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NOTES

Medical Implant Litigation and Failure to Warn: A New Extension for the Learned Intermediary Rule?

INTRODUCTION

Under the learned intermediary rule, the manufacturer of a prescription drug satisfies its duty to warn by warning the prescribing physician of the dangers of using the drug. The manufacturer is not required to warn the ultimate user of the drug—the patient—if adequate warning is given to the treating physician.¹ The learned intermediary rule thus represents an exception to the general rule that the manufacturer of a dangerous product has a duty to warn the ultimate consumer of the product's dangers.² Courts have articulated a number of rationales for the learned intermediary rule, and the rule has gained virtually universal acceptance in prescription drug cases.³

¹ See, e.g., *Sterling Drug, Inc. v. Comish*, 370 F.2d 82, 85 (8th Cir. 1966) (holding that drug manufacturer that adequately warns physician of drug's dangerous qualities satisfies its duty to warn and is not required to warn public directly). Even if the manufacturer fails to warn or inadequately warns the physician, the manufacturer might still escape liability for failure to warn the drug user if the physician would not have heeded an adequate warning, see *Bravman v. Baxter Healthcare Corp.*, 984 F.2d 71, 75 (2d Cir. 1993) (holding it to be up to the trier of fact to decide if the physician would or would not have warned the patient had he known of the danger), or if the physician was independently aware of the dangers, see *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 80 (1st Cir. 1992) (holding that a doctor's admission that he would not warn patients of the danger was an intervening-superseding cause of the injuries sustained by the patient); *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992) (stating that a manufacturer's inadequate warning cannot be said to have caused the injury if the physician already knew of the risk).

² See RESTATEMENT (SECOND) OF TORTS § 388(c) (1965); *infra* sources cited note 56.

³ See *infra* notes 42-70 and accompanying text.

A number of courts have extended the learned intermediary rule to cases outside the prescription drug context. In particular, some courts have held that manufacturers of certain medical devices, including intrauterine devices ("IUD") and breast implants, are governed by the learned intermediary rule.⁴ These courts conclude that the same justifications given for the rule's application in the prescription drug context warrant its extension to the analogous field of medical devices.⁵ However, this extension to medical device cases is not universal, and future challenges will no doubt test the rule's viability in medical device cases and elsewhere.⁶ Because these challenges can be expected to rely in large part on the few narrow exceptions to the rule that have been recognized, consideration of device cases also provides a useful vehicle for a reevaluation of the learned intermediary rule in general.

Some courts have created a limited exception to the learned intermediary rule in the case of prescription birth control pills.⁷ These courts have found that the lessened decision-making role played by the physician in prescribing birth control pills justifies an exception to the rule and, therefore, requires manufacturers to warn consumers directly of the dangers associated with birth control pills.⁸ Nonetheless, most courts have expressly rejected this distinction and apply the learned intermediary rule in oral contraceptive cases.⁹

Another exception to the learned intermediary rule involves mass immunization programs. This exception, founded on the premise that in a mass immunization setting physicians do not evaluate the needs of each patient individually, has been widely accepted by the courts.¹⁰ In reliance on

⁴ See *infra* cases cited note 166.

⁵ See, e.g., *Phelps v. Sherwood Medical Indus.*, 836 F.2d 296, 303 (7th Cir. 1987) (finding "no principled basis" on which to distinguish prescription drugs from medical devices).

⁶ See *infra* notes 167-68 and accompanying text.

⁷ The learned intermediary rule is itself an exception to the general rule that a manufacturer of a dangerous product has a duty to warn the ultimate consumer of the product's dangers. Thus, the birth control and mass immunization program exceptions are actually a reversion to the general rule that manufacturers have a duty to warn consumers. However, for ease of reading and language these will simply be referred to as exceptions to the learned intermediary rule.

⁸ See *infra* notes 88-142 and accompanying text.

⁹ See, e.g., *MacPherson v. Searle & Co.*, 775 F. Supp. 417, 425 (D.D.C. 1991) (noting that the overwhelming majority of decisions apply the learned intermediary rule in oral contraceptives cases); *Reaves v. Ortho Pharmaceutical Corp.*, 765 F. Supp. 1287, 1290 (E.D. Mich. 1991) (finding no factual basis for concluding that oral contraceptives differ significantly from other prescription drugs); see also *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 68 n.9 (Mass.) (listing oral contraceptive cases in which the court applied learned intermediary rule), *cert. denied*, 474 U.S. 920 (1985).

¹⁰ See *infra* notes 75-87 and accompanying text.

the reasoning behind these two exceptions, one court has recently announced an additional exception to the learned intermediary rule in cases involving IUDs.¹¹

Subsequent to the development of the oral contraceptives exception, and again after the recent creation of a similar exception in IUD cases, commentators heralded the end of the learned intermediary rule.¹² Yet, despite these exceptions, which are themselves best viewed as anomalies, and cryptic predictions of the rule's pending doom, the learned intermediary rule has not been significantly eroded.¹³ Quite the contrary, time has proven the hardiness of the rule and its adaptability to different applications. The key to the rule's continued viability is that it is founded on sound principles. Critical reexamination of these principles demonstrates that the rule's continued application best serves product liability's dual aims of protecting consumers without unreasonably burdening manufacturers.

This Note considers the continued viability of the learned intermediary rule, focusing on its applicability to medical device cases. Part I briefly discusses failure-to-warn jurisprudence and the law of unavoidably unsafe products.¹⁴ Part II traces the development of the learned intermediary rule, with particular emphasis on the underlying rationales asserted for its application.¹⁵ Part III explores the major recognized exceptions to the rule and examines several arguments asserted by commentators in favor of abrogating the doctrine altogether.¹⁶ Finally, Part IV considers the learned intermediary rule's applicability to medical devices, with emphasis on its applicability to IUD and breast implant cases.¹⁷ This Note concludes that the true justifications for the learned intermediary rule fully support the continued

¹¹ Hill v. Searle Lab., 884 F.2d 1064, 1070-71 (8th Cir. 1989) (deciding that IUDs are different than prescription drugs because it is the patient, not the physician, who decides which method of birth control is desirable); see *infra* notes 170-200 and accompanying text.

¹² See, e.g., Frederick H. Fern, *The Decline and Fall of the Learned Intermediary Doctrine*, 28 FOR THE DEFENSE 10, 10 (Sept. 1986); 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 (1990); see also William M. Sage, Note, *Drug Product Liability and Health Care Delivery Systems*, 40 STAN. L. REV. 989, 1007 (1988) (noting "judicial . . . erosion of the learned intermediary doctrine").

¹³ Margaret Gilhooley, *Learned Intermediaries, Prescription Drugs, and Patient Information*, 30 ST. LOUIS U. L.J. 633, 644 (1986) (finding that the learned intermediary rule remains the general rule).

¹⁴ See *infra* notes 18-38 and accompanying text.

¹⁵ See *infra* notes 39-70 and accompanying text.

¹⁶ See *infra* notes 71-165 and accompanying text.

¹⁷ See *infra* notes 166-242 and accompanying text.

application of the rule as originally announced and its extension to cases involving medical devices, including IUDs and breast implants.

I. FAILURE-TO-WARN CLAIMS AND UNAVOIDABLY UNSAFE PRODUCTS

In products liability, a failure-to-warn claim typically alleges that the manufacturer or seller of a product either knew, or should have known, of dangers inherent in the use of the product and failed to provide adequate warning of those dangers to the user of the product.¹⁸ Most litigation in this area can be traced to comment j to section 402A of the Restatement (Second) of Torts.¹⁹ Section 402A generally provides for strict liability on the part of the manufacturer of a defective product. Comment j provides that a product may be "unreasonably dangerous," and thus subject to strict liability, if the manufacturer does not adequately warn the user of dangers associated with the product and the manufacturer "has knowledge, or . . . should have knowledge, of the presence of the . . . danger."²⁰ In this sense, it is the failure to warn that constitutes the defect in the product that gives rise to strict liability.²¹

Comment k to section 402A creates a significant exception to strict liability in the case of "unavoidably unsafe products."²² Such products are those "which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use."²³ The manufacturer of an unavoidably unsafe product can avoid strict liability if the product is "properly prepared, and accompanied by proper directions and warning."²⁴

Pharmaceutical products generally fall within the definition of unavoidably unsafe products.²⁵ In fact, all of the examples given in

¹⁸ See RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (1965).

¹⁹ *Id.*

²⁰ *Id.*

²¹ See, e.g., *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 811 (5th Cir. 1992) ("a product may be unreasonably dangerous if the manufacturer fails to warn of a non-obvious risk"); *Hill v. Searle Lab.*, 884 F.2d 1064, 1067 (8th Cir. 1989) (holding that a "defect" need not be a matter of errors in manufacture, and that a product is 'defective' when it is . . . not accompanied by adequate instructions and warning of the dangers attending its use").

²² RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

²³ *Id.*

²⁴ *Id.* (emphasis added).

²⁵ See, e.g., *Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87, 90 (2d Cir. 1980) ("Unlike most other products . . . prescription drugs may cause untoward side effects despite the fact that they have been carefully and properly manufactured."); Wolfgruber

comment k to section 402A of the Restatement are medical products,²⁶ and courts often limit the unavoidably unsafe product classification to medical products.²⁷ For purposes of this Note, it is assumed that medical devices, including IUDs and breasts implants, are unavoidably unsafe products. This assumption helps isolate the application of the learned intermediary rule from issues concerning defective products²⁸ and comports with case law on the subject.²⁹

A manufacturer's duty to warn entails several elements. Substantively, the manufacturer must provide warnings of all known risks and their relative magnitude, which might include a duty to warn of even remote risks in the prescription drug context. The warning must be phrased in clear language and otherwise communicated in a manner likely to ensure its effectiveness. Finally, the warning must be adequately directed to the appropriate audience. Generally, the appropriate audience will be the product user. In the case of prescription drugs, however, the manufacturer typically must direct the warning to the treating physician under the learned intermediary rule.³⁰

In the learned intermediary context, it is important to consider failure-to-warn claims as a distinct cause of action from products liability suits that are based on design defects or defective manufacture. Courts generally limit the application of the learned intermediary rule to failure-to-warn cases and will not absolve a manufacturer of liability for a defective product due to the negligence of an intervening physician.³¹

v. Upjohn Co., 423 N.Y.S.2d 95, 97 (1979) (acknowledging that prescription drugs are "unavoidably unsafe products").

²⁶ RESTATEMENT (SECOND) OF TORTS § 402A cmt. k.

²⁷ See Richard C. Ausness, *Unavoidably Unsafe Products and Strict Liability: What Liability Rule Should be Applied to the Sellers of Pharmaceutical Products?*, 78 KY. L.J. 705, 714-15 (1989-90) (noting that courts have generally been quite reluctant to extend comment k to nonmedical products).

²⁸ In reality, of course, such a nice distinction is rarely available. Indeed, "[t]he theories of strict liability, the comment k defense to strict liability, negligence and breach of warranty often merge, particularly when it concerns the legal significance of the adequacy of the warnings given." *Hill v. Searle Lab.*, 884 F.2d 1064, 1066 (8th Cir. 1989).

²⁹ See cases cited *infra* note 166.

³⁰ Ausness, *supra* note 27, at 717-19.

³¹ See *McPheron v. Searle Lab., Inc.*, 888 F.2d 31, 34 (5th Cir. 1989) (comparing cases limiting the learned intermediary rule to warning cases with those indicating a further extension of the rule to apply to defects claims). The *McPheron* court noted that it had, in a case applying Mississippi law, "stated that 'the learned intermediary doctrine applies only to the inadequate warning claims; it does not address design defects.'" *Id.* (citing *Hurley v. Lederle Lab.*, 863 F.2d 1173, 1180 (5th Cir. 1988)). The court also noted a California Supreme Court ruling that "in California, strict liability attaches only if a

The policy objectives served by the learned intermediary rule as applied to failure-to-warn claims do not support a similar rule requiring physicians to warrant the actual fitness of a product.³²

Some courts and commentators group warnings into two basic categories: risk-reduction warnings and informed-choice warnings.³³ As the names imply, such warnings either promote safer use by ensuring a better-informed user or simply provide sufficient information to aid the user in deciding whether to use the product. Professors James Henderson, Jr., and Aaron Twerski analogize this distinction to the distinction between medical malpractice cases based on negligent conduct and those based on informed consent and assert that courts fail to recognize the distinction between risk-reduction and informed-choice warnings.³⁴ Henderson and Twerski suggest that significant policy differences between the two types of warnings might warrant greater judicial sensitivity to the distinction in assessing liability for failure to warn.³⁵

Although traditional failure-to-warn jurisprudence typically has involved risk-reduction warnings, informed-choice warning theory probably predominates in the case of unavoidably unsafe drugs and devices.³⁶ The most significant factor contributing to this conclusion is the basic nature of therapeutic drug treatment. In taking medication or receiving a medical implant, particular methods of use or other user-controlled factors are generally negligible; such usage, once undertaken, involves a degree of risk generally unassociated with any actions of the user beyond ingestion. The amount of the drug taken and the manner in

manufacturer fails to provide an adequate warning to the physician regarding the risks and potential side effects of the drug." *Id.* (citing *Brown v. Superior Court*, 751 P.2d 470, 477 (Cal. 1988)). Additionally, the court in *McPheron* noted two conflicting federal district court opinions reaching opposite conclusions regarding the viability of a design defect claim for an IUD when a learned intermediary had intervened. *Id.* at 33 (citing *Hill v. Searle Lab.*, 686 F. Supp. 720, 725-26 (E.D. Ark. 1988) (learned intermediary rule bars defect claim), and *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1147-50 (D. Or. 1989) (learned intermediary rule does not bar design defect claim)). See also *Bukowski v. Coopervision Inc.*, 592 N.Y.S.2d 807, 847 n.3 (N.Y. App. Div. 1993) ("The informed intermediary doctrine, by its very scope and definition, has no application to a design defect cause of action.").

