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Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine

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COMMENTS

LAYING AN OLD DOCTRINE TO REST: CHALLENGING THE WISDOM OF THE LEARNED INTERMEDIARY DOCTRINE

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I. INTRODUCTION

By conservative estimates, more than one million women have received silicone gel-filled breast implants.[1] Highly publicized hearings by the Food and Drug Administration (FDA) challenging the safety of implants[2], recent restrictions on the use of silicone gel-filled

1. The Department of Health and Human Services estimates that between 300,000 and one million women in the United States have breast implants. Laurie Jones, *FDA: Use Saline Implants or Enroll Patients in Silicone Trials*, 35 AM. MED. NEWS, May 4, 1992, at 2. *Cf.* Teich v. Food & Drug Admin., 751 F. Supp. 243, 245-46 (D.D.C. 1990) (estimating the number of silicone implant recipients at as high as two million). The Food and Drug Administration estimates that only 15% of these implants were undertaken for reconstructive purposes, while the other 85% were done for cosmetic reasons. *Id.*

2. The FDA initiated hearings about the safety of breast implants in the fall of 1991. In January 1992, the agency declared a moratorium on the manufacture, shipping, and use of silicone implants. Jones, *supra* note 1, at 3.

Although breast implants were first used more than 30 years ago, the FDA was

implants[3], and several multi-million dollar verdicts in breast implant actions[4] have provoked a rush to the courthouse.[5] Prior to this onslaught, some litigation concerning the product had been filed in the federal courts.[6]

Plaintiffs seeking recovery from breast implant manufacturers typically raise issues of breach of express and implied warranties, negli-

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not responsible for testing and approval because the product was developed before Congress amended the Food, Drug and Cosmetic Act to include medical devices. *See* 21 C.F.R. § 803 (1992).

When the FDA became responsible for medical devices in 1976, more than 960 types of high or medium risk machines or implants were being used in humans. Although the agency established safety and efficacy standards for new devices, it "grandfathered in" breast implants and other medical devices already on the market. Steven Finch, *Beyond Implants: What Else Haven't They Checked Out?*, HEALTH, July-Aug. 1992, at 74.

3. On April 16, 1992, the FDA limited access to silicone gel-filled breast implants. Silicone implants will continue to be available to women who require reconstruction following mastectomy or correction of a malformation. Women who desire breast implants for breast enlargement may have them inserted only under the auspices of a controlled clinical study. Update on Silicone Gel-Filled Breast Implants, FDA Letter, May 27, 1992. As of this writing, only one manufacturer, Mentor Corporation, has received FDA approval to begin clinical studies. *Id.*

4. *E.g.*, Toole v. McClintock, 778 F. Supp. 1543, 1550, 1553 (M.D. Ala. 1991) (finding breast implant manufacturer liable for $5.4 million; judgment subsequently reduced by remittitur to $2.3 million); Livshits v. Natural Y Surgical Specialties, No. 87-C2403, 1991 WL 261770, at *8, *11 (S.D.N.Y. November 27, 1991) (finding breast implant manufacturer liable for $1.5 million; lost wages and past pain and suffering awards set aside pending new trial); Hopkins v. Dow Corning, No. C-88-4703TEH (N.D. Calif., December 13, 1991) (finding breast implant manufacturer liable for $7.3 million). In December 1992, a Texas court awarded a record $25 million to a silicone breast implant recipient including $20 million in punitive damages, finding that the company had engaged in false or deceptive acts. Amy Singer, *Look Over Here*, AM. LAW., Mar. 1993, at 87.

5. As of September 13, 1993, 10,000 to 12,000 breast implant claims were pending in U.S. courts. 19 *The Gray Sheet* (FDC Reports, Inc.), Sept. 13, 1993, at 1.

6. *See, e.g.*, Knapp v. Dow Corning Corp., 941 F.2d 1336 (5th Cir. 1991); Klein v. Dow Corning Corp., 661 F.2d 998 (2d Cir. 1981); Toole v. McClintock, 778 F. Supp. 1543 (M.D. Ala. 1991); Lee v. Baxter Healthcare Corp., 721 F. Supp. 89 (D. Md. 1989), *aff'd*, 898 F.2d 144 (4th Cir. 1990); Desmarais v. Dow Corning Corp., 712 F. Supp. 13 (D. Conn. 1989).

The number of implant actions increased dramatically late in 1991 when Dow Corning Corporation, under order to comply with discovery, disclosed dozens of internal documents that previously were under court seal. These documents revealed that, as early as 1971, Dow possessed information that fluid and gel from breast implants could leak causing damage to surrounding tissue and that gel migrating from the breast could produce serious medical complications. Daniel Wise, *Bar Besieged with Queries on Breast Implant Claims*, N.Y.L.J., Jan. 30, 1992, at 1, 2.

As of September 13, 1993, Dow Corning was defending more than 6800 breast implant actions. Dick Lehr, *$4.75 Billion Accord Eyed on Breast Implants; Plaintiffs, Manufacturers Agree on Compensation Fund*, BOSTON GLOBE, Sept. 10, 1993, at 1.

gence, strict products liability, and failure to warn.[7] Among the issues that have barred recovery in breast implant cases is whether breast implant manufacturers owe a duty to warn patients directly or whether the manufacturer's duty is discharged by warning the physician or "learned intermediary."[8]

Almost as soon as the Eighth Circuit Court of Appeals first articulated the learned intermediary doctrine in 1966,[9] courts began limiting its effect by exempting claims arising from specific medical products.[10] By some curious lapse in the court's increasingly narrow application of the doctrine, breast implant actions eluded the judicial scrutiny that had exempted strikingly similar medical product actions.[11] Moreover, the courts have inconsistently applied the doctrine, leaving both the victims of defective medical products and the

7. *See generally* 2 MARDEN G. DIXON, DRUG PRODUCT LIABILITY § 9.08[4], at 9-67 (1990).

8. *See infra* part III.A.

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

10. *See* discussion *infra* parts III.B-D.

11. The learned intermediary doctrine barred plaintiff recovery in early breast implant actions. *See, e.g.*, Lee v. Baxter Healthcare Corp., 721 F. Supp. 89, 94-95 (D. Md. 1989), *aff'd*, 898 F.2d 144 (4th Cir. 1990); Desmarais v. Dow Corning Corp., 712 F. Supp. 13, 17-18 (D. Conn. 1989); Rosburg v. Minnesota Mining & Mfg. Co., 226 Cal. Rptr. 299, 305 (Ct. App. 1986); Perfetti v. McGhan Med., 662 P.2d 646, 650-51 (N.M. Ct. App. 1983). *See also* discussion *infra* part IV.A.

A turning point in breast implant litigation occurred in Stern v. Dow Corning Corp., No. C-83-2348-MMP (N.D. Cal. 1985), the first case that introduced evidence suggesting the defendant not only knew that silicone gel migrated but also that there was a relationship between silicone gel implants and autoimmune disease. Alison Frankel, *From Pioneers to Profits*, AM. LAW., June 1992, at 84. Prior breast implant cases involved judgments or settlements of $15,000 to $20,000. The *Stern* court, however, awarded the plaintiff $211,000 in compensatory damages and $1.5 million in punitive damages. *Id.* at 85.

In the wake of *Stern*, plaintiffs in breast implant actions against Dow Corning generally are not barred by the learned intermediary doctrine and may prevail on the grounds that the manufacturer failed to adequately warn the physician. Increasingly, juries are finding that the manufacturers acted with wanton disregard for breast implant recipients and are making large punitive damage awards. *See* Singer, *supra* note 4.

On September 9, 1993, Dow Corning announced a proposed $4.75 billion settlement that would compensate eligible silicone gel-filled breast implant recipients during a 30-year period. Gina Kolata, *Fund Proposed for Settling Suits Over Breast Implants*, N.Y. TIMES, Sept. 10, 1993, at 16. A plaintiff who is not satisfied with her settlement can reject it and sue for compensation and damages. *Id.*

Prior to exiting the breast implant industry, Dow Corning maintained only a 35% market share in the U.S. and a 40% market share worldwide. Telephone Interview with Ron Actis, Manager of External Communications, Dow Corning Corp. (April 21, 1993). It is likely, therefore, that the learned intermediary doctrine, as presently interpreted, will continue to play a role in breast implant actions against other manufacturers, as well as against manufacturers of other elective drugs and devices that similarly are promoted directly to consumers. *See* discussion *infra* part V.

products' manufacturers vulnerable in an inefficient and unpredictable tort liability system.[12]

This Comment examines judicial rulings that cast doubt on the continued vitality of the learned intermediary doctrine. Further, it suggests that, based on the rationale that the courts used to carve out exceptions for vaccines,[13] oral contraceptives,[14] and intrauterine devices (IUDs),[15] the learned intermediary doctrine is inapplicable to breast implant cases. This Comment encourages consideration of a new exception that would apply where manufacturers of elective drugs or devices promote their products directly to consumers and the consumer subsequently decides to use the drug or device without significant physician input.[16] Finally, this Comment examines changes in regulation and litigation since the creation of the learned intermediary defense and concludes that, wherever possible, the law should require that manufacturers of drugs and devices warn the patient directly.[17]

II. Strict Liability and Medical Products

Generally, the manufacturer of a defective product that is unreasonably dangerous is liable for any harm caused by the product regardless of whether the manufacturer acted with negligence.[18] A product can be defective due to an imperfect design, a flaw that was present at the time the defendant sold the product, or the manufac-

12. *Compare* Hill v. Searle Lab., 884 F.2d 1064, 1071 (8th Cir. 1989) (holding that manufacturer of IUD device owes duty to directly warn patients of inherent dangers) *with* Terhune v. A.H. Robins Co., 577 P.2d 975, 979 (Wash. 1978) (holding that, under the learned doctrine, manufacturer of IUD owes no duty to directly warn patients of inherent dangers).

