Hippocrates*, MEDWORD RESOURCES, http://www.medword.com/hippocrates.html (last visited Mar. 13, 2007).

132. Fabrice Jotterand, *The Hippocratic Oath and Contemporary Medicine: Dialectic Between Past Ideals and Present Reality?*, 30 J. MED. & PHIL. 107, 110-11 (2005).

133. Currently, medical students commonly only recite one-third of the Oath at their medical school graduations. *Id.* at 110.

134. Rush was a physician in Philadelphia. Rothman says, "Rush's ideal physician was not pecuniary minded; recognizing an ongoing obligation to the poor. . . ." ROTHMAN, *supra* note 121, at 103.

135. *Id.*

136. *Id.* at 104.

137. Marta Wosinska, *Just What the Patient Ordered? Direct-to-Consumer Advertising and the Demand for Pharmaceutical Products* 1 (Harvard Bus. Sch. Mktg. Research Papers, Paper No. 02-04, 2002), *available at* http://ssrn.com/abstract_id=347005.

magazine[138] reported that "29% of consumers who saw a drug ad talked to their physician about it and asked for the drug to be prescribed to them. Doctors, in turn, honored 73% of those consumer requests."[139] A heated debate about the potential effects of direct-to-consumer advertising on patients and the costs of healthcare ensued.

Proponents of direct-to-consumer advertising suggest three beneficial results for patients. First, patients can learn to describe their symptoms more effectively by hearing the advertisements, thus improving their communications with their physicians.[140] Second, individuals who previously were not under a doctor's care visited a physician for the first time for previously untreated chronic conditions such as obesity, hypertension, high cholesterol and depression.[141] Third, drug advertising can serve as a patient reminder, which can improve patient compliance.[142] Noncompliance is one of the most serious problems with drug therapies, contributing to as many as 125,000 deaths per year in the United States.[143] It also causes increased hospitalizations.[144] Direct-to-consumer advertising can therefore provide substantial health benefits for patients.

Many commentators in both the law and medicine were not so optimistic about direct-to-consumer advertising's benefits for patients and the community. Many of the arguments by legal commentators who advocate a change in the learned intermediary doctrine in the presence of direct-to-consumer advertising are shared by those who would like to abolish the doctrine completely. For instance, these commentators complain that increases in advertising "leav[es] the pharmaceutical company without the excuse that it could not communicate directly with consumers."[145] This Note argues that direct-to-consumer advertising does not "reach" consumers with adequate warnings, even if it could be shown that it translates into prescription drug sales.[146] In addition, there is concern that direct-to-consumer advertising changes the relative positions of decision making power in the doctor-patient relationship.[147] If the patient initiates a treatment by requesting a particular drug, then the physician is not

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138. *International Survey on Wellness and Consumer Reaction to DTC Advertising of Prescription Drugs*, PREVENTION MAG. 46-55 (2001).

139. Wosinska, *supra* note 137, at 1.

140. Michael C. Allen, Comment, *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, 127-28 (1997).

141. Alan F. Holmer, *Direct-to-Consumer Advertising—Strengthening Our Health Care System*, 346 NEW ENG. J. MED. 526, 528 (2002).

142. Dorothy L. Smith, *DTC Ads: Promoting Compliance a Win-Win Prospect*, 19 PHARMACEUTICAL EXECUTIVE 84 (1999).

143. Mary Wosinska, *Direct-to Consumer Advertising and Drug Therapy Compliance*, 42 J. MARKETING RES. 323, 323 (2005).

144. *Id.*

145. Calabro, *supra* note 2, at 2270.

146. *See supra* Part II.B.1.

147. Schwartz, *supra* note 1, at 844.

exercising his or her expertise.

One commentator points out the obvious fact that pharmaceutical advertising is an attempt to sell products rather than to educate consumers.[148] These advertisements are created based on "intensive research . . . [into] consumer purchasing psychology."[149] Therefore, the consumer will approach the physician with a strong desire for a product that may or not be appropriate, and thus will exert a "shadow pressure" on the physician.[150] The physician is then in the position where he or she is "forced to convince the patient that she is wrong, refuse further treatment, or compromise. Any of these options subvert the physician-patient relationship into a negotiation where a patient, relying on outside counsel, acts against the primacy of the physician to oversee the treatment of her illness."[151] This is a waste of physician energy and precious time. In addition, the patient may doctor shop for the physician who will acquiesce in the patient's wishes.[152] Finally, and most disturbingly, "the physician in a third-party-influence situation cannot with any certainty determine whether or how any advertising may have influenced the patient's description of her symptoms and aliments [sic]."[153] The argument is that "[c]ourts must see advertisements for what they are—manipulations that prey upon consumers in conscious and unconscious ways."[154]

Recent studies suggest that direct-to-consumer advertising is not the force it was expected to be (by its critics or its proponents). More data will become available in the future, but the current studies suggest three conclusions about this advertising that is relevant to debates about the learned intermediary doctrine.