³² See *infra* notes 49-70 and accompanying text.

³³ See, e.g., *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992) (noting the distinction between "preventable risk warnings" and "unavoidable risk warnings"); James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265, 285-99 (1990).

³⁴ See Henderson & Twerski, *supra* note 33, at 286.

³⁵ *Id.* at 288-89.

³⁶ *Cf. id.* at 286 ("Informed-choice warning litigation is generally limited to prescription drugs and cosmetics . . ." (footnote omitted)).

which it is ingested are predetermined by the physician. The patient's only input is generally whether to take the medication or have the device installed—the so-called “take it or leave it” theory.³⁷ Thus, in the typical scenario, warnings given to the patient do not reduce the risks to the patient but, rather, merely ensure that the patient is adequately informed of the risks of using a product before consenting to its use. Although this distinction has not received a great deal of attention in the context of medical device cases, the distinction clearly supports the application of the learned intermediary rule in device cases.³⁸

The learned intermediary rule does not relate to the type of warning given or to the adequacy of the warnings given. Instead, the rule concerns only the issue of to whom the warning must be given. Thus isolated, the issue is whether the manufacturer of an unavoidably unsafe medical device should be liable to a consumer who received the product from a physician-intermediary when the manufacturer has adequately warned this physician-intermediary of the product's dangers.

II. THE LEARNED INTERMEDIARY RULE

Modern commentators trace the current learned intermediary rule to the case of *Sterling Drug, Inc. v. Cornish*.³⁹ In fact, the rule announced in *Sterling* was not so much a new rule as it was the first clear articulation of principles that had been applied in prescription drug cases for some time.⁴⁰ In the years since *Sterling*, the doctrine has been refined and extended to areas outside the prescription drug context.⁴¹ Different courts and commentators have proffered varying justifications for the application and expansion of

³⁷ *Id.* at 285.

³⁸ See *infra* notes 183 & 213 and accompanying text.

³⁹ 370 F.2d 82, 85 (8th Cir. 1966) (holding that drug manufacturer that warns physician of drug's dangers has no duty to warn general public); see Gilhooley, *supra* note 13, at 643; Barbara Pope Flannagan, Comment, *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, 410 (1986).

⁴⁰ See, e.g., *Love v. Wolf*, 38 Cal. Rptr. 183, 192 (Ct. App. 1964) (“Parke-Davis has no contact with the ultimate consumer of the drug, the patient. The duty, therefore, whatever its extent may be, must be a duty to warn the doctor who prescribes the drug.”); *Marcus v. Specific Pharmaceuticals, Inc.*, 77 N.Y.S.2d 508, 509-10 (1948) (holding that manufacturer satisfied duty to warn by providing adequate warnings to treating physician); see also Flannagan, *supra* note 39, at 410 n.27.

⁴¹ See, e.g., *infra* note 166 (listing decisions applying learned intermediary rule in device cases).

the learned intermediary rule. Only through analysis of these rationales can the rule's utility in other contexts be appropriately evaluated.

A. *The Superseding Cause Rationale*

Causation is perhaps the most appealing label courts utilize in immunizing manufacturers who provide adequate warnings to the prescribing physician from failure-to-warn claims. An adequately warned physician who fails to pass the warning on to his patient constitutes a superseding cause between the manufacturer and the patient.⁴² This causation rationale is appealing because it is based on the familiar tort concept that a tortfeasor is liable only for the injuries that he or she proximately causes.⁴³

Despite its appeal, one problem with using the causation rationale is the inherent difficulty of establishing causation in failure-to-warn cases as compared with other product liability claims. In a typical defective design case, a plaintiff points to the existence of a viable alternative design and asserts that the manufacturer's failure to use that design proximately caused the plaintiff's injury.⁴⁴ Failure-to-warn claims, however, entail a different sort of showing. A plaintiff suing under a failure-to-warn theory must presumably establish that she would have heeded an adequate warning if one were given.⁴⁵ Due to the individualized nature of the inquiry into what warning

⁴² See, e.g., *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 79 (1st Cir. 1992) (recognizing the "principle that where a treating physician knows of the risks associated with a drug but does not pass that warning along to the patient, the doctor's decision not to warn constitutes an intervening, superseding cause of the patient's harm" (citation omitted)); *Beyette v. Ortho Pharmaceutical Corp.*, 823 F.2d 990, 993 (6th Cir. 1987) (holding that, even if warning received by patient was inadequate, adequately warned doctor's failure to pass warning on to patient constituted intervening, superseding cause between manufacturer's alleged failure to warn and injury); *Zanzuri v. G.D. Searle & Co.*, 748 F. Supp. 1511, 1515 (S.D. Fla. 1990) (holding that a "properly warned physician . . . becomes a 'learned intermediary' operating to break the causal link" between the drug manufacturer and the consumer); *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 68 (Mass.) (holding that under learned intermediary doctrine, "the manufacturer's immunity . . . is explicable on the grounds that the intermediary's failure to warn is a superseding cause of the consumer's injury" (citation omitted)), *cert. denied*, 474 U.S. 920 (1985).

⁴³ See RESTATEMENT (SECOND) OF TORTS § 5 (1965).

⁴⁴ See *Henderson & Twerski*, *supra* note 33, at 304-05 (comparing causation element in defects cases and failure-to-warn cases).

⁴⁵ See *id.* at 305. In fact, as *Henderson* and *Twerski* note, courts have faced a dilemma in resolving the causation issue in failure-to-warn cases. Because causation in such cases is highly speculative, courts that might appropriately take many, if not most, cases from the jury instead tend to "defer to juries' discretion." *Id.* at 305-06. Thus, "[t]he plaintiff's causal case is made excessively easy because any other reaction would

would have caused the plaintiff to alter her behavior, Professors Henderson and Twerski suggest that "predicting how additional information would have affected any given individual may be well nigh impossible."⁴⁶

Obviously, the causation issue is made more difficult in the case of a manufacturer that has in fact warned of the dangers associated with a product, but has extended that warning to a physician rather than directly to the patient. In this situation, a plaintiff might allege that the manufacturer's failure to warn her directly was the cause of her injury.⁴⁷ The manufacturer will then respond that the physician's legal and ethical obligations required him to exercise his medical judgment in determining what information to share with the patient.⁴⁸ Thus, the manufacturer will claim that any inadequacies in the warning given to the patient are the result of the physician's failure to satisfy his duty and were not caused by the manufacturer.

The essential problem with an intervening cause rationale is that it necessarily assumes the absence of a duty on the part of the manufacturer to communicate a warning *directly* to the consumer/patient and, therefore, begs the question of whether a direct warning should be required. Obviously, if there were a duty to warn the patient directly, the manufacturer could not satisfy it merely by warning the physician. Thus, rather than being a mere shorthand reference for an existing legal rule, the learned intermediary rule is a rule based on public policy.

B. *The Manufacturer-Doctor-Patient Relationship*

As one court has noted, the "entire system of drug distribution in America is set up so as to place the responsibility of distribution and use

make the case unacceptably difficult." *Id.* at 306.

⁴⁶ *Id.* at 307 (citation omitted). However, it might prove easier to establish how additional or different warnings affect a physician's course of action, if only because doctors, unlike the general populace, share common training and terminology.

⁴⁷ The plaintiff might allege that the warning to the physician was itself inadequate. This would give the plaintiff a valid failure-to-warn claim, the learned intermediary rule notwithstanding, since the warning to the doctor was for the plaintiff's benefit. *See, e.g.,* MacDonald v. Ortho Pharmaceutical Corp., 475 N.E.2d 65, 69 (Mass.) (noting that "the duty of the ethical [prescription] drug manufacturer is to warn the doctor, rather than the patient, [although] the manufacturer is directly liable to the patient for a breach of such duty" (second alteration in original)) (quoting McEwen v. Ortho Pharmaceutical Corp., 528 P.2d 522 (Or. 1974)), *cert. denied*, 474 U.S. 920 (1985). For purposes of this discussion, it is assumed that the treating physician was fully apprised of the dangers associated with the drug but failed to pass the warning on to the patient.

⁴⁸ *See* Hill v. Searle Lab., 884 F.2d 1064, 1070 (8th Cir. 1989) ("[M]edical ethics and practice dictate that the doctor must be an intervening and independent party between patient and drug manufacturer.").

upon professional people.⁴⁹ By definition and by law, prescription drugs can be obtained only through a prescription by a licensed physician.⁵⁰ Thus, there is necessarily an intervening party between the manufacturer and the consumer, and that party—a physician—is independently required by law to adequately inform the patient of the risks associated with the treatment provided.⁵¹ However, the mere existence of a physician-intermediary does not alone justify absolving the manufacturer, since it is common to allow parties to share liability for a single wrong.⁵² Rather, the nature of the

⁴⁹ *Gravis v. Parke-Davis & Co.*, 502 S.W.2d 863, 870 (Tex. Civ. App. 1973).

⁵⁰ 21 U.S.C. § 353(b)(1) (1992); see *Swayze v. McNeil Lab., Inc.*, 807 F.2d 464, 466 (5th Cir. 1987) ("Prescription drugs, on the other hand, due to their potency or unusual characteristics, are dispensed only upon a doctor's order."); *MacDonald*, 475 N.E.2d at 73 (noting that "by definition, before a consumer uses a prescription drug, that consumer must have some interaction with a doctor" (citation omitted)).

⁵¹ This requirement is generally considered part of the doctrine of informed consent. The physician's "obligation reflects principles of individual autonomy and rests on the premise 'that every person has the right to determine what shall be done to his own body.'" Gilhooley, *supra* note 13, at 654 (quoting *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir.) (citation omitted), *cert. denied*, 409 U.S. 1064 (1972)). See also Barbara Marticelli McGarey, Comment, *Pharmaceutical Manufacturers and Consumer-Directed Information—Enhancing the Safety of Prescription Drug Use*, 34 CATH. U. L. REV. 117, 119 (1984) ("The exact content of the information [patients] receive is left to the health professional's discretion. Liability for inadequate disclosure is based on the doctrine of informed consent."). See generally Gilhooley, *supra* note 13, at 653-58 (discussing evolution of the informed consent doctrine and the modern emphasis on patient autonomy).

⁵² See RESTATEMENT (SECOND) OF TORTS § 879 (1965). Courts and commentators calling for abrogation of the learned intermediary rule have noted that warnings provided directly to the patient from the manufacturer would be supplemental to the warnings already owed by the treating physician. See, e.g., *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 70 (Mass.) ("Thus, the manufacturer's duty is to provide to the consumer written warnings conveying reasonable notice of the nature, gravity, and likelihood of known or knowable side effects, and advising the consumer to seek fuller explanation from the prescribing physician. . . ."), *cert. denied*, 474 U.S. 920 (1985); Gilhooley, *supra* note 13, at 686; McGarey, *supra* note 51, at 140 ("Thus, consumer-directed labeling would neither replace the physician's responsibility to communicate warnings nor replace the learned intermediary system of apportioning liability."). Cf. Prescription Drug Products: Patient Package Insert Requirements, 45 Fed. Reg. 60,754, at 60,762-63 (1980) ("Patient package inserts are not intended to be a substitute for the information provided by the patient's physician Instead, their purpose is to supplement that instruction"), *repealed by* Prescription Drug Products; Revocation of Patient Package Insert Requirements, 47 Fed. Reg. 39,147 (1982). The patient package insert initiative, which would have required written inserts on certain prescription drugs for distribution to patients, was aborted by the Reagan Administration. See Gilhooley, *supra* note 13, at 665-68.

physician-patient relationship forms the foundation of the learned intermediary rule.

A treating physician is presumed to do more than merely distribute drugs. His or her primary duty is to treat the patient. Of course, a significant portion of this duty involves the prescription of drugs to patients.⁵³ In prescribing medication for a patient, a physician considers not only the relevant attributes of the pharmaceutical product, but also the needs and characteristics of the individual patient. This is, in essence, the rationale for prescription drugs: because they are too potentially dangerous to be available to the public at large, prescription drugs must be distributed by learned professionals who understand both the product and the patient.⁵⁴ Since the only means by which patients can receive prescription drugs is through a physician, the learned intermediary rule requires the manufacturer to warn the treating physician, not the patient. What is supposed to transpire from that point has been a matter of some debate.

Many courts and commentators who have considered the learned intermediary rule envision a filtering effect, whereby the physician will tailor

⁵³ For example, as early as 1978, U.S. doctors wrote 751 million new prescriptions and 658 million refills. PHARMACEUTICAL MANUFACTURERS ASSOCIATION, PRESCRIPTION DRUG INDUSTRY FACT BOOK 15-16, 55 (1980). This number has grown to 1.6 billion prescriptions each year. See Milt Freudenheim, *F.D.A. Gets Tough on Drugs Offered for Unproved Uses*, N.Y. TIMES, June 29, 1991, Financial Desk, § 1, at 1.

⁵⁴ As the court noted in *Reyes v. Wyeth Lab.*, 498 F.2d 1264, 1276 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974):

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 individual medical judgment bottomed on a knowledge of both patient and palliative.