13. *See* discussion *infra* part III.B.

14. *See* discussion *infra* part III.C.

15. *See* discussion *infra* part III.D.

16. *See* discussion *infra* part V.

17. *See* discussion *infra* part VI.

18. Restatement (Second) of Torts § 402A states the law of strict liability as follows:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
>
> (a) the seller is engaged in the business of selling such a product, and
>
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
>
> (2) The rule stated [above] applies although
>
> (a) the seller has exercised all possible care in the preparation and sale of his product, and
>
> (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Restatement (Second) Torts § 402A (1965).

turer's failure to adequately warn of risks inherent in the product.[19] Tort law recognizes, however, that some hazardous products offer social benefit or utility that outweighs their inherent dangers.[20]

Comment k of the *Restatement (Second) of Torts*, section 402A, relieves the manufacturers of these "unavoidably unsafe" products from strict liability for any injury resulting from their use if the products are properly manufactured and accompanied by adequate directions and warnings of the product's inherent dangers.[21] Accordingly, the manufacturer of any product it knows or should know is dangerous is held to an unequivocal duty to warn the consumer of its inherent or potential hazards and adverse effects.

Prescription drugs and devices are principal examples of unavoidably unsafe products.[22] Thus, one would expect that a duty to warn the patient would arise on the part of the drug or device manufacturer. Indeed, warnings are routinely provided to consumers of nonprescription, over-the-counter drugs.[23] The courts, however, have created an exception for the manufacturers of prescription drugs and devices, limiting the duty to warn not to the foreseeable user of the product or patient, but rather to the prescribing physician who acts as a "learned intermediary."[24]

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19. *See, e.g.*, W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 99, at 695 (5th ed. 1984) (stating that "[i]n strict liability . . . the product must be defective in the kind of way that subjects persons or tangible property to an unreasonable risk of harm.").

20. The RESTATEMENT (SECOND) OF TORTS defines "unavoidably unsafe" products as follows:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician.

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

21. *Id.* The exception does not apply to products that contain a manufacturing flaw or an inadequate warning but only where the plaintiff alleges a design defect. *See also* Toner v. Lederle Lab., 732 P.2d 297, 305-09 (Idaho 1987), *cert. denied*, 485 U.S. 942 (1988); Savina v. Sterling Drug, Inc., 795 P.2d 915, 925 (Kan. 1990).

22. *See supra* note 20.

23. *See, e.g.*, Torsiello v. Whitehall Lab., 398 A.2d 132, 139-40 (N.J. Super. Ct. App. Div. 1979) (finding liability for failure to warn of risk of gastrointestinal hemorrhaging where plaintiff took eight Anacin tablets daily for relief of arthritis pain).

24. *See generally* Margaret Gilhooley, *Learned Intermediaries, Prescription Drugs, and Patient Information*, 30 ST. LOUIS U. L.J. 633 (1986).

III. Learned Intermediary Doctrine

A. Development and Early Cases

Under the learned intermediary doctrine, the manufacturer of prescription or ethical[25] drugs is exculpated from what would otherwise be a breach of the duty to warn. This exception applies only where adequate information about a drug's related effects is furnished by the manufacturer to prescribing physicians.[26]

The learned intermediary doctrine was originally conceived in the case of *Marcus v. Specific Pharmaceuticals, Inc.*[27] *Marcus* involved a young child whose death resulted from an overdose of suppositories administered as prescribed by a physician.[28] The only product information supplied by the manufacturer was through advertisements in medical journals. These advertisements failed to include information on the proper dosage for infants.[29] The *Marcus* court granted the defendant's motion to dismiss, holding that a drug manufacturer could not be found negligent for failure to warn the ultimate consumer of a product that was available only by a physician's prescription.[30]

The California Court of Appeals maintained this position in *Love v.*

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25. "Ethical drugs" are medications that, by statute, can be dispensed only by a physician or with a physician's prescription, as distinguished from those which may be sold over the counter. *See* 21 U.S.C. § 353(b) (1988).

26. *See* Reyes v. Wyeth Lab., 498 F.2d 1264, 1276 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974). The *Reyes* court explained the prescription drug manufacturer's duty as follows:

> [W]here *prescription* drugs are concerned, the manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use. . . . Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medications against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.

Id. See also Mauldin v. Upjohn Co., 697 F.2d 644, 647 (5th Cir.), *cert. denied*, 464 U.S. 848 (1983) (holding that the manufacturer of antibiotics was not required to warn patient directly where physician was adequately warned); Dyer v. Best Pharmacal, 577 P.2d 1084, 1088 (Ariz. 1978) (holding that manufacturer of anorexiant pharmaceutical was under duty to warn the physician only); McKee v. Moore, 648 P.2d 21, 24 (Okla. 1982) (holding that IUD manufacturer was required to warn physician only); KEETON ET AL., *supra* note 19, § 96, at 688.

27. 77 N.Y.S.2d 508 (App. Div. 1948).

28. *Id.* at 509.

29. *Id.*

30. The *Marcus* court noted that "[t]here is no reason to believe that a physician would care to disregard his own knowledge of the effects of drugs and hence of the quantity to be administered, and substitute for his own judgment that of a drug manufacturer." *Id.* at 510.

Wolf,[31] where it held that the manufacturer of an antibiotic medication had no duty to warn the patient directly.[32] Rather, the court concluded, its common law duty to warn could be satisfied by providing adequate warning to either the physician *or* the patient.[33] This judicial reluctance to impose on manufacturers a direct duty to warn the patient ultimately evolved into the learned intermediary doctrine.

The term "learned intermediary" was first coined by Judge McManus writing for the Eighth Circuit Court of Appeals, in *Sterling Drug, Inc. v. Cornish*,[34] to describe the physician as a liaison between patient and drug manufacturer. The *Cornish* court, in considering whether the drug manufacturer had a duty to warn of newly-discovered side effects of an anti-arthritis medication, unequivocally held that the drug manufacturer did have a duty to warn the prescribing physician.[35]

Although the court's consideration of the learned intermediary rule comprised only one paragraph of its opinion, the phrase set a commanding precedent for subsequent rulings that a drug manufacturer had a duty to warn only the physician. From this relatively inauspicious inception, the doctrine of the learned intermediary emerged as an accepted tort principle that has been invoked either directly or indirectly in nearly every case where a plaintiff brought a warning-related action against a prescription drug manufacturer.[36]

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31. 38 Cal. Rptr. 183 (Ct. App. 1964).

32. *Id.* at 193.

33. *Id.* The court wrote:

> In the case of a drug it has been held there is a duty to exercise reasonable care to warn of potential dangers from use even though the percentage of users who will be injured is not large. But if adequate warning of potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to insure that the warning reaches the doctor's patient for whom the drug is prescribed.

Id. (citations omitted).

34. 370 F.2d 82 (8th Cir. 1966).

35. *Id.* at 85. The court described the patient-physician relationship as follows:

> [W]e are dealing with a prescription drug rather than a normal consumer item. In such a case 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. This is particularly true if the injury takes place slowly . . . .

Id.

36. *See, e.g.*, Anderson v. McNeilab, Inc., 831 F.2d 92, 93 (5th Cir. 1987) (applying Louisiana law) (Zomax); Beyette v. Ortho Pharm. Corp., 823 F.2d 990, 992 (6th Cir. 1987) (applying Michigan Law) (IUD); Kirsch v. Picker Int'l Inc., 753 F.2d 670, 671 (8th Cir.), *reh'g denied en banc*, 760 F.2d 183 (1985) (applying Missouri law) (radiation therapy); Stanback v. Parke Davis & Co., 657 F.2d 642, 644 (4th Cir. 1981) (applying Virginia law) (influenza vaccine); Brochu v. Ortho Pharm. Corp., 642 F.2d 652, 656 (1st Cir. 1981) (applying New Hampshire law) (oral contraceptives); Timm

The doctrine was significantly broadened in *Buckner v. Allergan Pharmaceuticals, Inc.*,[37] when Florida's Fifth District Court of Appeals ruled that the manufacturer has no duty to warn the patient even where the manufacturer is aware that the medical community is not warning the patient of known adverse effects associated with the use of a drug.[38] In dismissing the claim against the manufacturer, the court reasoned that because "physicians do not have an absolute duty to inform patients of all possible side effects in every instance, failure to do so in a particular instance should not give rise to a duty in the manufacturer."[39]

The modern rule states that the ethical drug manufacturer has a duty to adequately warn only the physician of the risks associated with the use of a prescription drug. This rule has been interpreted to encompass all physicians who may be involved with the patient in a "decision-making capacity."[40] A warning to the physician is adequate if it clearly discloses any risks or contraindications the manufacturer knows or should know are associated with the use of the drug.[41] The duty to warn is continuous, and the manufacturer is ob-

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v. Upjohn Co., 624 F.2d 536, 538 (5th Cir. 1980) (applying Louisiana law) (antibiotic cleocin), *cert. denied*, 449 U.S. 1112 (1981); Givens v. Lederle, 556 F.2d 1341, 1345 (5th Cir. 1977) (applying Florida law) (oral polio vaccine); Hoffman v. Sterling Drug, Inc., 485 F.2d 132, 142 (3d Cir. 1973) (applying Pennsylvania law) (chloroquine phosphate); Basko v. Sterling Drug, Inc., 416 F.2d 417, 426 (2d Cir. 1969) (applying Connecticut law) (chloroquine); Fellows v. USV Pharm. Corp., 502 F. Supp. 297, 299 (D. Md. 1980) (doriden); Goodson v. Searle Lab., Inc., 471 F. Supp. 546, 548 (D. Conn. 1978) (oral contraceptives); Dunkin v. Syntex Lab., Inc., 443 F. Supp. 121, 123 (W.D. Tenn. 1977) (oral contraceptives); Chambers v. G.D. Searle & Co., 441 F. Supp. 377, 381 (D. Md. 1975), *aff'd*, 567 F.2d 269 (4th Cir. 1977) (oral contraceptives).