First, data suggests that, even though direct-to-consumer advertising ("DTCA") affects overall pharmaceutical sales, it tends to do so at the level of a therapeutic class of medications, rather than at the level of an individual product.[155] A study on H_2 –antagonists (drugs used to inhibit the production of stomach acid) concludes that "own-brand physician-oriented detailing and medical journal advertising efforts have positive and long-lived impacts on own Rx market share, while DTCA of the Rx brand has no significant impact on own Rx market share."[156] In contrast, there are significant increases in sales associated with over-the-counter DTCA.[157] This suggests that physicians may prescribe for a particular symptom or condition of the patient at his or her

148. Richardson, *supra* note 2, at 1060.

149. *Id*. at 1050.

150. *Id.* at 1026.

151. *Id.*

152. *Id.*

153. *Id.*

154. *Id.* at 1060.

155. MEREDITH B. ROSENTHAL ET AL, DEMAND EFFECTS OF RECENT CHANGES IN PRESCRIPTION DRUG PROMOTION, KAISER FAMILY FOUNDATION 1, 5 (2003).

156. *Id.*

157. *Id.*

request, but will not prescribe the particular brand name product that is requested.

Second, when direct-to-consumer advertising does affect same-brand sales, it does so only when the brand is the preferred drug in its class in the formulary available to the physician.[158] Wosinska studied advertising and prescription sales of cholesterol-reducing medications.[159] She found that "DTCA, unlike detailing [sending salespeople out to doctor's offices to give them educational material and samples], affects individual drug market share only if that brand happens to have preferred status on the third party payer's formulary."[160]

Third, promotion to consumers is massively overshadowed by promotion directly to physicians, in terms of dollars spent and effectiveness. The promotion to sales ratio of physician promotion is 0.118, and the same ratio for direct-to-consumer advertising is 0.022.[161] Wosinska estimates that the "marginal impact of detailing is significantly larger than the marginal impact of consumer advertising (on the order of five times)."[162]

This data suggest that DTCA probably does not yet work to increase sales of particular brand name drugs, at least in a way that's predictable for pharmaceutical manufacturers. This data squares with what has, in fact, been the pharmaceutical manufacturers' actions in promotion. Although there has been a big increase in direct-to-consumer advertising since 1980 and exponential growth after the legal requirements were clarified in 1997,[163] physician-oriented approaches still comprise the vast majority of marketing budgets. Physician promotion "include[s] visits or phone calls by pharmaceutical sales representatives to physicians (detailing), free samples, print advertising, and sponsorship of medical education events."[164] Free samples account for 50.6% of spending on physician promotion.[165] In 2000, total physician promotion accounted for over $15.708 million, while DTCA promotion accounted for $2.467 billion.[166]

This Note concedes that direct-to-consumer advertising potentially has both positive and negative effects on patient care. It may educate consumers and bring them into the healthcare environment, but it can also lead to inappropriate use of

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158. *Id.* at 19.

159. *Id.* at 4-5.

160. *Id.* at 19.

161. *Id.* at 21.

162. Wosinska, *supra* note 137, at 3.

163. Department of Health and Human Services, Food and Drug Administration, *Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements*, 62 Fed. Reg. 43,171-43,173 (Aug. 12, 1997).