See *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 80 (1st Cir. 1992) ("The rationale underlying the prescription drug rule is that the prescribing physician, as the 'learned intermediary' standing between the manufacturer and consumer/patient, is generally in the best position to evaluate the potential risks and benefits of ingesting a certain drug and to advise the patient accordingly."); see also Gilhooley, *supra* note 13, at 659 ("The [Food and Drug Administration] was concerned that '[m]any drugs of great value to the physician are dangerous in the hands of those unskilled in the uses of the drugs.'" (second alteration in original) (footnote omitted) (quoting F.D.A. Ann. Rep. (1939), *reprinted in* FOOD LAW INST., FEDERAL FOOD, DRUG & COSMETIC LAW, 1907-49 ADMIN. REPS. 929 (1951))); Flanagan, *supra* note 39, at 413 ("It is the physician who has the education and expertise to understand the mass of information provided by drug manufacturers concerning the benefits and risks of [a particular drug]. . . . A physician is in a better position than the manufacturer to know the needs of a particular patient."); Sage, *supra* note 12, at 990 ("The chemistry of the [patient] may contribute to an adverse drug reaction . . . as much as the chemistry of the drug. . . .").

the warnings provided by the manufacturer to fit the needs of a given patient.⁵⁵ The physician thus takes the place of the manufacturer by assuming the duty to warn.⁵⁶ Under the filtering model, the physician exercises his judgment in determining not only which dangers the patient should be informed of, but also how best to inform the patient. Performance of this task requires the physician to have considerable knowledge of the individual patient, knowledge that the manufacturer cannot be expected to possess.

One advantage of allowing the physician to serve a filtering function between the manufacturer and the patient is the increased effectiveness of the warnings given. Too far removed from any individual patient to discern which of the potentially numerous warnings are appropriate or even necessary in a given case, the manufacturer's natural reaction would be to warn every patient of every conceivable risk. As noted by Professors Henderson and Twerski:

The most significant social cost generated by requiring distributors to warn against remote risks is the reduced effectiveness of potentially helpful warnings directed towards risks which are not remote. Bombard-

⁵⁵ See, e.g., *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992) ("Under [the learned intermediary] doctrine, the manufacturer's duty to warn extends only to the prescribing physician, who then assumes responsibility for advising the individual patient of risks associated with the drug or device."); *Hill v. Searle Lab.*, 884 F.2d 1064, 1070 (8th Cir. 1989) (noting that "the learned intermediary rule . . . assumes that it is reasonable for a manufacturer to rely on the prescribing physician to forward to the patient, who is the ultimate user of the drug products, any warnings regarding their possible side effects"); *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1232 (4th Cir. 1984) ("It is the physician's duty to remain abreast of product characteristics and, exercising an informed professional judgment, decide which facts should be told to the patient."); Gilhooley, *supra* note 13, at 642 ("[T]he courts continue to invoke the 'learned intermediary' doctrine to allow drug manufacturers to rely on an intermediary—the prescribing physician—to warn consumers about the risks involved in their use of a particular drug." (citation omitted)); McGarey, *supra* note 51, at 119 ("[P]hysicians, because of their education and experience, can best receive, understand and disseminate [information about prescription drugs]. . . . Thus, consumers must obtain almost all of the information necessary for the safe use of prescription drugs through their doctor . . .").

⁵⁶ Generally, the manufacturer of a dangerous product has the duty to warn consumers of dangers associated with the product. See *Zanzuri v. G.D. Searle & Co.*, 748 F. Supp. 1511, 1514 (S.D. Fla. 1990) (stating that manufacturers generally must warn consumers but noting the learned intermediary exception); RESTATEMENT (SECOND) OF TORTS § 388(c) (1965) (stating that a manufacturer must exercise reasonable care to make known dangerous aspects of the product); W. PAGE KEETON ET AL., PROSSER & KEETON ON THE LAW OF TORTS § 33, at 207 n.47 & § 99(2), at 697 (5th ed. 1984) (manufacturers generally must warn of the risks of dangerous products).

ed with nearly useless warnings about risks that rarely materialize in harm, many consumers could be expected to give up on warnings altogether.⁵⁷

The warnings to which Professors Henderson and Twerski refer are considered "nearly useless" because they pertain to remote risks. Presumably, such risks can be remote either by having a low incidence rate generally or by threatening only limited groups of patients. In either case, but particularly where certain identifiable groups are at risk, the physician's familiarity with the patient allows for effective targeting of warnings, thereby reducing the risk that patients will be overwhelmed by warnings.

In sharp contrast to the threat that consumers who are inundated with warnings will turn their backs on warnings altogether is the risk that some consumers will "continue to take warnings seriously in an environment crowded with warnings of remote risks [and will] probably overreact, investing too heavily in their versions of 'safety.'"⁵⁸ Again, the physician's proximity to his or her patient allows him or her to alleviate the risks of overwarning. A similar justification for treating the physician as a conduit through which warnings are relayed to the patient is the concern that, in some cases, patients should not be informed of risks for therapeutic reasons.⁵⁹ Thus, by filtering a complete catalog of risks associated with a particular drug through the treating physician, the warning eventually given to patients will be more effective and better for the patient than would be direct manufacturer-to-patient warnings.⁶⁰

⁵⁷ Henderson & Twerski, *supra* note 33, at 296 (citation omitted).

⁵⁸ *Id.*; see also Gilhooley, *supra* note 13, at 644-45 (taking note of the argument that labeling directed to consumers might "frighten patients so that they would not take necessary medications").

⁵⁹ See, e.g., *Brooks*, 750 F.2d at 1232. As the *Brooks* court noted:

One in a serious medical condition of the sort experienced by Brooks as a general matter faces unwanted, unsettling and potentially harmful risks if advice, almost inevitably involved and longwinded, from non-physicians, contrary to what the doctor of his choice has decided should be done, must be supplied to him during the already stressful period shortly before his trip to the operating room.

⁶⁰ See *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 74 (Mass.) (O'Connor, J., dissenting) (asserting that the learned intermediary rule, coupled with the physician's duty to secure the patient's informed consent, would "best ensure that a prescription drug user will receive in the most effective manner the information that she needs to make an informed decision as to whether to use the drug"), *cert. denied*, 474 U.S. 920 (1985).

Though widely espoused, the filtering theory has been explicitly rejected in some quarters. Critics of the filtering approach maintain that the physician is not an intermediary who assumes the manufacturer's duty to warn the consumer. Instead, these critics assert that the physician *is* the consumer.⁶¹ This interpretation of the learned intermediary rule contemplates a physician who, having received adequate warning from the manufacturer, independently weighs the risks and benefits of a particular drug in deciding whether to prescribe it for a patient.⁶² Under this theory, the physician, in effect, takes the place of the patient, not the manufacturer, in the duty-to-warn context. The physician receives the warning, weighs the risks against the benefits, and determines whether the use of the drug is warranted. As in the context of a physician who filters information for the patient, a physician who acts as the consumer for the patient must have considerable knowledge of the individual patient in order to perform this role properly.⁶³

The learned intermediary rule is thus susceptible to two significantly different constructions: the filtering versus the substituted consumer approaches. As with any theoretical distinction, however, courts often mix the models, defining the rule—and the physician's role—to entail both

⁶¹ See *McPherson v. Searle Lab., Inc.*, 888 F.2d 31, 33 (5th Cir. 1989) ("The prescribing physician acts as a 'learned intermediary' who determines whether the drug is appropriate for the patient." (citation omitted)); *Zanzuri v. G.D. Searle & Co.*, 748 F. Supp. 1511, 1515 (S.D. Fla. 1990) ("[T]he prescribing physician, acting as a 'learned intermediary' between the manufacturer and the consumer, weighs the potential benefits against the dangers in deciding whether to recommend the drug to meet the patient's needs." (citation omitted)).

The physician-as-consumer position was put forth most forcefully in Robert M. McKenna, Comment, *The Impact of Product Liability Law on the Development of a Vaccine Against the AIDS Virus*, 55 U. CHI. L. REV. 943, 959 (1988). Responding to the assertion in Gilhooley, *supra* note 13, at 637, that drug manufacturers should be required "to provide adequate information about a drug's risks directly to the drug user," McKenna stated:

This argument misconstrues the learned intermediary doctrine. The doctrine does not assume the physician will substitute for the drug manufacturer as a conduit of warnings to the drug user. Rather, it is the physician who is the consumer by making the decision whether the patient should use a given drug Hence, whether warnings ultimately reach the patient is irrelevant under the doctrine. The relevant issue is whether the drug manufacturer adequately warned the physician of the drug's risks.

McKenna, *supra*, at 959. See also Sage, *supra* note 12, at 1000 ("A problem with applying traditional liability rules to drugs is that the true 'consumer' of prescription drugs is the physician, not the patient.").

⁶² See McKenna, *supra* note 61, at 959.

⁶³ *Id.* at 958.

functions.⁶⁴ This commingling of constructions is entirely appropriate. While critics of the filtering model are correct in noting that the learned intermediary rule per se is not dependent upon warnings actually reaching the patient,⁶⁵ the physician's duty to obtain the patient's informed consent prior to treatment⁶⁶ is an ineluctable backdrop to any failure-to-warn claim involving pharmaceuticals. That the manufacturer may be able to demur to a patient's failure-to-warn claim does not negate the significance of the physician's duty to warn, as it is clear that many courts consider the physician's duty an indispensable element of the learned intermediary rule.⁶⁷

C. *Efficiency Rationales*

The other justifications given for the learned intermediary rule are in some form or another related to the special relationship between the physician and patient discussed above. These include the difficulty a manufacturer would face in distributing information directly to the patient,⁶⁸ the complexity of the warning information and difficulty

⁶⁴ See *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 80 (1st Cir. 1992) ("The rationale underlying the prescription drug rule is that the prescribing physician, as the 'learned intermediary' standing between the manufacturer and consumer/patient, is generally in the best position to evaluate the potential risks and benefits of ingesting a certain drug and to advise the patient accordingly."); *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1232 (4th Cir. 1984) ("Once adequate warnings are given to the physician, the choice of treatment and the duty to disclose properly fall on the doctor."); *MacPherson v. Searle & Co.*, 775 F. Supp. 417, 422-23 (D.D.C. 1991) ("[T]he pharmaceutical manufacturer's duty is to adequately inform the physician, who is 'expected to function as a 'learned intermediary' between the company and the patient in protecting the patient and in providing direct information about the drug to the patient.") (quoting WILLIAM J. CURRAN ET AL., *HEALTH CARE LAW, FORENSIC SCIENCE, AND PUBLIC POLICY* 1198 (4th ed. 1990)); *Terhune v. A.H. Robins Co.*, 577 P.2d 975, 978 (Wash. 1978) ("It is [the physician's] duty to inform himself of the qualities and characteristics of [prescription products] . . . , and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product. . . . The physician decides what facts should be told to the patient.").

⁶⁵ See *McKenna*, *supra* note 61, at 959 (noting that the learned intermediary rule does not simply assume that the physician will act as a conduit for information).

⁶⁶ See *MacPherson*, 775 F. Supp. at 423 ("At a minimum . . . a physician must disclose to a patient, *inter alia*, 'the nature of the proposed treatment . . . and the nature and degree of risks and benefits inherent in undergoing and in abstaining from the proposed treatment.'") (quoting *Crain v. Allison*, 443 A.2d 558, 562 (D.C. 1982)).

⁶⁷ See cases cited *supra* notes 54-55.

⁶⁸ See *Hill v. Searle Lab.*, 884 F.2d 1064, 1070 (8th Cir. 1989) ("[I]t is virtually impossible in many cases for a manufacturer to directly warn each patient."); *Sage*, *supra*

translating that information into layman's terms,⁶⁹ and the risk of interference with the doctor-patient relationship.⁷⁰ Together, these justifications bolster the conclusion that in the typical case, the physician is in the best position to warn the patient and is also best able to ensure that warnings are effective. Conversely, the manufacturer would face considerable obstacles in striving to satisfy a duty to warn patients directly and is much more suited to the task of warning the physician. Thus, the continued application of the learned intermediary rule in prescription drug and pharmaceutical device cases clearly offers the better course.

III. EXCEPTIONS TO THE LEARNED INTERMEDIARY RULE

The learned intermediary rule has been adopted in some form or another by virtually every jurisdiction that has considered it.⁷¹ Despite this overwhelming acceptance of the rule by the courts, the majority of commentators either urge the creation or expansion of exceptions to the rule, or call for a total abrogation of the rule.⁷² These entreaties have

note 12, at 1007 n.74 ("The major arguments for warning only the physician are the doctor-patient relationship and logistical problems of direct communication between manufacturers and patients.") (citing Britain, *Product Honesty Is the Best Policy: A Comparison of Doctors' and Manufacturers' Duty to Disclose Drug Risks and the Importance of Consumer Expectations in Determining Product Defect*, 79 NW. U. L. REV. 342, 375-76 (1984) and Victoria J. Kincke, Note, *Oral Contraceptives: Heading Into an Era of Unpredictability, Unlimited Liability, and Unavailability?*, 19 IND. L. REV. 615, 618-21 (1986)).

⁶⁹ See *Hill*, 884 F.2d at 1070 ("[T]he information regarding risks is often too technical for a patient to make a reasonable choice."); *Reyes v. Wyeth Lab.*, 498 F.2d 1264, 1276 (5th Cir.) ("Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect."), *cert. denied*, 419 U.S. 1096 (1974).

⁷⁰ See Gilhooley, *supra* note 13, at 645 (noting that such broad requirements "could potentially cause undue interference with the doctor-patient relationship") (citing *In re Certified Questions*, 358 N.W.2d 873, 883 (Mich. 1984)); Flannagan, *supra* note 39, at 413 (finding that the doctor-patient relationship could be put at risk) (citing *Dunkin v. Syntex Lab.*, 443 F. Supp. 121, 123 (W.D. Tenn. 1977)).