37. 400 So. 2d 820 (Fla. Dist. Ct. App.), *review denied*, 407 So. 2d 1102 (Fla. 1981).

38. *Id.* at 823-24.

39. *Id.* at 824.

40. McEwen v. Ortho Pharm. Corp., 528 P.2d 522, 529 (Or. 1974). In *McEwen*, the court reasoned that, "[i]f the prescribing physician is entitled to make an informed choice in deciding whether the patient should begin taking a prescription drug, it follows that a treating physician should have the same information in making his decision as to whether the patient should stop taking that drug." *Id. Cf.* Lindsay v. Ortho Pharm. Corp., 637 F.2d 87, 91 (2d Cir. 1980) (holding that the manufacturer owes a duty only to adequately warn the plaintiff's physician).

41. *See* Chambers v. G.D. Searle & Co., 441 F. Supp. 377, 381 (D. Md. 1975), *aff'd*, 567 F.2d 269 (4th Cir. 1977). There is split authority as to whether the adequacy of the warning is a question of fact to be determined at trial or whether it is a question of law. *Compare* Baker v. St. Agnes Hosp., 421 N.Y.S.2d 81, 86 (Sup. Ct. 1980) (upholding decision that the adequacy of warnings is a question of fact to be determined by the trial court) *with* Pierluisi v. E.R. Squibb & Sons, Inc., 440 F. Supp. 691, 694 (D.P.R. 1977) (finding warning by manufacturer sufficient as a matter of law if it is "sufficient to appraise [sic] a general practitioner as well as the 'unusually sophisticated medical man' of the dangers of the drug") (citing Park Davis & Co. v. Stromsodt, 411 F.2d 1390, 1440 (8th Cir. 1990)).

ligated to notify the medical profession of adverse effects subsequently discovered.[42] Moreover, the ethical drug manufacturer is directly liable to a patient for a breach of its duty to adequately warn the physician.[43]

Although the learned intermediary doctrine initially was limited to prescription drugs, it has since been extended to medical device cases.[44] The Seventh Circuit, in *Phelps v. Sherwood Medical Industries*,[45] rejected the plaintiff's argument that medical devices should be treated differently from prescription drugs. Finding "no principled basis" for a distinction between prescription drugs and prescription devices, the court held that the learned intermediary exception has equal application to those cases concerning medical devices.[46]

B. Early Erosion of the Doctrine: The Vaccine Exception

Only two years after the Eighth Circuit first articulated the phrase "learned intermediary,"[47] the Ninth Circuit Court of Appeals carved out the doctrine's first major exception.[48] In *Davis v. Wyeth Laboratories*,[49] the plaintiff contracted polio as a result of vaccination at a mass immunization clinic.[50] Although the manufacturer had supplied instructions and warnings to officials of the immunization program, neither the manufacturer nor the physicians operating the clinic provided information about potential adverse effects to the actual administrators of the vaccine or to those who received the vaccine.[51]

Because the vaccine was administered to all who requested it with-

42. Lindsay v. Ortho Pharm. Corp., 637 F.2d 85, 91 (2d Cir. 1980); *accord* Stanback v. Parke, Davis & Co., 502 F. Supp. 767, 770 (W.D. Va. 1980); *McEwen*, 528 P.2d at 528.

43. Schenebeck v. Sterling Drug, Inc., 423 F.2d 919, 923 (8th Cir. 1970); *McEwen*, 528 P.2d at 529.

44. A medical device is defined as any instrument, implant, or other article recognized by the National Formulary or the United States Pharmacopeia and designed to cure disease by affecting a patient's physical structure or bodily function without relying principally on some type of chemical action. 21 U.S.C. § 321(h) (1988). Medical devices, like prescription drugs, are obtainable only through the services of a physician. *See also* McPheron v. Searle Lab., Inc., 888 F.2d 296 (7th Cir. 1987) (holding manufacturer of IUD had no duty to warn consumer directly); Phelps v. Sherwood Medical Indus., 836 F.2d 296 (7th Cir. 1987) (holding manufacturer of heart catheter had no duty to warn patient directly); Brooks v. Medtronic, Inc., 750 F.2d 1227 (4th Cir. 1984) (holding manufacturer of cardiac pacemaker fulfilled its duty by warning physician).

45. 836 F.2d 296 (7th Cir. 1987).

46. *Id.* at 303.

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

48. Davis v. Wyeth Lab., 399 F.2d 121 (9th Cir. 1968), *cert. denied*, 419 U.S. 1096 (1974).

49. 399 F.2d 121 (9th Cir. 1968), *cert. denied*, 419 U.S. 1096 (1974).

50. *Id.* at 122.

51. *Id.* at 125.

out any patient-by-patient assessment by a physician, the court found the immunization process to be analogous to the sale of over-the-counter nonprescription drugs.[52] The court ruled that, because of the particular circumstances surrounding mass immunization programs, the learned intermediary doctrine was clearly inapplicable. Thus the Ninth Circuit revitalized the common law duty to warn the consumer directly.[53]

Six years later, the learned intermediary doctrine was again invalidated by the Fifth Circuit in *Reyes v. Wyeth Laboratories*.[54] Like *Davis*, the injured party in *Reyes* contracted polio after receiving the defendant's vaccine at a health clinic.[55] Although the manufacturer provided an advisory warning to physicians, hospitals, and other purchasers of the dangers associated with the vaccine, the consent form signed by the patient's mother contained "no warning of any sort."[56]

The *Reyes* court acknowledged the learned intermediary rule[57] but relied on *Davis* and imposed a duty to warn the consumer directly when the manufacturer's product is "dispensed without the sort of individualized medical balancing of the risks of the vaccinee that is contemplated by the prescription drug exception."[58]

Subsequent cases have expanded the exception, finding the learned intermediary doctrine inapplicable in immunization cases even when the vaccine was given in a physician's office rather than in a mass setting.[59] The doctrine was further restricted in its application to immunizations until the determinative factor became "whether the drug [was] commonly administered without individualized balancing by a physician of the risks involved and the individual's needs and circumstances."[60] It was only a matter of time

52. *Id.* at 131.

53. *Id.* at 130. Specifically, the *Davis* court said:

> [A]lthough the [polio vaccine] was denominated as a prescription drug it was not dispensed as such. It was dispensed to all comers . . . (as in the case of over-the-counter sales of nonprescription drugs) . . . .

Id. at 131.

54. 498 F.2d 1264 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096 (1974).

55. *Id.* at 1270.

56. *Id.*

57. *Id.* at 1276.

58. *Id.* at 1276-77.

59. *See, e.g.*, Givens v. Lederle, 556 F.2d 1341, 1345 (5th Cir. 1977) (holding that because vaccine was administered in clinic similar to the one in *Reyes* the manufacturer had duty to warn consumer directly). *But see* Walker v. Merck & Co., 648 F. Supp. 931, 934 (M.D. Ga. 1986) (denying recovery for blindness attributed to mass administration of measles-mumps-rubella vaccine because the *Davis-Reyes-Givens* line of decisions narrowly apply to polio cases only).

60. Williams v. Lederle Lab., 591 F. Supp. 381, 389 (S.D. Ohio 1984). With the enactment of the National Childhood Vaccine Injury Act in 1986, a no-fault compen-

before this test would be applied to prescription drugs outside the class of immunizations.

C. *Further Erosion: The Oral Contraceptive Exception*

Almost two decades elapsed following the *Davis* court's initial narrowing of the learned intermediary doctrine before the next opportunity for erosion emerged. In the wake of FDA hearings on the use and hazards of birth control pills,[61] several oral contraceptive users filed suit for injuries associated with taking the pill.[62] In the majority of cases, courts applied the learned intermediary doctrine and found no liability on the part of defendants where the manufacturers had adequately warned the physician, either directly or indirectly.[63] At issue in these cases was the adequacy of the warning given, not to whom the warning was owed.[64]

In 1985, a body of case law developed that completely disregarded the doctrine of the learned intermediary in the area of oral contraceptives and imposed a duty on the manufacturer to warn the ultimate consumer, the patient, directly.[65]

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sation system, manufacturers no longer have a duty to directly warn consumers of potential adverse effects from vaccines. 42 U.S.C. §§ 300aa-10 to -34 (1988).