164. ROSENTHAL ET AL., *supra* note 155 at 8.

165. *Id.*

166. *Id.* at 21. It is clear, however, that DTCA increased drug company profits. One study estimates that "$2.6 billion or 12% of the growth in total prescription drug spending between 1999 and 2000 was attributable to DTCA." *Id.* at 18. However, it still comprises only 15.7% of pharmaceutical marketing. *Id.* at 8.

drugs and overprescribing. However, the data regarding how direct-to-consumer advertising works so far is problematic as a justification for altering the learned intermediary doctrine for three reasons. First, it will be difficult to hold manufacturers liable for advertising that leads to inappropriate prescribing if the physician prescribes a different brand-name of the drug, which frequently happens. Second, the fact that physician promotion still dominates pharmaceutical manufacturing suggests that the pressures on physicians are not substantially different than they were before direct-to-consumer advertising. Finally, it is possible to manage these pressures without altering the doctrine. In fact, there are tools in quality managed care that can strengthen the ability of physicians to function as true learned intermediaries.

c. Managed care.—Managed care has also been identified as a major impediment to quality interactions between physicians and patients. Managed care principles have been used in some insurance companies since the early 1900s, but they became more popular during World War II, obviously predating *Sterling v. Cornish*.[167] It really began to take off, however, in the early 1990s, as costs of medical care began to rise dramatically. The goal of managed care was to increase access to healthcare and to free patients (and their physicians) from limitations on coverage that were common to indemnity plans.[168] A focus on costs of care was necessary to increase access and coverage. Managed care therefore "provides a mechanism for focusing the attention of decision makers on aggregate outcomes, and creates incentives for controlling aggregate costs, managing quality, and improving the overall health outcomes of the covered population."[169] Some of the tools it uses to manage quality and cost include: "screening and certifying the credentials of providers, assembling data that can help providers better understand and compare the track record of different treatment protocols for different diagnoses, and creating financial incentives to encourage providers to follow recommended protocols."[170]

All of these methods interfere, "to some degree, in what had been a relatively autonomous and uncontrolled relationship between providers and patients."[171] The relevant question vis-à-vis the learned intermediary doctrine, of course, is what effect these practices have on physician judgment. Does managed care, generally, help physicians serve as a learned intermediary? Or, as critics claim, does it undercut their effectiveness so substantially that the doctrine should not apply unless the managed care arrangement is carefully scrutinized in each case? Another way of putting this is: should pharmaceutical manufacturers decline to

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167. Insurance companies using managed care and fee-for-service payment arose simultaneously, but fee-for-service was more popular until the 1980s. Health care costs rose so rapidly that payors (employers and the government) "began urgently searching for a better system." WOODSTOCK THEOLOGICAL CENTER, ETHICAL ISSUES IN MANAGED HEALTH CARE ORGANIZATIONS 13 (1999).

168. *Id.*

169. *Id.*

170. *Id.*

171. *Id.*

trust the physician's judgment when he or she participates in a managed care insurance plan?

There are two characteristics of managed care that are particularly objectionable to commentators. First, commentators perceive time pressures on physicians under managed care that were absent in fee-for-service payment arrangements.[172] Although not spelled out by the commentators, the argument would be that managed care caused a reduction in physician income, so physicians felt compelled to see more patients per day. Therefore, physicians reduced the time spent with each patient, leaving less time to discuss side effects and other possible adverse reactions to prescription drugs.

One could argue (convincingly) that time pressures exist under any system of payment. Physicians get paid according to the number of patients they see and the number of billable procedures they do. It is malpractice under any system of payment for physicians to sacrifice competent care to increase their incomes. It does not follow that pharmaceutical manufacturers should now be responsible for investigating the individual contexts of medical care to see if physicians are committing malpractice.

The second troubling characteristic of managed care is the "control over the doctor patient relationship by third party payors."[173] Physicians clearly dislike having the involvement of third parties in their medical decision making. Physician autonomy was nearly absolute in fee-for-service payment arrangements; they were reimbursed for whatever they did, without being second guessed by bureaucrats.[174]

Physician autonomy does not improve patient safety. Physicians like practicing without external controls, and patients believe that physician freedom correlates with quality care. In fact, there is good reason to think that physician practice improves under managed care arrangements. Physician autonomy, combined with solo practitioners or those who practice in small groups, leads to astounding variances in physician practice.[175] One study found that 135 physicians would suggest eighty-two different treatments for the same patient.[176] Even Hall, a critic of managed care, notes the quality concerns under an unregulated system. "[L]ack of oversight led to well-documented overutilization and widely divergent and scientifically unsupported practice patterns."[177] Oversight "reduce[s] the instance of unnecessary, and even harmful, medical interventions."[178] There is no data to support the notion that undertreatment is more troubling than overtreatment because "few patient injuries occur from too

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172. Hall, *supra* note 2, at 227.

173. *Id.*

174. *Id.* at 226.

175. GEORGE C. HALVORSON & GEORGE J. ISHAM, EPIDEMIC OF CARE: A CALL FOR SAFER, BETTER, AND MORE ACCOUNTABLE HEALTH CARE 25 (2003).