⁷¹ See Gilhooley, *supra* note 13, at 644 (citing *In re Certified Questions*, 358 N.W.2d 873, 881, 881 n.4 (Mich. 1984)); McKenna, *supra* note 61, at 958 ("Every jurisdiction that has considered whether a drug manufacturer has a duty to warn has adopted the doctrine.") (citing Flannagan, *supra* note 39, at 411 n.32). McKenna places the number of states adopting the rule at forty-three. See *id.* at 958 n.68. Suffice it to say that the rule has received widespread acceptance.

⁷² See, e.g., Gilhooley, *supra* note 13, at 637 ("[P]rescription drug manufacturers should be required under state tort law to provide adequate information about a drug's risks directly to the drug user."); Flannagan, *supra* note 39, at 423 ("Where a warning can

usually fallen on deaf ears. However, significant exceptions to the rule have been created for vaccinations and oral contraceptives.⁷³ Some of the policy grounds behind these exceptions will no doubt fuel further challenges to the rule, particularly in the context of breast implant and IUD litigation.⁷⁴ For this reason, this part of the Note first examines the existing exceptions to the rule and next considers the proffered justifications for creating additional exceptions to the learned intermediary rule or for abandoning the rule altogether.

A. *The Mass Immunization Exception*

The most widely applied exception to the learned intermediary rule involves the use of vaccines in mass immunization programs. This exception was first noted in *Davis v. Wyeth Laboratories*,⁷⁵ soon after the learned intermediary rule itself was first recognized.⁷⁶ In *Davis*, the plaintiff allegedly contracted polio from a vaccine administered at a public health clinic. The Ninth Circuit rejected the defendant manufacturer's attempt to invoke the learned intermediary rule, determining that "without an individualized balancing by a physician of the risks involved . . . it is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warning itself or by obligating the purchaser to give warning."⁷⁷ The reasoning applied in *Davis* was adopted six years later by the Fifth Circuit in *Reyes v. Wyeth Laboratories*.⁷⁸

The rulings in *Davis* and *Reyes* represent explicit exceptions to the learned intermediary rule, because both courts recognized that vaccines

readily be conveyed in 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 caused by use of the drug." (footnote omitted)); McGarey, *supra* note 51, at 151 (calling for "[a] multi source system for the communication of prescription drug information to consumers" based primarily on the perceived inadequacies of the learned intermediary rule).

⁷³ See *infra* notes 75-142 and accompanying text.

⁷⁴ See *infra* notes 169-216 and accompanying text.

⁷⁵ 399 F.2d 121 (9th Cir. 1968).

⁷⁶ See *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966) (holding that a manufacturer has a duty to warn doctors of possible side effects of prescription drugs since the doctor can understand and apply the warning in his role as a learned intermediary between the manufacturer and the patient); *supra* notes 39-41 and accompanying text.

⁷⁷ *Davis*, 399 F.2d at 131.

⁷⁸ 498 F.2d 1264, 1276 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974).

are generally classified as prescription drugs and that manufacturers of prescription drugs generally must warn only the prescribing physician.⁷⁹ The difference with vaccines, at least as administered to the patients in *Davis* and *Reyes*, is that:

Where there is no physician to make an "individualized balancing . . . of the risks", . . . the very justification for the prescription drug exception evaporates. Thus, as in the case of patent drugs sold over the counter without prescription, the manufacturer of a prescription drug who knows or has reason to know that it will not be dispensed as [a prescription] drug must provide the consumer with adequate information so that he can balance the risks and benefits of a given medication himself.⁸⁰

The validity of the vaccine exception is evident in the *Reyes* court's discussion of the defendant's attempts to distinguish the facts of *Reyes* from those in *Davis*. In *Reyes*, defendant Wyeth Laboratories offered four grounds on which to distinguish its case factually from *Davis*:

First, the appellant argues, *Davis* received his vaccine during a mass immunization program, whereas Anita Reyes ingested her vaccine at her parents' request. Second, Wyeth stresses the fact that *Davis* received his vaccine from a pharmacist, but *Reyes*' was administered by a public health nurse. Third, Wyeth's active participation in the mass immunization program involved in the *Davis* case is contrasted to its relatively passive role here. Finally, Wyeth urges that unlike the situation in *Davis*, here it had no knowledge that the vaccine would not be administered as a prescription drug.⁸¹

Rejecting these distinctions, the *Reyes* court emphasized that "Wyeth had ample reason to foresee the way in which its vaccine would be distributed" and hinted that absent such foreseeability, the case might have been legitimately distinguishable from *Davis*.⁸²

⁷⁹ See *id.*; *Davis*, 399 F.2d at 130.

⁸⁰ *Reyes*, 498 F.2d at 1276 (first omission in original) (quoting *Davis*, 399 F.2d at 131).

⁸¹ *Id.* at 1277.

⁸² *Id.* The issue of the manufacturer's ability to foresee the absence of a learned intermediary is controlling in many cases. See, e.g., *Givens v. Lederle*, 556 F.2d 1341, 1345 (5th Cir. 1977) (holding that it is foreseeable that a nurse would administer the drug without physician supervision and that the manufacturer thus had a duty to warn the

Just as the mass immunization exception recognizes the inapplicability of the learned intermediary rule when there is no intervening physician, when a physician does play a meaningful role in prescribing the drug/vaccine the exception has no place, and the learned intermediary rule should apply.⁸³ This "meaningful role" might entail simply being present in a supervisory capacity after the establishment of a physician-patient relationship.⁸⁴ The mass immunization exception thus underscores the prominent role of the doctor-patient relationship in the learned intermediary context: the existence or absence of this relationship controls the applicability of the mass immunization exception.

Although accepted universally and grounded in the legitimate basis that immunizations are often administered without intervention by a learned intermediary, the mass immunization exception is costly in certain respects. In particular, the cessation of production of some vaccines can be traced to manufacturers' unwillingness to expose themselves to unpredictable and unavoidable liability for failure to warn.⁸⁵ The uncertainty intimidating these manufacturers is that failure-to-warn claims leave to a jury the decision of whether a warning was adequate. This decision is made on the facts of the individual case and can easily fail to account for the practical limitations involved in providing warnings and

patient directly); *Mazur v. Merck & Co.*, 767 F. Supp. 697, 701 (E.D. Pa. 1991) ("The issue of whether or not the reasonableness standard has been met will most likely turn on the issue of foreseeability, (i.e., . . . 'was it foreseeable that a learned intermediary would not be present at inoculation?')").

⁸³ See, e.g., *Hurley v. Lederle Lab.*, 863 F.2d 1173, 1178 (5th Cir. 1988) (holding that where "the child's personal physician prescribed the shot, and the vaccine was administered under the supervision of the physician in his office by his nurse," the mass immunization exception was inapplicable).

⁸⁴ See *Swayze v. McNeil Lab., Inc.*, 807 F.2d 464, 471 (5th Cir. 1987) (holding that despite the physician's apparently unlawful delegation of duty to determine proper dosage of anesthetic, the physician still constituted a learned intermediary); *Hurley*, 863 F.2d at 1179. *But see* *Givens v. Lederle*, 556 F.2d 1341, 1345 (5th Cir. 1977) (applying mass immunization exception despite the fact that private physician administered the vaccine because physician's office was run much like a public clinic).

⁸⁵ See Gilhooley, *supra* note 13, at 648 n.77 (noting that "[t]he liability of the vaccine manufacturers has had an impact on the availability of vaccines . . ."). As Professor Gilhooley explained:

One reason why many manufacturers of vaccines have ceased production is because prospective liability outweighs prospective profits. The liability problems of vaccine manufacturers may be attributable, in part, to the treatment of vaccines under tort law as an exceptional drug for which manufacturers must provide patient warnings.

Id. at 689 (citation omitted); see also Sage, *supra* note 12, at 990 n.6 ("A 'liability insurance crisis' has forced many companies to stop producing vaccines.").

the potential noneconomic costs involved in adding or changing even a single word or phrase in the warning information provided.⁸⁶ Juries often erroneously conclude that giving an additional or different warning to the individual patient would have cost the manufacturer almost nothing and would have prevented considerable harm.⁸⁷ In the face of such potentially absolute liability, manufacturers can, and have, decided to exit the market altogether, at untold cost to the public.

B. *The Oral Contraceptive Exception*

The mass immunization exception was recognized very soon after the learned intermediary rule itself was announced,⁸⁸ allowing the two rules to develop harmoniously. Conversely, the other noted exception—involving oral contraceptives—was created relatively recently and has been accepted by a very small minority of courts.

The first court to recognize an exception to the learned intermediary rule for oral contraceptives was the Massachusetts Supreme Court in *MacDonald v. Ortho Pharmaceutical Corp.*⁸⁹ Plaintiff, Carole MacDonald, alleged that the warning that she had received with her birth control pills, which warned of a risk of “abnormal blood clotting which can be fatal”⁹⁰ and “may threaten life if the clots break loose and then lodge in the . . . brain”⁹¹ was inadequate due to its failure to specifically warn of the risk of stroke.⁹²

⁸⁶ Cf. *Cotton v. Buckeye Gas Prods. Co.*, 840 F.2d 935, 938 (D.C. Cir. 1988) (noting that “[t]he primary cost is, in fact, the increase in time and effort required for the user to grasp the message” and that “[t]he inclusion of each extra item dilutes the punch of every other item”).

⁸⁷ Courts are sometimes sensitive to this problem. See *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003-04 (4th Cir. 1992) (noting that “[a]ny alternative warning that [plaintiff] proposes must bear some reasonable relation to the 1.84% risk [of injury]”); see *Henderson & Twerski*, *supra* note 33, at 296-303.

⁸⁸ See *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966) (recognizing, for the first time, the learned intermediary rule); *Davis v. Wyeth Lab., Inc.*, 399 F.2d 121, 130-31 (9th Cir. 1968) (recognizing an exception to the learned intermediary rule where the vaccine is distributed at “mass clinics”).

⁸⁹ 475 N.E.2d 65 (Mass. 1985), *cert. denied*, 474 U.S. 920 (1985).

⁹⁰ *Id.* at 66 (footnote omitted).

⁹¹ *Id.* at 67 n.4.

⁹² *Id.* at 67. The warning was distributed directly to patients in the form of a label on the pill dispenser. See *id.* at 66-67 & nn.3-4. Preserved for the moment is the question of how, even accepting the court's abrogation of the learned intermediary rule, the adequacy of this relatively exhaustive warning was allowed to go to a jury. See *Henderson & Twerski*, *supra* note 33, at 303 (noting the courts' “overwhelming temptation

The *MacDonald* court noted Massachusetts precedent embracing the principles underlying the learned intermediary rule.⁹³ While recognizing the learned intermediary rule as being applicable “in jurisdictions that have addressed the question of the extent of a manufacturer’s duty to warn in cases involving prescription drugs,”⁹⁴ the court did not explicitly adopt the rule. Instead, the court simply concluded that “[o]ral contraceptives . . . bear peculiar characteristics which warrant the imposition of a common law duty on the manufacturer to warn users directly of associated risks.”⁹⁵

The *MacDonald* court then identified the justification for imposing on the manufacturer a duty to warn the consumer directly in oral contraceptive situations. The first, and seemingly most important, factor was the patient’s typically increased decision-making role in obtaining a prescription for “the pill.”

Whereas a patient’s involvement in decision-making concerning the use of a prescription drug necessary to treat a malady is typically minimal or nonexistent, the healthy, young consumer of oral contraceptives is usually actively involved in the decision to use “the pill,” as opposed to other available birth control products, and the prescribing physician is relegated to a relatively passive role.⁹⁶

This justification might be viewed as encompassing three factors. First is the principal one noted by the court—that the patient generally initiates the consideration of oral contraceptives. Second is the correspondingly diminished role of the physician whose patient specifically

. . . to view a claim as prima facie valid and thus to allow the jury to decide, putting off to another day and another place the uncomfortable task of ‘getting tough’ with plaintiffs”).

⁹³ *MacDonald*, 475 N.E.2d at 68 (citing *Carter v. Yardley & Co.*, 64 N.E.2d 693 (Mass. 1946), and RESTATEMENT (SECOND) OF TORTS § 388 cmt. n (1965)). The *MacDonald* court stated:

In such narrowly defined circumstances, the manufacturer’s immunity from liability if the consumer does not receive the warning is explicable on the grounds that the intermediary’s failure to warn is a superseding cause of the consumer’s injury, or, alternatively, that, because it is unreasonable in such circumstances to expect the manufacturer to communicate with the consumer, the manufacturer has no duty directly to warn the consumer.

Id. (citation omitted).

⁹⁴ *Id.* at 69 (citation omitted).

⁹⁵ *Id.*

⁹⁶ *Id.* (citation omitted).

requests a particular drug. Third is the notion that the use of oral contraceptives constitutes an elective course of treatment, as indicated by the court's description of pill users as "healthy, young" individuals.⁹⁷

The *MacDonald* court next examined the standard practice of prescribing and renewing prescriptions for oral contraceptives based on annual examinations.

[T]he physician prescribing "the pill," as a matter of course, examines the patient once before prescribing an oral contraceptive and only annually thereafter. . . . Thus, the patient may only seldom have the opportunity to explore her questions and concerns about the medication with the prescribing physician. Even if the physician, on those occasions, were scrupulously to remind the patient of the risks attendant on continuation of the oral contraceptive, "the patient cannot be expected to remember all of the details for a protracted period of time."⁹⁸

Once again, the court's reasoning on this point encompasses a number of interrelated factors. To begin with, the indefinite duration of the treatment is readily distinguishable from conventional prescription products. Related to the durational aspect is the lowered monitoring function served by the physician once the medication is prescribed.⁹⁹ Finally, the court's concern that the typical patient could not remember the information for extended periods of time hints at the relative complexity of the warning information provided.¹⁰⁰

The court then pointed to the "extensive Federal regulation"¹⁰¹ of oral contraceptives undertaken by the Food and Drug Administration ("FDA"), noting in particular agency findings that oral contraceptives were generally taken electively and entailed a "relatively high incidence of serious illness."¹⁰² Other FDA findings that the court relied upon supported the court's earlier conclusions that the information was too complex to be effectively disseminated orally and that absent written

⁹⁷ *Id.*

⁹⁸ *Id.* (citing 35 Fed. Reg. 9002 (1970) (requiring that a booklet containing full disclosure of risks be made available to the doctor for dissemination to the patient and that the dispensing package alert the patient of the advisability of a doctor-patient discussion of the use of the drugs)).