61. In 1970, the FDA mandated that warnings about birth control pills be provided directly to patients, giving rise to the question of whether a private cause of action accrues to the patient when such warnings are not given. *See Hearings on Present Status of Competition in the Pharmaceutical Industry Before the Subcomm. on Monopoly of the Senate Comm. on Small Business*, 91st Cong., 2d Sess. 6787 (1970). The court addressed this question in Lukaszewicz v. Ortho Pharm. Corp., 510 F. Supp. 961 (E.D. Wis. 1981), and held that the FDA regulations created a duty to warn the patient. *Id.* at 965. Although the *Lukaszewicz* ruling seems to introduce another exception to the learned intermediary doctrine, the court merely relied on an alternative theory—violation of a federal regulation—for recovery. The *Lukaszewicz* court never addressed the learned intermediary doctrine. *Id.*

62. *E.g.*, Brochu v. Ortho Pharm. Corp., 642 F.2d 652 (1st Cir. 1981); Lindsay v. Ortho Pharm. Corp., 637 F.2d 87 (2d Cir. 1980); Skill v. Martinez, 91 F.R.D. 498 (D.N.J. 1981), *aff'd*, 677 F.2d 368 (3d Cir. 1982); Goodson v. Searle Lab., 471 F. Supp. 546 (D. Conn. 1978); Dunkin v. Syntex Lab., 443 F. Supp. 121 (W.D. Tenn. 1977); Chambers v. G.D. Searles & Co., 441 F. Supp. 377 (D. Md. 1975), *aff'd*, 567 F.2d 269 (4th Cir. 1977); Hamilton v. Hardy, 549 P.2d 1099 (Colo. Ct. App. 1976); Mahr v. G.D. Searle & Co., 390 N.E.2d 1214 (Ill. App. Ct. 1979); Ortho Pharm. Corp. v. Chapman, 388 N.E.2d 541 (Ind. Ct. App. 1979); Cobb v. Syntex Lab., 444 So. 2d 203 (La. Ct. App. 1983); Leibowitz v. Ortho Pharm. Corp., 307 A.2d 449 (Pa. Super. Ct. 1973).

63. See cases cited *supra* note 62. *But see Lukaszewicz*, 510 F. Supp. at 965 (holding that manufacturer had a duty to warn patient directly but compliance with FDA regulations would satisfy such duty).

64. *But see* McEwen v. Ortho Pharm. Corp., 528 P.2d 522, 529 (Or. 1974) (recognizing the learned intermediary doctrine but extending the duty to warn to encompass treating physicians as well as prescribing physicians).

65. Odgers v. Ortho Pharm. Corp., 609 F. Supp. 867 (E.D. Mich. 1985); Ste-

In *MacDonald v. Ortho Pharmaceutical Corp.*,[66] the plaintiff's use of oral contraceptives allegedly resulted in a stroke. The Massachusetts Supreme Court abandoned the learned intermediary doctrine, contending that oral contraceptives usually are not taken out of medical necessity; rather, oral contraceptives are drugs personally selected by the patient from among other available birth control options.[67] A prescription for oral contraceptives, therefore, is not the result of a physician's skilled balancing of individual benefits and risks but originates instead as a product of patient demand.[68]

At the same time that *MacDonald* was proceeding through the Massachusetts court system, two similar actions were filed in the federal district court of Michigan. In *Odgers v. Ortho Pharmaceutical Corp.*,[69] the plaintiff received a prescription for oral contraceptives only after examination by her physician and receipt of a warning pamphlet prepared by the manufacturer.[70] The birth control pills allegedly caused a blood clot that resulted in the plaintiff's partial paralysis.[71]

Following a verdict for the plaintiff, the trial court granted the defendants' motion for a new trial and certified a question to the Michigan Supreme Court.[72] The central question was whether the manufacturer had a duty to warn the patient directly.[73] In a four to three decision, the court declined to decide the question,[74] holding that to judicially determine the scope of Ortho's duty to warn would

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phens v. G.D. Searle & Co., 602 F. Supp. 379 (E.D. Mich. 1985); MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65 (Mass.), *cert. denied*, 474 U.S. 920 (1985).

66. 475 N.E.2d 65 (Mass. 1985).

67. *Id.* at 69.

68. *Id.* The *MacDonald* court also cited FDA regulations mandating patient labeling of oral contraceptives to support the imposition of a common law duty to warn. *Id.* at 69-70 (citing 21 C.F.R. § 310.501 and 21 C.F.R. § 130.45 for the FDA's rationale for patient labeling). The FDA considered direct patient warnings necessary because use of oral contraceptives is "too complex to expect the patient to remember everything told her by the physician," thus patients need information "in an organized comprehensive, understandable, and handy-for-future-reference form." 35 Fed. Reg. 9002 (1970).

69. 609 F. Supp. 867 (E.D. Mich. 1985).

70. *Id.*

71. *Id.* at 868.

72. The defendant moved for a new trial arguing that the jury had been improperly instructed on the scope of Ortho's duty to warn. Specifically, the trial judge instructed the jury that "Ortho owed [the plaintiff] the duty of reasonable care in the preparation of the booklet accompanying the drug that, under federal regulations, Ortho was required to distribute to physicians." *In re* Certified Questions, 358 N.W.2d 873, 873 (Mich. 1984).

73. *Id.*

74. The majority maintained that to render any decision on the issue of Ortho's duty would require a choice between different systems for allocating between manufacturers, physicians, and pharmacists the duty to warn patients of the risks and potential side effects associated with the use of prescription drugs. *Id.* at 877. "[A]ny decision of this Court implicates the obligations of members of professions who are

be to assume a function best left to state legislative bodies.[75]

Three dissenting justices, however, suffered no similar reluctance in imposing a duty on Ortho to warn the users of oral contraceptives directly.[76] Focusing on the nontherapeutic purpose of oral contraceptives, the dissent noted the absence of any of the arguments commonly used to justify the learned intermediary exception to the common law duty to warn.[77] The dissent distinguished oral contraceptive users from other prescription drug users, noting that the former generally do not rely on their physician's diagnostic and treatment skills but decide independently to use the pill.[78]

Moreover, the *In re Certified Questions* minority, like the *MacDonald* court, noted that oral contraceptives are frequently prescribed for extended periods of time without ongoing examination and evaluation by the physician.[79] Thus, the intended goal of the learned intermediary doctrine, reducing patient injuries through physician monitoring,[80] does not apply in the context of oral contraceptives.[81]

The majority opinion in *In re Certified Questions* left the federal judge in *Odgers v. Ortho Pharmaceutical Corp.* without any definitive ruling on an oral contraceptive manufacturer's duty to warn under Michigan law.[82] The *Odgers* court ultimately inferred from the Michigan Supreme Court's reluctance to apply the learned intermediary doctrine to oral contraceptives that Ortho had a duty to warn the consumer directly where oral contraceptives are prescribed for nontherapeutic purposes.[83]

The second Michigan federal case, *Stephens v. G.D. Searle & Co.*,[84] was decided after the ruling in *In re Certified Questions* but before *Odgers*. The *Stephens* court relied heavily on the dissenting opinion of *In re Certified Questions* to impose a duty to warn the consumer directly

involved in the distribution of prescription drugs but not represented in these proceedings." *Id.*

75. Specifically, the majority noted that "the allocation of the duty to warn patients is a public policy question involving the marketing system and economics of a major industry and the everyday practice of an essential profession. We believe that the Legislature is in a better position to allocate those duties." *Id.* at 874.

76. *Id.* at 886 (Boyle, J., dissenting).

77. *In re* Certified Questions, 358 N.W.2d 873, 884-85 (Mich. 1984) (Boyle, J., dissenting).

78. *Id.* at 884. The dissent specifically stated that "[p]atient choice plays a much more prominent role [in oral contraceptive use] than in the case of drugs prescribed for the treatment of illness or injury. The role of patient choice in this process supports the need for a direct patient warning." *Id.*

79. *Id.* at 885.

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

81. *In re* Certified Questions, 358 N.W.2d at 885.

82. Odgers v. Ortho Pharm. Corp., 609 F. Supp. 867, 878 (E.D. Mich. 1985).

83. *Id.*

84. 602 F. Supp. 379 (E.D. Mich. 1985).

on the manufacturer when its product had been used solely for contraceptive purposes.[85]

In all three cases, the learned intermediary doctrine was found inapplicable in the distribution of oral contraceptives, at least in cases where oral contraceptives were used exclusively for nontherapeutic purposes. Despite the colorable distinction between nontherapeutic oral contraceptives and other prescription drugs, this exception to the learned intermediary doctrine is not universally accepted.[86]

D. The Last Challenge: The Intrauterine Device Exception

The Eighth Circuit, which first articulated the concept of the learned intermediary, later delivered a significant blow to the doctrine by exempting IUDs. In *Hill v. Searle Laboratories,*[87] the plaintiff was implanted with a copper IUD (CU-7) after consultation and examination by her personal physician.[88] Three years later, it was discovered that the device had penetrated her uterus, was embedded in her small intestine, and required surgical removal.[89] In her action against Searle Laboratories, the plaintiff alleged that the IUD was manufactured and designed defectively and that the defendant had failed to adequately warn her of the risk of perforation associated with use of the device.[90]

The district court ruled that the CU-7 was a prescription drug falling within the ambit of comment k of the *Restatement (Second) of Torts* section 402A.[91] The court noted that all prescription drugs fell within the scope of comment k and were thus entitled to be insulated from a strict liability claim.[92] Moreover, the court held that, under the learned intermediary doctrine, the drug manufacturer had a duty to warn only the physician of its product's inherent dangers.[93] Because Searle had provided Mrs. Hill's physician with adequate warnings, she was barred from recovery.[94]

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85. *Id.* at 381.

86. *See, e.g.*, Taurino v. Ellen, 579 A.2d 925 (Pa. Super. Ct. 1990) (applying the learned intermediary doctrine in an action involving oral contraceptives despite the fact that the pills were dispensed by a clinic worker, not a physician); *see also* MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 68 n.9 (Mass.) (listing cases from 14 states where the court applied the learned intermediary doctrine to the distribution of oral contraceptives), *cert. denied*, 474 U.S. 920 (1985).

87. 884 F.2d 1064 (8th Cir. 1989).

88. *Id.* at 1065.

89. *Id.*

90. Hill v. Searle Lab., 686 F. Supp. 720, 721 (E.D. Ark. 1988), *aff'd in part and rev'd in part*, 884 F.2d 1064 (8th Cir. 1989).

91. *Id.* at 725.

92. *Id.*

93. *Id.*

94. *Id.* at 727.