176. *Id.* at 24.

177. Timothy S. Hall, *Bargaining with Hippocrates: Managed Care and the Doctor-Patient Relationship*, 54 S.C. L. REV. 689, 693-94 (2003).

178. *Id.* at 694.

much care."[179] Therefore, physicians likely function better as learned intermediaries with limited, rather than full, professional autonomy. Consumer safety is best served by well-trained physicians with information available about new studies of drug safety and with oversight of practice patterns, so that a patient can be confident that his or her physician is not among the unsafe outliers in medical practice.

IV. DEFENSE OF THE TRADITIONAL APPLICATION OF THE LEARNED INTERMEDIARY DOCTRINE

The learned intermediary doctrine in its current form is the most efficient way to serve the goals of tort law and the goals of healthcare in general. Physician expertise relating to the effects of prescription pharmaceutical products on individual patients justifies the doctrine. Physicians are the best parties for pharmaceutical manufacturers to warn because they can understand the warnings and communicate information about risks tailored to each individual patient. This warning system is efficient and serves the tort law goal of minimizing accident avoidance costs. Despite the ability of pharmaceutical manufacturers to reach consumers with package inserts and direct-to-consumer advertising, it remains just as difficult (if not impossible) for pharmaceutical manufacturers to tailor warnings to individual patients as it was when the term "learned intermediary" was coined in 1966.[180]

Although the learned intermediary doctrine remains the best and most efficient way to warn patients of potential side effects of prescription drugs, more can be done to strengthen the expertise of physicians and further protect patients. Managed care, far from being the source of problems, can be used to improve care and guard against illicit influences on physician prescribing behaviors, both in terms of direct-to-consumer advertising and physician promotions.

CONCLUSION

Two basic arguments have been advanced in favor of abrogating or altering the learned intermediary doctrine. The first is that physicians are no longer needed to act as intermediaries because patients are empowered and educated. It is therefore a vestige of paternalism to allow pharmaceutical manufacturers to warn physicians instead of the users of prescription drugs. This argument fails because educated consumers still need learned intermediaries that can tailor medical information to each individual's unique medical history.

The second argument is that the environment of healthcare delivery has changed so substantially that physicians can no longer be trusted to act in their

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179. This is Calabro's claim, but she cites no studies to confirm this position, and it does not make common sense. Calabro, *supra* note 2, at 2267. If 200,000 Americans die from adverse drug reactions each year (the statistic she cites) or even if the more conservative "ballpark" estimate of 100,000 deaths is true (Noah, *supra* note 91, at 449), overprescribing is a very serious problem and will likely lead to adverse patient health outcomes.

180. Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966).

patients' best interests. This Note argues that calls for changing the learned intermediary doctrine are partly based on mistaken assumptions about the current healthcare environment. In particular, proponents of changing the learned intermediary doctrine tend to romanticize the doctor-patient relationship when the doctrine was adopted (circa 1966) and exaggerate pressures on physicians today. Physicians have always faced pressures of time constraints and financial conflicts of interest. Yet, the legal community (and society as a whole) has still expected them to exercise professional judgment. In addition, the effects of direct-to-consumer advertising have not been as pronounced as both critics and advocates had expected. It has had a modest impact on pharmaceutical sales, which tends to increase sales of therapeutic classes of drugs rather than at the level of specific brand-name prescriptions.[181]

Despite direct-to-consumer advertising, it remains true that the physician is in the best position to warn effectively the consumer about potential adverse effects of prescription drugs. It is untrue that managed care makes it impossible for physicians to act as learned intermediaries. Moreover, managed care in its best, modern form, can be a tremendous asset in providing quality healthcare, monitoring prescribing practices, and minimizing drug accidents in the first place. It should be seen as an ally, not an enemy, in physician judgment and patient health.

Opening up pharmaceutical manufacturers to additional liability for failure to warn does not change the fact that they cannot effectively warn individual patients and is unnecessary in light of the speculative data about both harms and benefits of direct-to-consumer advertising and managed care. If future studies demonstrate that direct-to-consumer advertising has become more effective and has subverted the physician's ability to exercise professional judgment, then this issue will need to be revisited. However, the important first step that healthcare delivery systems need to take is to strengthen the expertise of physicians so that they have all of the tools to function as experts on their patients' behalves.

181. Wosinska, *supra* note 137, at 2.