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.* at 69-70 (quoting 43 Fed. Reg. 4215 (1978) (requiring that labels warn of the risks of blood clots, circulatory problems, cancer and the effects on unborn children associated with the use of oral contraceptives)).

¹⁰² *Id.*

warnings directed to the patients, "many potential users of 'the pill'"¹⁰³ would be inadequately informed.

The *MacDonald* court concluded that manufacturers of oral contraceptives have a duty "to provide the consumer written warnings conveying reasonable notice"¹⁰⁴ of the risks attendant with the use of birth control pills.¹⁰⁵ The court specifically rejected the defendant's contention that its compliance with FDA labeling requirements served to "preempt or define the bounds of the common law duty to warn,"¹⁰⁶ leaving to the jury the decision of whether the warning given had been adequate.¹⁰⁷

The only other court to recognize the rule announced in *MacDonald* is the United States District Court for the Eastern District of Michigan. In two 1985 decisions, the court ruled that Michigan law required the manufacturer of a prescription drug to warn users of oral contraceptives directly.¹⁰⁸ Both cases were decided after the Michigan Supreme Court announced, in response to certified questions, that it was "not prepared . . . to state a rule of law regarding the duty of prescription drug manufacturers that depends on some other person providing warnings."¹⁰⁹ The Michigan Supreme Court thus not only declined to decide whether Michigan law provided for an oral contraceptive exception to the learned intermediary rule, but refused to determine whether the rule itself was the law in Michigan. The Michigan Supreme Court also dismissed as dictum an earlier decision purporting to recognize the learned intermediary rule and similar decisions of the intermediate appellate courts.¹¹⁰

Forced to decide the issue on its own, the United States District Court for the Eastern District of Michigan, in *Stephens v. G.D. Searle & Co.*,

¹⁰³ *Id.* at 70 (quoting 35 Fed. Reg. 9002 (1970) (requiring that a full disclosure booklet be made available to the doctor for dissemination to the patient)).

¹⁰⁴ *Id.* at 70-71.

¹⁰⁵ *MacDonald* is interesting not only because it recognized a manufacturer's duty to warn patients directly, but also because it acknowledged that manufacturers were already obligated by FDA regulations to provide such warnings. *See id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Odgers v. Ortho Pharmaceutical Corp.*, 609 F. Supp. 867 (E.D. Mich. 1985) (holding that contraceptive manufacturer has duty to warn user directly of possible side effects); *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379 (E.D. Mich. 1985) (holding that contraceptive manufacturer has duty to warn user directly of side effects when prescribed for contraceptive purposes).

¹⁰⁹ *In re Certified Questions*, 358 N.W.2d 873, 877-78 (Mich. 1984).

¹¹⁰ *Id.* at 877.

adopted the reasoning set forth by the dissent in *In re Certified Questions* and recognized an exception to the learned intermediary rule for oral contraceptives.¹¹¹ Consequently, the *In re Certified Questions* dissent warrants discussion.

The dissent in *In re Certified Questions* would have adopted the learned intermediary rule as applied to therapeutic drugs. The dissent would have based this result on the rationale that patients rely "almost completely"¹¹² on their physicians in deciding whether to take such drugs. In addition, the dissent expressed concern that any other rule would interfere with the doctor-patient relationship.¹¹³ However, the dissent distinguished common prescription practice in the oral contraceptive context from that employed with more common drugs, noting that "[t]he focus with oral contraceptives is patient choice. . . . The physician makes no assessment of medical need."¹¹⁴ In noting the pervasive "marketing and resultant widespread use of oral contraceptives,"¹¹⁵ the *In re Certified Questions* dissent indicated a belief that the manufacturers' marketing efforts increased consumer demand in a manner uncommon in the prescription drug field and thus warranted a requirement that manufacturers warn consumers directly.¹¹⁶ The dissent bolstered its conclusion with evidence that two-thirds of the women who had taken oral contraceptives before the FDA required manufacturers to provide warnings directly to patients "had never been warned of possible hazards by their physicians."¹¹⁷ In this regard, the dissent quoted a statement issued by the American Medical Association ("AMA") explaining the medical profession's position on oral contraceptives as follows: "The medical profession regards the pill, in most cases, as a convenience, rather than a traditional medication and hence the patient must bear her share [of] the legal and moral responsibility for taking it."¹¹⁸

¹¹¹ *Stephens*, 602 F. Supp. at 380-81 (discussing *In re Certified Questions*, 358 N.W.2d at 878-87 (Boyle, J., dissenting)).

¹¹² *In re Certified Questions*, 358 N.W.2d at 883.

¹¹³ *Id.* ("A warning to the patient under these circumstances could potentially . . . cause patient confusion, and result in a hampering of the healing process.")

¹¹⁴ *Id.* at 884 (citation omitted).

¹¹⁵ *Id.* at 884-85.

¹¹⁶ *Id.*

¹¹⁷ *Id.* at 885 (citing *Poll on the Pill—18 Percent of U.S. Users Have Recently Quit*, NEWSWEEK, Feb. 9, 1970, in Hearings on Present Status Competition in the Pharmaceutical Industry Before the Subcommittee on Monopoly of the Senate Committee on Small Business, 91st Cong., 2d Sess., pt. 16, p. 6628 (1970)).

¹¹⁸ *Id.* (quoting SCIENCE NEWS, Mar. 14, 1970, quoted in Note, *Liability of Birth Control Pill Manufacturers*, 23 HASTINGS L.J. 1526, 1532 (1972)).

The *In re Certified Questions* dissent refuted assertions that their holding would interfere with the physician-patient relationship and would impose an impossible duty on manufacturers. In rejecting the interference argument, the dissent relied on the special circumstances outlined above regarding prescription practice in the case of oral contraceptives.¹¹⁹ As for the impossibility argument, the dissent noted existing FDA requirements as conclusive evidence against the assertion that providing warnings to consumers would be impossible.¹²⁰ Finally, the dissent rejected the argument that allowing a state tort action would "pose[] unacceptable problems of federal-state conflict,"¹²¹ by noting language indicating that the FDA had not intended such preemption when it promulgated the regulation requiring manufacturers of oral contraceptives to provide warnings directly to the consumer.¹²²

The district court in *Stephens* adopted the *In re Certified Questions* dissent without extensive discussion.¹²³ This paucity of discussion was noted in the case of *Odgers v. Ortho Pharmaceutical Corp.*,¹²⁴ decided by the same Michigan district court later the same year. The *Odgers* court therefore undertook a more thorough review of the law before agreeing that the Michigan Supreme Court would impose upon "a manufacturer of oral contraceptives . . . a duty to warn users of its products for birth

¹¹⁹ *Id.*

¹²⁰ *Id.* at 885-86 (citation omitted). The dissent was careful to point out, however, that its reliance on the FDA provisions was solely for the purpose of refuting the manufacturer's argument regarding feasibility; the dissent's assertion that direct warnings to consumers should be required in the case of oral contraceptives did "not rest on the existence of an FDA requirement to do so." *Id.* at 886 n.15. Compare with this holding that of *Lukaszewicz v. Ortho Pharmaceutical Corp.*, 510 F. Supp. 961, *modified*, 532 F. Supp. 211 (E.D. Wis. 1981), in which a negligence per se cause of action was allowed to proceed based on the violation of federal labeling requirements. See *infra* notes 133-38, 234-40 and accompanying text.

¹²¹ *In re Certified Questions*, 358 N.W.2d at 886.

¹²² *Id.* at 886 (citing 43 Fed. Reg. 4214 (1978)).

¹²³ See *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379, 380-81 (E.D. Mich. 1985).

¹²⁴ 609 F. Supp. 867, 875 (E.D. Mich. 1985) ("Aside from describing the dissent as 'vigorous and intelligent', the court, however, failed to clearly articulate its reasons for concluding that should the Michigan Supreme Court be faced again with the question the majority would adopt the dissent's position."). Actually, the *Odgers* court's analysis is somewhat misleading, since the Michigan Supreme Court's refusal to rule on the issue was due in large part to its perception that a concrete controversy was not before it. See *In re Certified Questions*, 358 N.W.2d at 874 ("We believe that the Legislature is in a better position to allocate those duties. If, because of legislative inaction, this Court is constrained to make the choices necessary for deciding this question, it would be better to do so in a case where the factual record is fully developed . . .").

control purposes directly of any risks inherent in their use."¹²⁵ The *Odgers* court first summarized the justifications for the direct-warning requirement that the *MacDonald* and *Stephens* courts had accepted and that the *In re Certified Questions* dissent had proffered:

[The justifications for a direct-warning requirement include:] use attributed to consumer demand rather than physician's advice, use for extended periods without medical assessment, and FDA regulations requiring direct warnings to patients. In addition, the dissent and the court in *Stephens* found that consumers of oral contraceptives are subjected to much laudatory publicity attributable to the manufacturers and aimed directly at consumers.¹²⁶

The *Odgers* court placed no reliance on the marketing justification, due in part to the defendant's claims that such a justification was unsupported save for citation to a single law journal note.¹²⁷ The court considered the defendant's assertion that, because some contraceptive prescriptions were for legitimately therapeutic purposes, the risk of interference with the physician-patient relationship was more severe than previously estimated in earlier cases. The court found this threat outweighed, however, by the need for direct warnings to users.¹²⁸ In addition, the assertion that the FDA requirements in effect preempted the imposition of state tort liability was once again rejected.¹²⁹

One element considered in somewhat greater detail by the *Odgers* court was the idea that part of the rationale behind the learned intermediary rule is the notion that, in some cases, patients should not be warned directly because they might overestimate the risk and refuse treatment that they should accept.¹³⁰ This rationale was found inapplicable, since

¹²⁵ *Odgers*, 609 F. Supp. at 879.

¹²⁶ *Id.* at 875 (citations omitted). Of noteworthy significance is the language at the end of the quoted passage indicating that the manufacturer's extensive promotion of the product was a factor in the decision to require a direct manufacturer-to-patient warning. See *infra* notes 143-54 and accompanying text (discussing "over-promotion" as basis for discarding learned intermediary rule).

¹²⁷ *Odgers*, 609 F. Supp. at 876 (citing Note, *Liability of Birth Control Pill Manufacturers*, 33 HASTINGS L.J. 1526 (1972)).

¹²⁸ *Id.* at 876-77.

¹²⁹ *Id.* at 877-78.

¹³⁰ *Id.* at 878. Another justification sometimes given for the actual withholding of information from the patient is the so-called "therapeutic privilege." See *supra* cases cited notes 59 & 113. See generally Gilhooley, *supra* note 13, at 655-56, 686-87 (discussing the "therapeutic privilege" that allows physicians to withhold information from a patient

“rejection of an oral contraceptive for purposes of birth control . . . is not life threatening.”¹³¹ Similarly, as in *Stephens*, the *Odgers* court referred to the FDA requirements already in place in rejecting the assertion that directly warning consumers was prohibitively difficult. The court also refuted the assertion that the FDA requirements effectively mandated the substantive content of the warning.¹³²

One final case that warrants consideration in this context is *Lukaszewicz v. Ortho Pharmaceutical Corp.*,¹³³ which preceded but has been said to have anticipated the 1985 Michigan and Massachusetts cases.¹³⁴ In *Lukaszewicz*, the court accepted a negligence per se theory based on the defendant company’s violation of FDA regulations requiring direct written warnings to consumers.¹³⁵ As one commentator has noted, however, the *Lukaszewicz* court’s reliance on the violation of universally followed warning requirements renders its current significance highly questionable.¹³⁶ Perhaps more importantly, *Lukaszewicz* is not so much an exception to the learned intermediary rule as it is a determination that particular federal regulations should form the basis for a state tort law action.¹³⁷ Nonetheless, the case did formulate a duty on the part of oral contraceptive manufacturers to warn patients directly. Moreover, *Lukaszewicz* might, in fact, represent a better balancing of interests than that reached in the 1985 cases due to its reliance on objectively ascertainable standards of which the manufacturer was aware prior to commencement of litigation.¹³⁸

The oral contraceptive exception to the learned intermediary rule has not been widely accepted by other courts¹³⁹ and has been the target of criticism from numerous commentators.¹⁴⁰ Nonetheless, the exception

when the information is not in the patient’s best interests).

¹³¹ *Odgers*, 609 F. Supp. at 878.

¹³² *Id.* at 878-79 (citation omitted).

¹³³ 510 F. Supp. 961, *modified*, 532 F. Supp. 211 (E.D. Wis. 1981).

¹³⁴ See Gilhooley, *supra* note 13, at 649 n.82.

¹³⁵ *Lukaszewicz*, 510 F. Supp. at 963-64 (citation omitted).

¹³⁶ See Flannagan, *supra* note 39, at 416-17 (stating that under *Lukaszewicz*, “the manufacturer need only comply with the regulations to fulfill its duty to warn the consumer directly”).

¹³⁷ See *id.* at 417 (stating that the *Lukaszewicz* court merely utilized an alternative theory of recovery—violation of a federal regulation).

¹³⁸ See *infra* notes 230-36 and accompanying text.