Judge Heaney, writing for the Eighth Circuit Court of Appeals, rejected the learned intermediary doctrine and reversed the district court's decision.[95] In its interpretation of Arkansas products liability law, the court of appeals predicted that, if faced with the issue of determining the adequacy of warnings, the Arkansas Supreme Court would adopt the test articulated in *Reyes* which requires "*either* a warning . . . *or* an individualized medical judgment that this treatment or medication is necessary and desirable. . . ."[96] Consistent with a literal reading of *Reyes*, the Eighth Circuit held that IUD patients failed to receive individual medical judgment on the appropriateness of the IUD and hence were entitled to direct warnings from the manufacturer.[97]

Additional support for rejecting the learned intermediary doctrine in IUD actions is found in the Eighth Circuit's determination that IUDs were comparable to oral contraceptives.[98] First, the court acknowledged that decisions about birth control generally were made with minimal involvement of the physician.[99] Second, the defendant manufacturer marketed the IUD directly to consumers.[100] Third, there was no ongoing relationship between the physician and patient after the IUD is inserted.[101] Finally, providing warnings directly to the patient was feasible in light of FDA regulations requiring patient package inserts.[102] The court concluded that the patient makes the final choice regarding IUD use and thus must be provided with direct warnings to allow her to make a conscious and informed decision.[103]

Although the *Hill* court analogized IUDs to oral contraceptives and relied on the reasoning of *Odgers*, *Stephens*, and *McDonald* to ex-

95. *Hill*, 884 F.2d at 1071. The Eighth Circuit also rejected the lower court's unqualified application of comment k to all prescription drug products. In dictum, the court reasoned that comment k should be interpreted as an affirmative defense and that its protection from strict liability for drug manufacturers required evidence of exceptional social need for the product. *Id.* at 1068-70.

96. Virginia H. Castleberry, *Hill v. Searle Laboratories: The Decline of the Learned Intermediary Doctrine in Favor of Direct Patient Warnings of Drug Product Risks*, 43 ARK. L. REV. 821, 841-42 (1990) (quoting Reyes v. Wyeth Lab., 498 F.2d 1264, 1295 (5th Cir. 1974)).

Only three years later, the Arkansas Supreme Court rejected the *Hill* court's exemption of contraceptives from the learned intermediary doctrine. In West v. Searle & Co., 806 S.W.2d 608 (Ark. 1991), the court applied the doctrine to oral contraceptives, reasoning that it was impossible for the manufacturer to warn the patient directly and that to do so would interfere with the physician-patient relationship. *Id.*

97. Hill v. Searle Lab., 884 F.2d 1064, 1070-71 (8th Cir. 1989).

98. Castleberry, *supra* note 96, at 842.

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

100. *Id.*

101. *Id.*

102. *Id.* IUDs must be accompanied by appropriate patient labeling. 21 C.F.R. § 310.502(b)(2) (1992).

103. Castleberry, *supra* note 96, at 842.

empt IUD-related injuries from the learned intermediary defense, other courts have consistently held that these decisions should not apply to cases involving IUDs.[104]

At the same time the Eighth Circuit was hearing *Hill*, the United States District Court in Oregon was considering another case involving Searle's CU-7 IUD.[105] In *Allen v. G.D. Searle & Co.*, the court distinguished *Reyes* on the grounds that IUD insertion required an individualized medical judgment that did not exist in a mass immunization setting.[106] Reasoning that, in the IUD context, the physician performed a balancing of the benefits and risks of IUD use for the patient before prescribing the device, the court held that the learned intermediary doctrine applied with full force.[107]

In *Lacy v. G.D. Searle & Co.*,[108] the Delaware Supreme Court ruled that the oral contraceptive exception could not be applied to IUD cases because, unlike oral contraceptives, IUDs must not only be prescribed by the physician but actually inserted by the physician.[109] Courts confronted with IUD actions also have rejected the *Hill* court's argument that the patient, not the physician, makes the final choice on the use of an IUD. Most courts have found that the degree of patient involvement may indeed be greater in the choice of contraceptives than in other prescription drugs but that the physician makes the ultimate decision as to whether a particular contraceptive requested by the patient is appropriate.[110]

Although *Hill* represents a minority view, it raises the question of

104. Most of these courts have concluded that IUDs are unavoidably unsafe products within the meaning of comment k, so the learned intermediary doctrine applies. *See, e.g.*, McPheron v. Searle Labs., Inc., 888 F.2d 31, 34 (5th Cir. 1989); Allen v. G.D. Searle & Co., 708 F. Supp. 1142, 1147-48 (D. Or. 1989); Spychala v. G.D. Searle & Co., 705 F. Supp. 1024, 1031-32 (D.N.J. 1988); Lacy v. G.D. Searle & Co., 1988 WL 67825 (Del. Super. June 22, 1988); Dupre v. G.D. Searle & Co., Prod. Liab. Rep. (CCH) ¶ 11,426 (D.N.H. 1987); McKee v. Moore, 648 P.2d 21, 23-25 (Okla. 1982); Terhune v. A.H. Robins Co., 577 P.2d 975, 977-79 (Wash. 1978) (en banc). *But see* Kociemba v. G.D. Searle & Co., 680 F. Supp. 1293, 1300-01 (D. Minn. 1988) (holding that the question of whether a prescription medical device is an unavoidably unsafe product entitled to comment k protection is a question of fact for the jury).

105. Allen v. G.D. Searle & Co., 708 F. Supp. 1142 (D. Or. 1989).

106. *Id.* at 1147-48.

107. *Id.* at 1148.

108. 567 A.2d 398 (Del. 1989).

109. The *Lacy* court stated:

> The rationale supporting the learned intermediary doctrine is even stronger when applied to the IUD, as opposed to an oral contraceptive, because 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.

Id. at 401.

110. 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); Terhune v. A.H. Robins Co., 577 P.2d 975, 978 (Wash. 1978) (en banc).

whether the Eighth Circuit opinion is an anomaly or whether it suggests expansion of a drug or device manufacturer's duty to warn patients directly. A comparison of the rationale behind the learned intermediary defense and the reasoning on which each exception was based is useful as a framework for evaluating the likelihood of further erosion of the learned intermediary doctrine as it applies to breast implants as well as to other prescription drugs and devices.

E. Unraveling the Doctrine's Intent

1. Rationale for the Learned Intermediary Doctrine

Commentators have justified the learned intermediary doctrine by arguing that warnings directed to patients are "unnecessary, impractical and unwise."[111] Further, Justice Wisdom effectively articulated the doctrine's rationale in *Reyes v. Wyeth Laboratories*:

> This special standard for prescription drugs is an understandable exception to the Restatement's general rule that one who markets goods must warn foreseeable ultimate users of dangers inherent in his products . . . . Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.[112]

Thus, the principal support for limiting a prescription drug manufacturer's duty to warn to physicians arises from the nature of the patient-physician relationship. Individuals who seek medical care place considerable trust in the skill and expertise of their physicians,[113] generally complying with the doctor's treatment plan without question.[114] Therefore, supporters of the learned intermediary defense consider direct warnings to the patient to be extraneous[115] and the potential source of inappropriate interference with the physician-patient relationship.[116]

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111. Gilhooley, *supra* note 24, at 642.

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

113. *See* Seley v. G.D. Searle & Co., 423 N.E.2d 831, 840 (Ohio 1981); *Terhune*, 577 P.2d at 978.

114. *See Seley*, 423 N.E.2d at 840; *Terhune*, 577 P.2d at 978.

115. *See* Gilhooley, *supra* note 24, at 643.

116. *In re* Certified Questions, 358 N.W.2d 873, 883 (Mich. 1984) (Boyle, J., dissenting).

A second justification for the doctrine stems from concern that direct warnings to patients may, in fact, actually endanger the patient's health. According to this theory, some patients, confronted with information of a drug's adverse effects, may become intimidated by the potential consequences or confused by the medical terminology and forego treatment.[117] Fearing a confrontation with the prescribing physician, the patient may avoid informing the physician and theoretically go for months without receiving any therapy for an ailment which otherwise could be treated virtually risk free.[118]

Finally, the doctrine is frequently supported by the argument that direct communication between the drug manufacturer and the patient is difficult—if not virtually impossible—because often the product is not distributed in its original packaging.[119] This position is based on the premise that, when the learned intermediary doctrine was adopted, one-on-one contact between manufacturer and patient was rare. Additionally, magazines and television had yet to assume their function as disseminators of medical information.[120]

These rationales, however, are less important in understanding the significance of the learned intermediary doctrine in medical product liability actions than is the doctrine's principal purpose. As set forth by the *Cornish* court, warnings must be provided to the physician who, if properly warned of potential side effects, can avoid injury to the patient.[121]

Soon after the doctrine's adoption, courts began to recognize and to expand exceptions to the learned intermediary doctrine, acknowledging that the doctrine should *not* be adopted if it fails to protect—or worse precipitates—patient injury.[122]

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117. *See* Gilhooley, *supra* note 24, at 645. As one court noted, "[p]ackage inserts, written for the physician, are detailed and technical, and may confuse and frighten the patient." McKee v. American Home Prods. Corp., 782 P.2d 1045, 1055 (Wash. 1989) (en banc).

118. *In re* Certified Questions, 358 N.W.2d at 882 (Boyle, J. dissenting) (citing amicus brief of the Michigan Defense Trial Counsel).

119. *See* Gilhooley, *supra* note 24, at 643.

120. *See Direct to Consumer Advertising of Prescription Drugs*, AM. PHARM., Feb. 1984, at 20 (discussing the FDA's continued testing of direct to consumer advertising of prescription drugs); *Advertising and Ethics: Prescription Drugs on TV?*, HOSP. PRAC., Oct. 1983, at 13 (discussing the ethical implications of advertising prescription drugs on television).