¹³⁹ See *MacPherson v. Searle & Co.*, 775 F. Supp. 417, 425 (D.D.C. 1991) (“The dissent to the *MacDonald* decision noted that ‘no other court has embraced the rule laid down today by the court,’ . . . and that observation appears to remain true today.” (citations omitted)).

¹⁴⁰ See, e.g., Gilhooley, *supra* note 13, at 651 (“Although there are some important

definitely survives in Massachusetts and, possibly, in Michigan.¹⁴¹ Hopeful plaintiffs will no doubt continue to extol the reasoning applied in those few cases in hopes of imposing liability on the manufacturers of prescription drugs. Moreover, the reasoning applied in those cases recognizing the oral contraceptive exception has been influential in other contexts¹⁴² and is thus of continuing significance.

C. Over-Promotion

According to the "over-promotion" or "advertising" exception to the learned intermediary rule, a prescription drug manufacturer might, in effect, assume a duty to warn consumers directly if the manufacturer's efforts to market its product to the consumer are viewed as excessive.¹⁴³

differences between therapeutic drugs and elective drugs, in the end these differences do not seem as important as the similarities among prescription drugs."); McKenna, *supra* note 61, at 960 & 960 n.76 (citing Fern, *supra* note 12, at 15-18, and Flannagan, *supra* note 39, at 419-20); Flannagan, *supra* note 39, at 420 (noting that "[i]t is possible that the MacDonal standard imposes an 'absolute liability' which could inevitably prompt oral contraceptive manufacturers to withdraw their product from the market").

¹⁴¹ Michigan law on the subject is unclear. While the Michigan Supreme Court has been silent on the issue since it refused to resolve the conflict in *In re Certified Questions*, 358 N.W.2d 873 (Mich. 1984), a judge in the same federal district court in which *Stephens* and *Odgers* were decided has ruled that Michigan law encompasses the learned intermediary rule and makes no exception for oral contraceptives. *Reaves v. Ortho Pharmaceutical Corp.*, 765 F. Supp. 1287, 1291 (E.D. Mich. 1991). See also *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024, 1032 & n.5 (D.N.J. 1988) (stating that "the Michigan cases are of questionable precedential value" based on the existence of a Sixth Circuit decision applying the learned intermediary rule and a Michigan Court of Appeals decision applying the rule in a case involving contraceptives (citing *Beyette v. Ortho Pharmaceutical Corp.*, 823 F.2d 990, 992 (6th Cir. 1987) and *Mowery v. Crittenton Hosp.*, 400 N.W.2d 633 (Mich. App. 1986))).

¹⁴² See, e.g., *Hill v. Searle Lab.*, 884 F.2d 1064, 1070-71 n.11, 1071 (8th Cir. 1989) (recognizing an exception to the learned intermediary rule for IUDs) (citing *Odgers v. Ortho Pharmaceutical Corp.*, 609 F. Supp. 867 (E.D. Mich. 1985) and *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65 (Mass.) (recognizing an exception to the learned intermediary rule for oral contraceptives), *cert. denied*, 474 U.S. 920 (1985)). See *infra* notes 170-200 and accompanying text.

¹⁴³ See, e.g., *Hill*, 884 F.2d 1064, 1071 (recognizing exception to learned intermediary rule in IUD case based, in part, on the fact that the manufacturer "marketed the product with the idea of convincing women to choose" to use it); *Garside v. Osco Drug, Inc.*, 764 F. Supp. 208, 211 n.4 (D. Mass. 1991) ("In an appropriate case, the advertising of a prescription drug to the consuming public may constitute a third exception to the learned intermediary rule [, the other two being vaccines and, in some jurisdictions, oral contraceptives]. By advertising directly to the consuming public the manufacturer bypasses the traditional patient-physician relationship, thus lessening the role of the

Earlier cases involving intensive marketing efforts directed toward the medical community provide support for such a policy requiring direct manufacturer-to-patient warnings because of manufacturer over-promotion.¹⁴⁴

The court in *Love v. Wolf*¹⁴⁵ laid the foundation for the principle that a manufacturer's warnings could be diluted by excessive promotion efforts that caused physicians to overlook the warning information given to them.¹⁴⁶ The *Love* court determined that a genuine issue of material fact existed regarding whether the manufacturer had "watered down its regulatory-mandated warnings and had caused its detail men to promote a wider use of the drug by physicians than proper medical practice justified."¹⁴⁷ The court's discussion of the intensive marketing efforts of the drug manufacturer, and the resulting conclusion that these efforts had diluted the effectiveness of the warnings given, could be relied upon in the somewhat analogous context of bypassing the learned intermediary rule in cases involving excessive promotional efforts of drug manufacturers.¹⁴⁸

'learned intermediary.'"), *rev'd on other grounds*, 976 F.2d 77 (1st Cir. 1992).

¹⁴⁴ *Holley v. Burroughs Wellcome Co.*, 348 S.E.2d 772, 777 (N.C. 1986) (stating that "the failure of medical personnel to timely recognize and treat such condition [if due to overpromotion] . . . would establish the essential element of proximate cause in plaintiff's negligence action"); *Mahr v. G.D. Searle & Co.*, 390 N.E.2d 1214, 1238 (Ill. App. Ct. 1979) (stating that "the jury was entitled to consider [evidence of overpromotion] in arriving at a decision as to the adequacy of the warnings").

¹⁴⁵ 38 Cal. Rptr. 183 (Ct. App. 1964). *Love* also recognized the doctrine that became the learned intermediary rule. *Id.* at 192 ("Parke-Davis has no contact with the ultimate consumer of the drug, the patient. The duty, therefore, whatever its extent may be, must be a duty to warn the doctor who prescribes the drug.").

¹⁴⁶ *Id.* at 193.

¹⁴⁷ *Id.* at 197. The drug involved in *Love*, Chloromycetin, was over-promoted despite evidence of its unreasonable dangers. See *Sage*, *supra* note 12, at 1018 n.118 which stated:

Despite conclusive evidence of the drug's danger and the fact that it was superior to other antibiotics in only a handful of emergencies, Parke-Davis downplayed the drug's toxicity so effectively that ten years after the discovery of its adverse effects, Chloromycetin was being prescribed wrongly in about 90% of cases, including for acne and the common cold.

(citing MILTON SILVERMAN & PHILLIP R. LEE, PILLS, PROFITS AND POLITICS 59-61, 283-88 (1974)). *Cf. id.* at 1017 ("Drug companies spend nearly as much money on promotion as American medical schools spend on all their educational activities." (citation omitted)).

¹⁴⁸ *Love*, 38 Cal. Rptr. at 193 ("[E]ven conceding a proper warning had been given Dr. Wolf and the rest of the medical profession, such warnings must be deemed cancelled out if over-promotion through a vigorous sales program persuaded doctors to disregard the warnings given.").

The theme in *Love* is evident in other oral contraceptive cases, insofar as those cases consider consumer demand as a result of advertising to be a factor in creating an exception to the learned intermediary rule.¹⁴⁹ In *Love*, the result was that an otherwise adequate warning was found to have been so diluted by promotion as to be rendered inadequate.¹⁵⁰ In the oral contraceptive or other prescription drug context, it might be similarly found that a manufacturer can assume a duty to warn consumers directly when the manufacturer, through marketing activities directed toward the consumer, in effect "bypasses the traditional patient-physician relationship"¹⁵¹ and thus causes exceptional consumer demand.¹⁵² The effect of over-promotion is quite similar to that observed in the oral contraceptive context in that patients are presumed to play a greater role in seeking out and deciding to take the medication, while doctors are uncharacteristically excluded from the decision-making process.

The over-promotion basis for creating an exception to the learned intermediary rule was recently invoked in *Hill v. Searle Laboratories*.¹⁵³ In *Hill*, an IUD manufacturer was found to have marketed its product directly to the consumer, thus increasing demand for the product and diminishing the physician's relative role in the decision-making process.¹⁵⁴ *Hill* thus represents the continuing evolution of the learned intermediary rule and, particularly, the potential impact that marketing efforts can have on manufacturer liability for failure to warn.

D. The Head-On Challenges

The discussion of exceptions to the learned intermediary rule has thus far focused on limited exceptions based on particular applications of the rule. Courts have generally limited the exceptions to fact-specific situations; even Massachusetts and Michigan retain the learned intermediary rule outside the oral contraceptive context.¹⁵⁵ However, some commentators have called for total abrogation of the rule and posit a number of justifications for doing so.

¹⁴⁹ See *supra* notes 116, 126-27 and accompanying text.

¹⁵⁰ *Love*, 38 Cal. Rptr. at 196.

¹⁵¹ *Garside v. Osco Drug, Inc.*, 764 F. Supp. 208, 211 n.4 (D. Mass. 1991), *rev'd on other grounds*, 976 F.2d 77 (1st Cir. 1992).

¹⁵² *Id.*

¹⁵³ 884 F.2d 1064 (8th Cir. 1989).

¹⁵⁴ *Id.* at 1071.

¹⁵⁵ See, e.g., *Garside*, 764 F. Supp. 208 (D. Mass. 1991) (applying learned intermediary rule under Massachusetts law), *rev'd on other grounds*, 976 F.2d 77 (1st Cir. 1992); *Mowery v. Crittenton Hosp.*, 400 N.W.2d 633 (Mich. Ct. App. 1986) (holding that under Michigan law a manufacturer has no duty to warn consumer directly).

The most serious justification for abrogation of the learned intermediary rule is the assertion that the learned intermediary rule is based on an erroneous assumption that doctors are equipped to provide adequate warnings to consumers. In this regard, some commentators maintain that doctors are woefully unprepared to provide adequate warnings to consumers.¹⁵⁶ Putting warning material directly into the hands of patients would supplement warnings provided by the overloaded physician and facilitate a more focused consideration of the warning information by the patient, who does not have the distraction of warnings concerning myriad other drugs. As one commentator put it, "the patient is not concerned with knowing the risks of a broad spectrum of drugs, but only of the risks of the drug prescribed."¹⁵⁷

Another challenge to the learned intermediary rule is based on the right of a patient to be fully informed of the risks of any drug she takes.¹⁵⁸ In this regard Margaret Gilhooley points to the changing face of the informed consent doctrine, which has been moving away from what she considers a paternalistic standard and toward a greater emphasis on patient autonomy, as a justification for the rule's abrogation. Gilhooley thus suggests that the learned intermediary rule is a remnant of the days when patients were expected to follow doctors' orders without question, and argues that the learned intermediary rule should be replaced by a requirement that manufacturers of prescription drugs warn consumers

¹⁵⁶ See, e.g., Gilhooley, *supra* note 13, at 670 ("Recent developments have shown, however, that [the assertion that physicians will adequately inform patients] is suspect—there are serious drawbacks in relying solely on the physician to provide risk information to patients orally."); Sage, *supra* note 12, at 1001 ("Indeed, there is overwhelming evidence that physicians work with inadequate information [regarding drug risks], a problem that manufacturers alone cannot remedy." (citation omitted)); Donald E. Thompson II, *The Drug Manufacturer's Duty to Warn—To Whom Does It Extend?*, 13 FLA. ST. U. L. REV. 135, 143 (1985) ("The doctrine substantially overstates the ability and willingness of the medical community to act as a 'learned intermediary,' impedes the right of the patient to knowledge of the substances which he places in his body, and ignores the substantial benefits derived from having an informed patient."); *id.* at 145 ("[I]n light of the constant bombardment with large volumes of rapidly changing drug literature, the physician is 'unable to keep up with this ever-changing sea of knowledge.'" (citation omitted)).

Of course, these commentators assume that doctors are supposed to pass warnings along to consumers, as opposed to simply deciding for the patient which drugs are appropriate. See *supra* notes 55-67 and accompanying text (discussing different theories of the physician's role in the intermediary context).

¹⁵⁷ Thompson, *supra* note 156, at 145.

¹⁵⁸ Gilhooley, *supra* note 13, at 654-55.

directly.¹⁵⁹ In essence, this challenge to the learned intermediary rule states that patients should have full information and decide for themselves what goes into their bodies.

Apart from the issue of what a patient ought to know in order to decide whether or not to ingest a drug is the issue of what a patient needs to know in order to use a drug safely and to monitor its effects. Critics of the learned intermediary rule who assert safety concerns as a justification for abandoning the rule generally assume, reasonably enough, that manufacturers who are left open to liability will provide warning information directly to patients.¹⁶⁰ Such commentators contend that patients who are better informed can recognize danger signs and thus ensure proper use of medications.¹⁶¹ The goal sought by these writers is greater patient information, which would presumably result in more informed patients who are better able to safely use drug products;¹⁶² the means to the end is manufacturer liability for failure to warn.

Finally, many commentators have made attempts to attack the learned intermediary rule on economic grounds. Some of these commentators contend that the learned intermediary rule removes any economic incentive a manufacturer might have to ensure that patients are adequately warned.¹⁶³ Commentators also point to the inefficiency of burdening physicians with the responsibility of ensuring that adequate warnings are given.¹⁶⁴ One writer, anticipating challenges to mandatory patient inserts

¹⁵⁹ Gilhooley, *supra* note 13, at 653-58, 673-74; *see also* Thompson, *supra* note 156, at 146 ("Undoubtedly, the single most important reason for imposing upon the manufacturer of prescription drugs the duty to warn consumers of possible side effects is the notion of informed consent.").

¹⁶⁰ Gilhooley, *supra* note 13, at 672-73; Thompson, *supra* note 156, at 150-53. *But see infra* notes 229-35 and accompanying text (arguing that prescription drug manufacturer liability might, in fact, leave manufacturers unable to meet unrealistic duties to warn and force many to exit the market altogether). Commentators also tend to assume that manufacturer liability would lead to written warnings to patients from the manufacturers, which would be in addition to the oral warnings received from the physician. The advantages of written warnings are thus incorporated into the gains to be expected if the learned intermediary rule were abolished. *See* Gilhooley, *supra* note 13, at 672-73; Thompson, *supra* note 156, at 151.

¹⁶¹ *See* Thompson, *supra* note 156, at 150.

¹⁶² *See* Gilhooley, *supra* note 13, at 672-73; Thompson, *supra* note 156, at 150.

¹⁶³ *See* McGarey, *supra* note 51, at 140 ("From an economic standpoint, there is no reason to provide consumers with information where no liability is imposed. Additionally, judicial language suggesting that consumer-direct labeling is not effective to communicate warnings to consumers further dampens manufacturer incentive to provide such information.").

¹⁶⁴ *See id.* at 144.

on cost grounds, cited surveys indicating consumer willingness to pay a few cents extra per prescription in exchange for written warning information.¹⁶⁵

The above-cited commentators raise a number of valid points and clearly establish imperfections in the learned intermediary rule. The fact remains, however, that the rule is virtually universally accepted by courts and is subject to only a few limited exceptions. Nonetheless, the issue of whether those exceptions should be expanded, or indeed whether the rule itself should be discarded, is far from settled. Moreover, it is clear that the learned intermediary rule will play an increasingly important role in pending and ongoing litigation concerning breast implants, IUDs and other medical devices.

IV. DEVICE CASES: A NEW SHAPE FOR THE DOCTRINE?

The learned intermediary rule was developed in the context of prescription drugs, but the policies behind the rule have led many courts to extend the rule's application to medical device cases.¹⁶⁶ However, this application is by no means universal, and some courts have indicated a variety of factors that will be considered in deciding whether to apply

¹⁶⁵ Thompson, *supra* note 156, at 152 n.96 ("A survey of certain television viewers found that 69% of the noon and 57% of the evening viewers said they were willing to pay an additional thirty cents per prescription to receive patient package inserts. Of those not willing to pay thirty cents, 69% of the noon and 64% of the evening viewers were willing to pay an additional ten cents." (citing 45 Fed. Reg. 60,754, 60,759 (1980))). See also Gilhooley, *supra* note 13, at 679 ("[P]atients have expressed a willingness to pay more for the benefits that they perceive will be derived from patient labeling than the FDA has estimated the labeling might actually cost them." (citation omitted)); McGarey, *supra* note 51, at 147-48 (Patient package inserts "would add only 1.5 cents to the cost of a prescription [and] . . . the average cost of a prescription [is] \$11.20." (citations omitted)).

¹⁶⁶ See, e.g., *Bravman v. Baxter Healthcare Corp.*, 984 F.2d 71, 75 (2d Cir. 1993) (accepting the argument that under the learned intermediary rule, heart valve manufacturer's "duty to warn, if any, was to give information to [the treating physician] as a 'learned intermediary'"); *Phelps v. Sherwood Medical Indus.*, 836 F.2d 296, 303 (7th Cir. 1987) (finding "no principled basis" on which to distinguish prescription drugs from medical devices); *Zanzuri v. G.D. Searle & Co.*, 748 F. Supp. 1511, 1514-18 (S.D. Fla. 1990) (applying the learned intermediary rule in IUD case without distinguishing prescription drugs from medical devices); *Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89, 94-95 (D. Md. 1989) (holding that under the learned intermediary rule, the manufacturer's duty to warn of risks of rupture of breast prosthesis was satisfied by warning the physician); *Collins v. Ortho Pharmaceutical Corp.*, 231 Cal. Rptr. 396, 399 (1986) (IUD case holding that products—drugs and devices—are to be treated alike); *Perfetti v. McGhan Medical*, 662 P.2d 646, 650 (N.M. Ct. App.) (mammary prosthesis case finding that the manufacturer's duty was to warn the physician, not the patient), *cert. denied*, 662 P.2d 645 (N.M. 1983).

the learned intermediary rule in medical device cases.¹⁶⁷ The current wave of high-profile cases involving controversial devices such as IUDs and breast implants will test the appropriateness of the rule's application in device cases and will perhaps prompt a reexamination of the rule itself. For these reasons, this portion of the Note considers the viability of the learned intermediary rule in medical device cases generally, with emphasis on recent cases involving IUDs and breast implants,¹⁶⁸ and

¹⁶⁷ See *Hill v. Searle Lab.*, 884 F.2d 1064, 1071 (8th Cir. 1989) (holding that IUD manufacturer must warn patients directly, based on diminished role of physician in decision-making process).

¹⁶⁸ This discussion is undertaken despite the possibility that failure-to-warn claims involving medical devices might eventually be deemed to be preempted by federal regulations. See *Desmarais v. Dow Corning Corp.*, 712 F. Supp. 13, 16 (D. Conn. 1989) (holding that Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act worked to preempt failure-to-warn claims based on breast implants received after Amendments' effective date). The law remains unclear as to whether failure-to-warn claims involving breast implants, IUDs and other medical devices will be preempted by section 360K(a) of the Amendments, which provides:

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (1988). In IUD cases, a number of factors may bear on whether or not preemption bars state failure-to-warn claims. To date, *Desmarais* is the only breast implant case finding preemption, and its preemption holding was not necessary to the case because the plaintiff in *Desmarais* received her implants prior to the Amendments' effective date. *Desmarais*, 712 F. Supp. at 15. A more recent decision allowed a claim involving implants received *after* the Amendments took effect to proceed without reference to the preemption issue. *Toole v. McClintock*, 778 F. Supp. 1543 (M.D. Ala. 1991). Thus, the status of preemption remains unclear. However, preemption may eventually provide the best balance for resolving failure-to-warn claims in the prescription drug and device context. See *infra* notes 236-42 and accompanying text.

While the preemption issue is beyond the scope of this Note, suffice it to say that the law remains unclear, and the learned intermediary rule's viability continues in device cases. Moreover, the rule might still have a role even if preemption is conclusively established. As previously indicated, the learned intermediary rule does not involve the adequacy or form of warnings, but only concerns the issue of to whom warnings must be given. See *supra* text following note 38. Thus, even if federal warning and labeling requirements set the standard of what warnings might be given, it is still conceivable that state law, via judicial decision, could require direct manufacturer-to-patient warnings and thereby, at least tangentially, broach the issue of the learned intermediary rule. The *Lukaszewicz* case, which allowed a negligence per se claim based on failure to comply with federal labeling regulations, see *supra* notes 133-38 and accompanying text, is

reevaluates in this context the benefits of the learned intermediary rule in general.

A. IUDs

Thus far, courts have almost unanimously applied the learned intermediary rule in IUD cases.¹⁶⁹ The one glaring exception is the case of *Hill v. Searle Laboratories*.¹⁷⁰ Likening IUDs to birth control pills, the *Hill* court refused to apply the learned intermediary rule to such devices and held that the manufacturer of an IUD must warn consumers directly.¹⁷¹ Because the comprehensive challenge to the learned intermediary rule which prevailed in *Hill* could serve as a model for future challenges to the rule, a closer look at the *Hill* decision is warranted.

The *Hill* decision reflects an analysis of the two primary justifications for the learned intermediary rule and the specific exceptions to the rule that courts have recognized. Relying on both the oral contraceptive exception¹⁷² and the mass immunization exception,¹⁷³ the *Hill* court determined that the learned intermediary doctrine was inapplicable to manufacturers of IUDs:

representative of this continued possibility. Such state actions would seemingly not entail different, or even additional, requirements but would instead simply allow a state action based on failure to meet federal requirements. In any event, consideration of the learned intermediary rule in device cases provides a useful testing ground for the learned intermediary rule's continued viability generally.

¹⁶⁹ See, e.g., *Odom v. G.D. Searle & Co.*, 979 F.2d 1001 (4th Cir. 1992) (Cu-7 IUD); *Beyette v. Ortho Pharmaceutical Corp.*, 823 F.2d 990 (6th Cir. 1987) (Lippes Loop IUD); *Zanzuri v. G.D. Searle & Co.*, 748 F. Supp. 1511 (S.D. Fla. 1990) (Cu-7 IUD); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293 (D. Minn. 1988) (Cu-7 IUD); *McKee v. Moore*, 648 P.2d 21 (Okla. 1982) (Lippes Loop IUD). It should be noted that the Cu-7 IUD is classified as a prescription drug and thus is not really an extension of the learned intermediary rule to device cases. On the other hand, this fact may make the decision in *Hill v. Searle Laboratories* to except the Cu-7 IUD from the learned intermediary rule, see *infra* notes 170-200 and accompanying text, a somewhat more significant deviation from common practice than if the case had involved a device that was not classified as a drug. In any event, the distinction of drug from device should not be controlling: the recipient of a medical device, just like the recipient of a prescription for medication, "is expected to and, it can be presumed, does place primary reliance upon" the physician in deciding whether to consent to the treatment. *Terhune v. A.H. Robins Co.*, 577 P.2d 975, 978 (Wash. 1978) (Dalkon Shield). Indeed, the court in *Terhune* found no legitimate basis on which to distinguish "devices such as the Dalkon Shield" from prescription drugs. *Id.*

¹⁷⁰ 884 F.2d 1064 (8th Cir. 1989).

¹⁷¹ *Id.* at 1071.

¹⁷² See *supra* notes 88-142 and accompanying text.

¹⁷³ See *supra* notes 75-87 and accompanying text.

Recognizing that these factors limit the role that a physician plays in determining the necessity and desirability of birth control, and the fact that physicians are inundated with information about various prescription drug products, we think that in the case of IUDs, prescribing physicians do not make an individualized medical judgment. Thus, Hill's treating physician was not an intervening party between herself and Searle. It was feasible to warn Hill. Moreover, such warning was required by FDA regulation. Therefore, the trial court erred in applying the learned intermediary rule to the facts of this case.¹⁷⁴

In carving out an IUD exception, the *Hill* court, in effect, employed virtually every factor that has heretofore been applied or asserted to justify exceptions to the learned intermediary rule. The primary reason for creating an IUD exception was the court's impression that the patient's increased role in the decision-making process, and the doctor's uncharacteristically "limited input"¹⁷⁵ into the making of that decision, readily distinguish the use of an IUD from use of typical prescription drugs.¹⁷⁶ In concluding that a patient-doctor role reversal had occurred in the IUD context, the court "shotgunned" a number of individual factors into the balance, all within one paragraph and with little or no explanation of how each factor was particularly significant in the context of IUDs as opposed to other drugs. The following discussion considers these factors independently in order to determine their collective worth.

1. Patient Choice

The *Hill* court, like other courts recognizing an exception for oral contraceptives,¹⁷⁷ placed great weight on the fact that patients themselves seek out IUDs from their physicians, thereby diminishing the typically exclusive control that physicians exercise over treatment selection.¹⁷⁸ While this characterization might reflect common practice, the physician's role in *selecting* a general course of treatment, such as intrauterine birth control, is in reality only a small part of the justification for the learned intermediary rule. More important is the physician's expert knowledge of the treatment and the product, and his or her ability to match a given treatment with a given patient according to the characteris-

¹⁷⁴ *Hill*, 884 F.2d at 1071 (citations omitted).

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

¹⁷⁷ See *supra* notes 88-142 and accompanying text.

¹⁷⁸ *Hill*, 884 F.2d at 1071.

tics of both. The mere fact that a patient walks into the doctor's office and mouths the letters "IUD" hardly relieves the physician of his or her duty to independently gauge the benefits and costs of that patient's use of an IUD and to obtain the patient's informed consent prior to agreeing to perform the operation or prescribe the product.

2. *The Patient's Retention of "Final Choice" in Deciding on a Method of Contraception*

The *Hill* opinion also stresses the fact that "the final choice" among methods of birth control "remains that of the woman."¹⁷⁹ This assertion, like the focus on patient initiative in seeking out treatment, assumes that physicians play no meaningful role in the decision-making process. More importantly, however, the assertion implies that the final choice in other treatment contexts rests with someone other than the patient. This is simply not the case. Whether the prescription is for penicillin or triple bypass surgery, the patient always retains final authority to determine what is done to, or ingested by, his or her body.¹⁸⁰ The physician is relied upon to assist in making that determination, and patients inevitably vary as to the extent to which they will rely on the physician's advice. Nonetheless, in the vast majority of treatment contexts, the patient, in the end, makes the decision.

3. *The Decreased Level of Physician Supervision or Monitoring After the Insertion of the IUD*

The *Hill* court also noted that the patient in the case at bar had no contact with her prescribing physician "for over two years after receiving the [IUD]."¹⁸¹ The court apparently viewed this scenario as typical, without further documentation, and implied that the lack of physician monitoring justified requiring manufacturer-to-patient warnings.¹⁸² Assuming that such long-term monitoring is necessary due to the long-term use of IUDs, it remains open to question how manufacturer-to-patient warnings are more effective than physician-to-patient warnings in the case of long-term treatments.

¹⁷⁹ *Id.*

¹⁸⁰ *Cf. Terhune v. A.H. Robins Co.*, 577 P.2d 975, 978 (Wash. 1978) ("There is, for example, a patient's choice between continuing to endure a physical ailment or submitting to surgery or some other course of treatment . . .").

¹⁸¹ *Hill*, 884 F.2d at 1071 n.12.

¹⁸² *Id.*

Obviously, if the manufacturer provides written inserts, the patient will be better able to refresh his or her knowledge of the warnings over a long period of time.¹⁸³ This advantage is somewhat dubious, however, in the case of an IUD. The nature of the risks associated with IUDs are such that a patient should ideally weigh them fully before having the device installed; once the IUD is inserted, the danger has been accepted, and the treatment requires no further action. Compare this with oral contraceptives, which because they generally are taken daily entail a recurring and deliberate exposure to danger by the patient, and thus make a better case for repetitive warnings. The advantage of written inserts accompanying IUDs must therefore be attributed primarily to the need for patient self-monitoring in the absence of regular physician supervision. Certainly, written warnings in this context could conceivably fill any gap left by a perceived lack of physician monitoring.