121. "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." Sterling Drug Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1967).

122. *In re* Certified Questions, 368 N.W.2d 873, 885 (Mich. 1984) (Boyle, J., dissenting).

2. *Rationale for the Exceptions*

Although the vaccine exception arose in clinic settings, the crucial factor to consider is not whether a large number of patients receive treatment but whether the patient has had the opportunity to have his or her needs individually evaluated before accepting treatment.[123] Where the manufacturer knows or has reason to know that the drug will be dispensed without individualized weighing of the drug's benefits and patient's specific needs, the manufacturer retains the duty to warn the patient.[124] Where little or no physician involvement in the decision-making process takes place, presumably, the rationale for directly warning the patient is to allow patients, individually, to balance any benefits and risks concerning the medication.

The courts' rationale for extending the duty to warn to patients using oral contraceptives has been based on four factors.[125] First, oral contraceptives are used by healthy patients for personal convenience and not therapeutic purposes.[126] Second, the use of contraceptives is attributed to patient demand rather than physician advice.[127] Third, unlike the patient who uses a drug for therapeutic reasons, the patient taking oral contraceptives frequently has no ongoing relationship with the dispensing physician.[128] Because the patient uses the drug for extended periods of time without physician involvement, she may not have adequate "opportunity to explore her questions and concerns about the medication with the prescribing physician."[129] Finally, women who use oral contraceptives are exposed to substantial positive publicity generated by manufacturers and targeted to potential consumers. These media campaigns influence the decision to use oral contraceptives more than physicians' recommendations, thereby distinguishing the product from other nonadvertised ethical drugs.[130]

The factors that rationalize exceptions to the learned intermediary doctrine are evident in numerous physician-patient relationships. The whole of these factors suggests that new inroads will continue to limit the duty to warn to physicians only. It is peculiar, therefore,

123. *See supra* notes 57-58 and accompanying text.

124. *See* Reyes v. Wyeth Labs., 498 F.2d 1264 (5th Cir. 1974).

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

126. *Id.*

127. *Id.*

128. *Id.*

129. *Id.*

130. Stephens v. G.D. Searle & Co., 602 F. Supp. 379, 380 (E.D. Mich. 1985) (citing *In re* Certified Questions, 358 N.W.2d 873, 884 (Mich. 1984) (Boyle, J., dissenting)).

that the courts failed to recognize the opportunity for yet another exception when breast implant cases began to be filed.

IV. Breast Implants and the Duty to Warn

A. The Early Cases

Although breast implants have been used for more than thirty years, actions for breast implant product liability were not reported until 1978.[131] Five years later, the New Mexico Court of Appeals first cited the learned intermediary doctrine in a breast implant action. In *Perfetti v. McGhan Medical*,[132] the plaintiff, a mastectomy patient, received a silicone gel-filled implant that subsequently deflated.[133]

Ms. Perfetti's claim was brought under the theories of strict products liability, breach of express and implied warranty, and failure to adequately warn of the risk of deflation.[134] The jury returned a verdict in favor of the plaintiff.[135] On appeal, the defendant questioned whether the duty to warn was owed to the plaintiff or to her surgeon.[136] The court of appeals ruled that the manufacturer fulfilled its duty by warning the physician. Further, the court stated that the manufacturer need not additionally warn the patient, because "federal law restricted [breast implants] to sale by or on the order of a licensed physician."[137] Although the *Perfetti* court was the first to apply the learned intermediary doctrine to breast implant actions, the doctrine did not materially affect the outcome of the case because the question put to the jury was the adequacy of the warning to the physician.[138]

In *Desmarais v. Dow Corning Corp.*,[139] the injured party electively sought augmentation mammoplasty and two silicone gel-filled im-

131. Mueller & Co. v. Corley, 570 S.W.2d 140 (Tex. Civ. App. 1978). Because the plaintiff did not bring a cause of action for negligent failure to warn, relying instead on theories of strict liability and negligence, the court did not address the learned intermediary defense. *Id.* However, law suits against physicians for injuries resulting from breast implantation were reported as early as 1967. 2 Marden G. Dixon, Drug Product Liability § 9.08[4] (1990).

132. 662 P.2d 646 (N.M. Ct. App.), *cert. denied*, 662 P.2d 645 (N.M. 1983).

133. *Id.* at 648.

134. *Id.* at 648-49.

135. *Id.* at 656.

136. Perfetti v. McGhan Medical, 662 P.2d 646, 650 (N.M. Ct. App.), *cert. denied*, 662 P.2d 645 (N.M. 1983).

137. *Id.*

138. *Id.* The case was remanded, however, because the issue of express warranty was erroneously submitted to the jury. *Id.* at 656. Three theories of liability were submitted to the jury. Because a general verdict was returned, the court was unable to determine on what basis the jury found the defendant liable. *Id.*

139. 712 F. Supp. 13 (D. Conn. 1989).

plants were implanted in her breasts.[140] The implants were subsequently removed when each leaked silicone into the surrounding tissue.[141] Although the court cited *Davis*, an early exception based on the absence of individualized balancing by a physician, it affirmed the application of the learned intermediary doctrine and denied the plaintiff a cause of action for failure to warn.[142]

The most recent breast implant case denying a plaintiff recovery under the learned intermediary doctrine was *Lee v. Baxter Healthcare Corp.*[143] Following two consultations with a plastic surgeon, the plaintiff underwent breast augmentation surgery.[144] The implants ruptured and leaked silicone into the surrounding tissue. Subsequently, palpable nodules formed in the plaintiff's breasts.[145] Although her surgeon testified that he normally discussed possible complications with his breast implant patients and supplied them with an informational brochure published by the defendant, the plaintiff alleged that she was not warned. Further, the plaintiff claimed that had she been warned of possible complications, she would not have proceeded with the surgery.[146]

The trial court granted the defendant's motion for summary judgment on the issues of strict liability, negligence, and breach of warranty.[147] The principal issue on appeal was whether the manufacturer owed a duty to directly warn the patient of the risks associated with its breast implants.[148] The court of appeals reaffirmed that the learned intermediary doctrine "has been applied to devices, requiring the manufacturer to warn only the doctor."[149] As a manufacturer of medical devices, the defendant "had no duty to warn the plaintiff directly of the risks associated with breast prosthesis."[150] Finding the manufacturer's warning to the physician legally

140. *Id.* at 13.

141. *Id.* at 13-14.

142. *Id.* at 17-18. Although the court barred the plaintiff's cause of action for failure to warn, it denied the defendant's motion for summary judgment on the grounds that the adequacy of the warning to the physician, specifically whether it warned of possible implant rupture, was a genuine issue of material fact. *Id.* at 18.

The standards by which the courts have considered the adequacy of physician warnings have become substantially more rigorous following disclosure of the information originally exposed in *Stern* proving that breast implant manufacturers had prior knowledge of the dangers of implants. *See supra* note 6.

143. 721 F. Supp. 89 (D. Md. 1989).

144. *Id.* at 91.

145. *Id.*

146. *Id.*

147. *Id.* at 90.

148. Lee v. Baxter Health Care Corp., 721 F. Supp. 89, 94-95 (D. Md. 1989).

149. *Id.* at 95.

150. *Id.*

adequate,[151] the *Lee* court granted summary judgment in favor of the defendant.[152]

Although these actions affirm the applicability of the learned intermediary doctrine to breast implant cases, the courts reached their conclusions without plumbing the depths of analysis found in the *Odgers* and *MacDonald* line of cases.[153] Rather, the courts relied almost exclusively on the rationale that breast implants are not available except through the professional services of a physician. Had the courts considered the factors leading to the vaccine, contraceptive, and IUD exceptions, it is likely that breast implant actions, at least those arising from nontherapeutic use, would be exempt from the doctrine.

B. Rationale for a Breast Implant Exception

As the vaccine and contraceptive cases confirm, certain factual situations can establish the justification for exemption from the learned intermediary doctrine. When comparing the circumstances of these exemptions to the circumstances attending the use of breast implants, it becomes apparent that the courts were too hasty in their blanket application of the doctrine to breast implant litigation.

First, most breast implant recipients decide to have implants prior to consultation with a physician. Like the healthy consumers identified by the *MacDonald* court,[154] more than 80% of the women who receive breast implants do so for cosmetic, and not therapeutic reasons.[155] Patient choice plays a "much more prominent role"[156] in cases where women elect to have implants inserted for breast augmentation than in the case of patients who require drugs for treatment of illness or injury.[157] In the former case, the patient can make a rational choice to forego breast augmentation. Thus, if she rejects breast implants, the decision will not be life threatening.[158] Given the propensity for implants to rupture and the devastating effects silicone can wreak on the immune system, direct-to-patient information is likely to prevent many women from opting for elective breast

151. "A warning is legally adequate when it explains the risk which the plaintiff alleges has caused the injury." *Lee*, 721 F. Supp. at 95 (citing Weinberger v. Bristol-Myers Co., 652 F. Supp. 187, 191 (D. Md. 1986)).

152. *Id.* at 96.

153. *See supra* notes 66-86 and accompanying text.

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

155. Teich v. Food & Drug Admin., 751 F. Supp. 243, 245-46 (D.D.C. 1990).

156. Stephens v. G.D. Searle & Co., 602 F. Supp. 379, 380 (E.D. Mich. 1985) (quoting *In re* Certified Questions, 358 N.W.2d 873, 884 (Mich. 1984) (Boyle, J., dissenting)).

157. *Id.*

158. *See* Odgers v. Ortho Pharm. Corp., 609 F. Supp. 867 (E.D. Mich. 1985).

augmentation.[159]

Second, breast implants are inserted at one specific time but are intended to be used for a long period of time without frequent, if any, return visits to the implanting surgeon.

Unlike the patient who requires treatment for illness or injury, breast implant recipients frequently have no ongoing relationship with the implanting surgeon. Because of the "relatively high incidence of serious adverse effects" associated with breast implants and the "long duration of use without medical evaluation," the recipient may not have adequate "opportunity to explore her questions and concerns . . . with the . . . physician."[160] Although breast implant recipients may return to the care of general practitioners, nonsurgical physicians lack specialized knowledge about breast implants and the symptoms of their adverse effects.

Third, the side effects associated with breast implants can more readily be detected by the patient if she is informed of their nature and symptoms and is instructed to return to her physician for professional evaluation. From its inception, the primary objective of the learned intermediary doctrine was to avoid injury to the patient.[161] Given that breast implant surgeons are specialists who lack ongoing relationships with their patients, it is unlikely that the surgeon is in the best position to detect symptoms of potentially threatening side effects. A patient who is fully informed of the risks of adverse reactions and their attendant symptoms is in a far better position to recognize an adverse reaction before it fully develops, thereby decreasing the severity of potential injury.[162]

Fourth, breast implant patient information can easily be developed in a manner that is understandable to the patient. The complexity of the information a patient requires in order to make an informed judgment regarding breast implant surgery and to recognize symptoms that may require medical assessment may be "too scanty"[163] or "insufficient"[164] if left to oral communication by the physician.[165] When written, this type of information is not only more understand-

159. *See* Lee v. Baxter Health Care Corp., 721 F. Supp. 89, 91 (D. Md. 1989).

160. *Id.*

161. *See supra* note 121.

162. 2 MARDEN G. DIXON, *supra* note 7, § 9.02[2], at 9-14.12. Mr. Dixon notes:

> The average patient does not see a physician when the early danger signs appear, *because the significance of the danger is not recognized*. . . . In many clinical circumstances, the patient continues . . . until serious problems develop which provide the incentive to return to a physician. . . . The time delay may spell the difference between safety and catastrophe.

163. MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 70 (Mass.), *cert. denied*, 474 U.S. 920 (1985).

164. *Id.*

165. *Id.*

able to patients but also more readily available for future reference. Moreover, breast implant manufacturers have voluntarily supplied patients with direct information,[166] demonstrating that the development and distribution of patient information is no longer "virtually impossible" as the *Cornish* court noted so long ago.[167] Finally, manufacturers promote breast implants to the public and specifically to potential users. The court in *Stephens* found that the manufacturers of oral contraceptives had engaged in zealous marketing practices and had targeted highly positive publicity directly to potential users.[168] Such practices, the court noted, necessitated that comparable disclosure of the risks be made directly to the user.[169]

Similarly, the breast implant industry has generated considerable publicity, the majority of which is found in so-called "women's magazines" that celebrate the virtues of large breasts and overpromote the simplicity and safety of breast augmentation surgery.[170] If the dubious benefits of breast implants can so feasibly be provided directly to patients, the risks can and should be similarly communicated.

V. The Next Logical Inroad: The "Advertising" Exception

Despite FDA opposition, manufacturers are increasingly taking advantage of popular media to promote prescription drugs and devices directly to the consumer public.[171] Notwithstanding the judiciary's

166. *See, e.g.*, Lee v. Baxter Health Care Corp., 721 F. Supp. 89, 91 (D. Md. 1989).

167. Further support for the feasibility of direct-to-patient warnings stems from dramatic changes in the pharmacy industry. Many drugs, and certainly breast implants, are dispensed in unit-of-use packages intended to be transmitted to or used in the patient without repackaging by the pharmacist. MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 68 n.7 (Mass.), *cert. denied*, 474 U.S. 920 (1985).

168. Stephens v. G.D. Searle & Co., 602 F. Supp. 379, 380 (E.D. Mich. 1985) (quoting *In re* Certified Questions, 358 N.W.2d 873, 884 (Mich. 1984)).

169. *Id.*

170. *See, e.g.*, Nissa Simon, *The Career Woman's Guide to Cosmetic Surgery and Other Ways to Change Your Image*, Working Woman, May 1988, at 127; Newsweek, Jan. 11, 1988, at 58; *Cheek It Out*, People, Aug. 24, 1987, at 45; Paule Dranov, *Vanity Fair: Plastic Surgery Can Give Your Body and Spirit a Needed Life*, Health, May 1987, at 65; *New Bodies for Sale*, Newsweek, May 27, 1985, at 64; *Changing an Image*, Newsweek, May 27, 1985, at 70.

171. *See* Alan R. Styles, *Prescription Drugs*, 39 Clev. St. L. Rev. 111, 137-38 (1991). For a comprehensive analysis of direct-to-consumer drug promotion, see Teresa Moran Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 Food Drug Cosm. L.J. 829 (1991). The author identifies these examples of advertising and media placement of press releases to promote: Seldane, an antihistamine, Newsweek, Aug. 19, 1991, at 13; Premarin, an estrogen therapy to prevent osteoporosis, Woman's Day Mag., Apr. 2, 1991, at 75-76; Rogaine, a drug to encourage hair growth, Newsweek, May 6, 1991, at 54-56; Tagamet, an ulcer medication, The Washington Post, May 24, 1991, at F3; N.E.E. 1/35, a birth control pill, Drug Store News, June 18, 1990, at IP1; Estraderm, a estrogen replacement ther-

obvious reluctance to further erode the learned intermediary doctrine, this direct-to-consumer advertising may prompt a reassessment of the doctrine's applicability.[172] The question the courts should consider is whether manufacturers that promote health care decision-making by consumers through direct advertising likewise assume the duty to warn those consumers directly.[173]

Although several courts pondered the effect of consumer advertising,[174] subsequent courts have given scant notice to the relationship between direct advertising and the duty to warn. For example, despite widespread consumer-directed promotion of Accutane,[175] courts have consistently invoked the learned intermediary doctrine to bar recovery for injuries resulting from Accutane use.[176] The learned intermediary doctrine has similarly shielded manufacturers of penile implants[177] and collagen implants[178] that have actively pro-

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apy, LADIES' HOME J., Aug. 1991, at 54-56; Nicorette, a chewing gum to ease withdrawal from cigarette smoking, PEOPLE, Feb. 18, 1991, at 52; Hismanal, an allergy medication, PARADE, July 28, 1991, at 6-8; Transderm Scop, a medicated patch to prevent motion sickness, PEOPLE, Aug. 19, 1991, at 23-24; Actigall, a medication to dissolve gallstones, LADIES' HOME J., June 1991, at 55-56; and Calan, a blood pressure lowering drug, NEWSWEEK, Feb. 11, 1991, at 9-10. *Id.* at 836.

172. Schwartz, *supra* note 171, at 835.

173. *Id.* at 838.

174. *See supra* text accompanying note 100 and *infra* text accompanying notes 180-81. *See also* Schwartz, *supra* note 171, at 841-42.

175. *See, e.g.*, *Skin Perfect*, HEALTH, Sept. 1983, at 46; Matt Clark & David Grant, *Now a Real Cure for Acne*, NEWSWEEK, Sept. 13, 1982, at 56. Accutane is Hoffman-La Roche's brand name for isotretinoin, an acne control. PHYSICIANS' DESK REFERENCE 1960 (47th ed. 1993).

176. Thomas v. Hoffman-LaRoche, Inc., 949 F.2d 806 (5th Cir. 1992); Hunt v. Hoffman-La Roche, Inc., 785 F. Supp. 547 (D. Md. 1992); Bealer v. Hoffman-La Roche, Inc., 729 F. Supp. 43 (E.D. La. 1990). In each case, the court found there was no duty to warn the patient where the manufacturer gave adequate warning to the physician.

177. Harwell v. American Med. Sys., Inc., 803 F. Supp. 1287 (M.D. Tenn. 1992) (holding that inflatable penile prosthesis manufacturer satisfied its duty to warn by providing adequate disclosure of potential adverse effects to plaintiff's physician); Hufft v. Horowitz, 5 Cal. Rptr. 2d 377 (Ct. App. 1992) (holding that manufacturer of inflatable penile implant had no duty to warn consumer where adequate warning was provided to physician).

178. Ramey v. Collagen Corp., 821 S.W.2d 208 (Tex. Ct. App. 1991) (holding that manufacturer of collagen implant failed to provide patient's physician with adequate warnings, however, the inadequate warnings were not the proximate cause of the patient's injury). As the result of a recent First Circuit Court of Appeals ruling, plaintiffs injured by collagen implants will no longer be able to bring suit under state law for negligence, fraud or faulty warnings. Jill Gambon, *Court Axes Suits on FDA-Approved Medical Devices*, BOSTON BUS. J., Feb. 1, 1993, at 3. The appeals court ruled that state tort law is preempted by the Medical Devices Amendment (MDA), enacted in 1976, that gives the FDA authority to regulate medical devices. *Id. See also supra* note 2. In effect, the ruling strips consumers who are injured by FDA-approved medical devices of legal recourse under state law. Although breast implants are devices fall-

moted their products directly to ultimate users.[179]

The only court that has thus far ventured to articulate the merits of an advertising exception was a Massachusetts federal district court in *Garside v. Osco Drug, Inc.*[180] In dicta, the court suggested that "by-pass[ing] the traditional patient-physician relationship" through direct-to-consumer advertising "may constitute a third exception to the learned intermediary rule."[181]

Commentators support the advertising exception on grounds that consumer-directed advertising undermines the rationales on which the learned intermediary doctrine is premised. First, the fact that manufacturers are advertising their drugs and devices to consumers suggests that consumers are active participants in their health care decisions, invalidating the concept that it is the doctor, not the patient, who decides whether a drug or device should be used.[182] Second, it is illogical to argue that requiring manufacturers to provide direct warnings to consumers will undermine the patient-physician relationship[183] when, by its very nature, consumer-directed advertising encroaches on that relationship by encouraging consumers to ask for advertised products by name.[184] Finally, consumer-directed advertising rebuts the notion that prescription drugs and devices and their potential adverse effects are too complex to be effectively communicated to lay consumers.[185] Because the FDA requires that prescription drug and device advertising carry warnings,[186] the consumer may reasonably presume that the advertiser guarantees the adequacy of its warnings. Thus, the common law duty to warn the ultimate consumer should apply.[187]

Although precedents set by the *Stephens* and *Hill* courts and the more recent ruling in *Garside* appear to have set the stage for an advertising exception to the learned intermediary doctrine, it is relevant to note that courts have steadfastly ignored opportunities to

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ing within the definition of the MDA, the ruling will not affect liability cases against implant manufacturers because implants were marketed before the medical device law was enacted. *Id.*

179. *See, e.g., The Latest Wrinkle,* PEOPLE, Aug. 24, 1987, at 45 (promoting injectable collagen); *Changing an Image*, NEWSWEEK, May 27, 1985, at 70 (promoting collagen implants).

180. 764 F. Supp. 208, 211 n.4 (D. Mass. 1991).

181. *Id.*

182. *See supra* text accompanying note 112; Schwartz, *supra* note 171, at 842-43.

183. *See supra* text accompanying notes 113-114.

184. Schwartz, *supra* note 171, at 843.

185. *See supra* notes 119-20 and accompanying text; Schwartz, *supra* note 171, at 843.

186. *See* James M. Johnstone, *Direct-to-Consumer Advertising: An Industry Perspective*, 47 FOOD DRUG COSM. L.J. 63 (1992).

187. Schwartz, *supra* note 171, at 845.

expand exceptions to the rule.[188] Despite compelling evidence to the contrary, courts may fail to accept the premise that consumer-directed advertising has so altered the patient-physician relationship that it warrants further erosion of the doctrine since the physician ultimately authorizes the prescription, without which the patient has no access to the desired drug or device.[189]

VI. DIRECT MANUFACTURER-TO-PATIENT WARNINGS

Even if the courts were to recognize an advertising exception, the learned intermediary doctrine, contrary as it is to both the modern realities of medical practice and to contemporary public policy, is a concept that has outlived its erstwhile value. Principal among its shortcomings is the fact that the doctrine substantially overstates the ability and willingness of the medical community to act as a learned intermediary, contradicts the concept of informed consent and a patient's right to self-determination, and ignores the substantial benefits of an informed patientry.[190]

First, the volume and potential for overpromotion of drug information renders the physician an ineffective intermediary. Challenged by a constant bombardment of drug literature from manufacturers, the physician frequently is unable to keep up with the daily changes in the state of medical knowledge.[191] The sheer volume of drug literature argues against the physician being informed of all the hazards of all the drugs and devices he or she prescribes. This is especially true when a drug's side effects are discovered only after the physician has received and relied upon the drug manufacturer's initial marketing literature.

Direct-to-patient warnings, however, would not result in similar inundation. The patient, with no need or interest in knowing the potential hazards of a wide variety of medical products, would only be concerned with the risks associated with the specific drug prescribed.

Another factor militating against the physician as learned intermediary stems from a phenomenon generally referred to as "overpromotion."[192] Physicians who initially received adequate warnings

188. *See supra* parts III.D., IV.A.

189. Schwartz, *supra* note 171, at 839-40. Schwartz noted that prescription drug and device advertising is unique in that it directs consumers to visit their physicians and emphasizes that it is the physician who is responsible for informing patients of the risks and benefits of the product and who ultimately determines whether a prescription should be given. *Id.*

190. *See generally* Gilhooley, *supra* note 24.

191. Manufacturers provide physicians with product information through package inserts, advertisements in the *Physician's Desk Reference*, advertising in medical journals, direct letters, personal contact at professional meetings, and through their direct sales force. *See* 2 MARDEN G. DIXON, *supra* note 7, § 3.05, at 3-16.

192. Courts have recognized that, even when an adequate warning is originally

may become so influenced by the manufacturer's advertising that they disregard the warnings. Overpromotion is unlikely to affect direct-to-patient warnings since ethical drug manufacturers rarely advertise their products directly to the public.

Second, the learned intermediary doctrine is based on medical paternalism that is inconsistent with the concept of informed consent. The single most important argument in favor of direct-to-patient warnings is the notion of informed consent.[193] Although early informed consent actions occurred where the physician exceeded the scope of the patient's consent, the situation as it now arises involves the physician's duty to advise the patient of the risks inherent in a particular course of treatment.[194]

The extent to which the patient is entitled to knowledge of the risks attending a prescribed treatment has been a source of dispute in the courts. Under the traditional customary-practice standard, the scope of the duty to warn is determined by the standard of practice in the community.[195] At best, this standard affords the patient only a limited knowledge of the risks associated with her treatment; at worst, it affords none at all.

The other view is represented by the reasonable-patient standard articulated in *Canterbury v. Spence*.[196] The *Canterbury* court found that the standard of review is not the standard set by custom of physicians practicing in the community;[197] rather "[r]espect for the patient's right of self-determination . . . demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves."[198]

Although controversy over the right of disclosure is understandable in the context of surgery and alternative methods of treatment, the same cannot be said of the disclosure of risks associated with prescription drugs and devices. With regard to the former, there is

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supplied by the manufacturer, the warning is invalidated by subsequent advertising and promotions that downplay the risks of the drug or encourage its application to ailments for which the drug is inappropriate. *See, e.g.*, Love v. Wolf, 38 Cal. Rptr. 183 (Dist. Ct. App. 1964) (holding that advertising extolling minimal side effects nullified prior warnings of risks).

193. The theory of "informed consent" was first articulated by Justice Cardozo in 1914: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages." Schloendorff v. Society of New York Hosp., 105 N.E. 92, 93 (N.Y. 1914). *See also* Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972).

194. *See* PROSSER & KEETON, *supra* note 19, at 189-92.

195. *See* Buckner v. Allergan Pharm., Inc., 400 So. 2d 820, 822 (Fla. Dist. Ct. App. 1981).

196. 464 F.2d 772 (D.C. Cir. 1972).

197. *Id.* at 784.

198. *Id.*

no third party who is qualified to make disclosure. Only the physician can do so. But in the case of drugs and devices, both the physician and the manufacturer are qualified to disclose material information regarding risks and adverse effects. By imposing on manufacturers the duty to inform patients directly, the patient would be assured of full disclosure without being needlessly subjected to the physician's or the courts' discretion.

Third, an informed patientry is more likely to satisfy the initial goal of the learned intermediary doctrine: preventing avoidable patient injury. Patients who are fully informed of the potential risks associated with a prescribed drug or treatment are better able to recognize the symptoms of adverse reactions before they fully develop.[199] Short of round-the-clock surveillance, it is unlikely that a physician will be present when initial symptoms manifest. The patient, therefore, is more likely to be the initial observer of the symptoms of adverse reactions to drugs and therapies. Without adequate warnings, the patient will not know how to interpret what may appear to be seemingly innocuous symptoms.[200]

Similarly, direct-to-patient warnings may increase compliance with the proper and safe use of drugs and devices.[201] The FDA has reported that patients' noncompliance with proper drug use is a principal cause for therapeutic failure.[202]

Direct-to-patient warnings have distinct advantages over the same information being supplied by the physician. A warning from the manufacturer would, by necessity, be in writing, while the physician's warnings frequently are verbal. Written information has the advantage of serving as a future reference, permitting further study by the patient and availability when the patient has a specific question or concern.[203]

For these reasons and for the reasons espoused in *MacDonald* and its progeny, it is time for revitalization of the common law duty to warn the consumer directly. Because a common law duty to warn might engender confusing inconsistency among jurisdictions, patient warnings ought to be administratively regulated to ensure standardized patient information that is easy to understand.[204]

Where a warning can readily be conveyed in a lay person's language, a drug manufacturer's failure to warn the consumer directly should result in liability for any injuries to the consumer proximately

199. *See* Gilhooley, *supra* note 24, at 672.
200. *Id.*
201. *Id.* at 673.
202. 44 Fed. Reg. 40,016, 40,021 (1979).
203. Gilhooley, *supra* note 24, at 673 (citing 45 Fed. Reg. 60,760 (1980)).
204. Styles, *supra* note 171, at 139.

caused by use of the drug or device.[205] But where potential adverse effects cannot easily be communicated, the physician should also have the duty to warn the patient.[206] In rare instances where the manufacturer cannot communicate the necessary information directly to the consumer in a manner that adequately minimizes risk, the regulations should allow the physician discretion in determining whether the manufacturer's information should be withheld.[207]

VII. CONCLUSION

The learned intermediary doctrine, gradually eroded since it was first articulated, has now outlived its usefulness. In the future, courts should not so readily adopt the rationale of the "learned intermediary." Instead, courts should scrutinize its underlying premise, taking into account the developments in the doctrine of informed consent, the substantial benefits of an informed patientry, and the feasibility of reasonable methods for compliance with the imposition of a duty to warn the consumer. The logical conclusion of this more reasoned judicial scrutiny is that the time has come to put the learned intermediary defense to rest.

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205. *Id.* at 138-39 (quoting Barbara P. Flannagan, *Products Liability: The Continued Viability of the Learned Intermediary Rule as It Applies to Product Warnings for Prescription Drugs*, 20 U. RICH. L. REV. 405, 423 (1986)).

206. *Id.* at 139.

207. *Id.*