What is not clear is why an asserted need for written warnings necessitates manufacturer-to-patient warning. Obviously, the manufacturer has greater access to the distribution network and is generally in a better position both to produce and distribute written warnings. But if the void that creates the need for written warnings is due to the physician's failure to monitor, shifting the duty to the manufacturer, while also expanding the duty to entail written warnings, is not an altogether satisfactory remedy.

4. *The Manufacturer's Efforts to Market the Product*

The *Hill* court suggested that the manufacturer's marketing efforts warranted a deviation from the learned intermediary rule.¹⁸⁴ The notion that "over-promotion" might justify an exception to the learned intermediary rule can be traced to relatively established doctrine,¹⁸⁵ and one can imagine cases in which advertising is so pervasive as to compel an exception to the learned intermediary rule. However, factual findings of this sort were not made by the court in *Hill*, which stated only that

¹⁸³ The asserted need for written warnings has formed the basis of several articles calling for the abolition of the learned intermediary rule. See, e.g., Gilhooley, *supra* note 13, at 672-75 (detailing the reasons why increased patient information promotes tort objectives); McGarey, *supra* note 51, at 138-41 (arguing that direct written warnings to the patient provide better protection than is provided under the learned intermediary rule).

¹⁸⁴ *Hill*, 884 F.2d at 1071.

¹⁸⁵ See *supra* notes 143-54 and accompanying text (discussing the over-promotion exception to learned intermediary rule). The issue of drug manufacturer advertising and its impact on liability is an interesting topic worthy of greater consideration than the cursory treatment it receives in this Note and in *Hill*.

“Searle marketed the product with the idea of convincing women to choose the CU-7 [IUD].”¹⁸⁶ Thus, the *Hill* decision provides no indication of the types or extent of advertising or marketing activities that may cause a manufacturer to be held liable for not providing warnings directly to consumers. Indeed, the language in *Hill* leaves the possibility open that *any* marketing efforts by a pharmaceutical company could conceivably be the factor that tips the scales in favor of liability for failure to warn. While marketing activities, in extreme form, might in a rare case justify an exception to the learned intermediary rule, one would hope that the underlying facts surrounding those activities—and not the mere existence of such activities—would form the basis for the exception.

5. *FDA Regulations Required Warnings Directly to the Consumer*

The *Hill* court rather summarily concluded, based on the foregoing factors, that “in the case of IUDs, prescribing physicians do not make an individualized medical judgment,”¹⁸⁷ and thus “Hill’s treating physician was not an intervening party.”¹⁸⁸ Subsequently, almost as an afterthought, the court added that “[i]t was feasible to warn Hill” and, “[m]oreover, such warning is required by FDA regulation.”¹⁸⁹

The presence of FDA regulations has been similarly relied upon in another case, *Lukaszewicz v. Ortho Pharmaceutical Corp.*¹⁹⁰ In *Lukaszewicz*, the court employed a negligence per se theory to impose liability upon the manufacturer of an oral contraceptive based on its failure to comply with federal package insert requirements.¹⁹¹ The *Lukaszewicz* holding, however, creates not so much an exception to the learned intermediary rule as it implies a state cause of action based on a violation of existing federal regulations. Likewise, in *Hill* there was a dispute as to whether the patient had received the FDA-required warnings.¹⁹² Thus, insofar as it was willing to base a damages claim on

¹⁸⁶ *Hill*, 884 F.2d at 1071.

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

¹⁹⁰ 510 F. Supp. 961, *modified*, 532 F. Supp. 211 (E.D. Wis. 1981). See *supra* notes 133-38 and accompanying text.

¹⁹¹ *Lukaszewicz*, 510 F. Supp. at 965 (applying 21 C.F.R. § 310.501 (1975), which required manufacturers of oral contraceptives to include warnings in the form of package inserts to be distributed to patients as well as physicians).

¹⁹² *Hill*, 884 F.2d at 1066.

failure to comply with such regulations, the decision in *Hill* is not entirely without precedent. However, the *Hill* court made it clear that it was creating a categorical exception for IUDs, not one limited to cases in which noncompliance with federal regulations was established.¹⁹³

6. The "Clinic-Type Conditions" Under Which IUDs Are Given

The *Hill* court's bald assertion that IUDs are usually inserted under "clinic-type conditions" attempts to analogize IUD cases to those involving mass immunizations.¹⁹⁴ This analogy echoes the theme that physicians do not exercise medical judgment in prescribing IUDs and ignores the physician's nondelegable duties to inform herself and her patient before commencing treatment or prescribing drugs.¹⁹⁵ Indeed, the *Hill* court's attempt to analogize IUD practice to the mass immunization practice is perhaps the chief flaw of the decision.

The court's consideration of the various factors listed above was triggered by language in the landmark vaccine case *Reyes v. Wyeth Laboratories*,¹⁹⁶ which the court erroneously interpreted as requiring a case-by-case inquiry into the nature of the physician-patient relationship in order to determine whether to apply the learned intermediary rule. The language in *Reyes* on which the *Hill* court relied stated "that there must either be a warning—meaningful and complete so as to be understood by the recipient—or an individualized medical judgment that this treatment or medication is necessary and desirable for this patient."¹⁹⁷ The *Reyes* holding is well-established and is the source of a continuing line of cases concerning the mass immunization exception to the learned intermediary rule. However, reliance on the *Reyes* holding in a case such as *Hill* is entirely misplaced.

Reyes and its progeny concern prophylactic dispensation of vaccines, typically by nurses or other nonphysicians at public health clinics where there either is no doctor or there is not an established physician-patient

¹⁹³ *Id.* at 1071 ("[W]e think that in the case of IUDs, prescribing physicians do not make an individualized medical judgment.").

¹⁹⁴ *Id.* (citing *Plummer v. Lederle Lab.*, 819 F.2d 349 (2d Cir. 1987)). See *supra* notes 75-87 and accompanying text (discussing the mass immunization exception).

¹⁹⁵ See Gilhooley, *supra* note 13, at 653-58 (discussing the rationale and nature of informed consent doctrine).

¹⁹⁶ 498 F.2d 1264 (5th Cir. 1974). The *Reyes* court, in fact, was operating in the limited field of mass immunizations and did not opine as to the physician-patient relationship in other contexts.

¹⁹⁷ *Hill*, 884 F.2d at 1070 (citing *Reyes*, 498 F.2d at 1295).

relationship.¹⁹⁸ Most courts have held that the mere presence of a physician-patient relationship, even if the actual administering of the drug is done by a nurse, invokes the learned intermediary rule.¹⁹⁹ Such an approach has two distinct advantages. First, it places manufacturers and physicians in their appropriate roles. Thus, as noted in a recent decision:

The [manufacturer] cannot control the individual practices of the medical community [even if prevailing practice in the locale is for doctors to delegate important functions], and we decline to impose such a duty. Drug manufacturers must adequately warn physicians of the potential side-effects of their prescription drugs; thereafter, the physician, with his special knowledge of the patient's needs, assumes the burden of presiding over the patient's best interests.²⁰⁰

The second advantage of this more limited construction of the mass immunization exception is that it recognizes the impracticability of conducting a factual inquiry into the circumstances surrounding each prescription of a drug and instead presumes that the learned intermediary rule will apply unless special factors dictate otherwise. One such factor would be the absence of a physician-patient relationship. However, a mere perceived lack of particular qualities in that relationship does not warrant an exception to the learned intermediary rule. The mass immunization exception as described in *Reyes* is thus best viewed as a narrow exception to the learned intermediary rule, not as the foundation for a

¹⁹⁸ See *supra* notes 75-87 and accompanying text.

¹⁹⁹ See *Hurley v. Lederle Lab.*, 863 F.2d 1173, 1178 (5th Cir. 1988) (rejecting the argument that a nurse-administered vaccine that took place while the physician was out of the office amounted to a "clinic-like" environment, since the physician prescribed the vaccine); *Swayze v. McNeil Lab., Inc.*, 807 F.2d 464, 470-71 (5th Cir. 1987) (distinguishing the *Reyes* case, where the vaccine was administered in "'assembly line' fashion," from the facts at bar, where although the anesthesia was administered by a nurse, the supervising physician was nevertheless considered the learned intermediary). *But see Givens v. Lederle*, 556 F.2d 1341, 1345 (5th Cir. 1977) (holding that if vaccine administration in private physician's office was conducted "more like that at a small county health clinic," the mass immunization exception would apply despite the physician's presence). The precedential weight of *Givens* is suspect in light of the more recent Fifth Circuit cases cited *supra*. In any event, the more recent approach is obviously more in keeping with *Reyes*, which called for a specific limited exception and did not envisage an inquiry into the factors surrounding each individual prescription before applying the learned intermediary rule.

²⁰⁰ *Swayze*, 807 F.2d at 472. It should be noted in this regard that the foreseeability of the absence of a learned intermediary is a significant factor in mass immunization cases. See cases cited *supra* note 82.

new approach to the rule requiring detailed examination of the underlying facts and circumstances surrounding every drug prescription.

B. Breast Implants

Like IUDs, breast implants are susceptible to many of the distinctions on which exceptions to the learned intermediary rule have been justified. Despite the fact that courts have thus far generally applied the learned intermediary rule in breast implant failure-to-warn cases,²⁰¹ cases such as *Hill* indicate the very real potential for judicial abrogation of the rule in this scenario. Moreover, because a serious challenge to the rule's application in breast implant cases has yet to be raised,²⁰² the likely response of the courts remains open to speculation.²⁰³

In light of the creation of yet another categorical exception to the learned intermediary rule for IUDs in *Hill v. Searle Laboratories*²⁰⁴ and despite the still uncertain issue of preemption,²⁰⁵ a direct assault on the doctrine's application in breast implant cases will, no doubt, soon be

²⁰¹ See, e.g., *Toole v. McClintock*, 778 F. Supp. 1543 (M.D. Ala. 1991); *Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89 (D. Md. 1989); *Desmarais v. Dow Corning Corp.*, 712 F. Supp. 13 (D. Conn. 1989); *Perfetti v. McGhan Medical*, 662 P.2d 646 (N.M. Ct. App. 1983).

²⁰² For instance, the courts in the four cases cited *supra* note 201 accepted the learned intermediary rule's application either implicitly or without significant discussion. See *Toole*, 778 F. Supp. at 1547 (noting without comment that "[t]he jury was also told that under the 'learned intermediary' doctrine, the manufacturer did not have to warn [the patient] about the dangers of its product, but only had to warn [the treating physician]"); *Lee*, 721 F. Supp. at 95 (applying learned intermediary rule after brief discussion of cases applying rule to heart catheter and pacemaker) (citing *Phelps v. Sherwood Medical Ind.*, 836 F.2d 296 (7th Cir. 1987) (heart catheter) and *Brooks v. Medtronic, Inc.*, 750 F.2d 1227 (4th Cir. 1984) (pacemaker)); *Desmarais*, 712 F. Supp. at 17-18 (accepting without discussion learned intermediary rule's application); *Perfetti*, 662 P.2d at 650-51 (implicitly accepting the learned intermediary rule by refuting as factually inaccurate defendant's assertion that jury instruction allowed finding of duty to warn patient directly).

²⁰³ What is relatively clear is that future challenges to the rule will be raised. See *In re Oklahoma Breast Implant Cases*, 847 P.2d 772, 774 (Okla. 1993) (explaining standards for use of deposition of nonparties at pending trial with example that deposition concerning "information furnished to the physician arguably in satisfaction of the learned intermediary rule" would require written designation of intention to use such testimony); *First State-Court Breast Implant Class Action Certified*, PR Newswire, Apr. 17, 1992, available in LEXIS, Nexis Library, Wires File ("Common defenses by implant manufacturers, according to several lawyers, will [include] possibly a learned intermediary defense where manufacturers blame plastic surgeons.").

²⁰⁴ 884 F.2d 1064, 1071 (8th Cir. 1989).

²⁰⁵ See *supra* note 168.

waged. Breast implants have many of the same characteristics that initially led some courts to carve out exceptions to the rule in cases of oral contraceptives and vaccines, and are also analogous in many respects to IUDs, which the *Hill* court recently excepted from the rule. Since the *Hill* court based its decision on a virtual cornucopia of factors, it is likely that a breast implant plaintiff hoping to circumvent the learned intermediary rule would take a similar tack. Indeed, the factors asserted by the *Hill* court would likely play a prominent role in such an argument.²⁰⁶ Thus, several of the factors enunciated in *Hill* warrant brief discussion.

The elective nature of breast implants will no doubt be asserted as a factor in favor of a departure from the learned intermediary rule. In the oral contraceptive exception cases, the courts made much of the fact that women, and not their doctors, initiated consideration of birth control pills as a course of treatment. This factor indicated to those courts that the physician-patient relationship in the context of oral contraceptives was qualitatively different from that found in typical drug treatments, with the patient's role in selecting the course of treatment being much more pronounced and the physician's role being correspondingly diminished. This peculiarity seemingly undermined the rationale behind the rule and thus led the courts to require direct manufacturer-to-patient warnings.²⁰⁷ Obviously, breast implants raise many similar concerns.

First, like oral contraceptives, breast implants are generally elective devices. One source estimates that "[a]bout 80 percent of the 1 million women who have silicone gel-filled implants have them for augmentation"²⁰⁸ and "[t]he rest have the devices for reconstruction after mastectomies or other disfigurement."²⁰⁹ Thus, patient demand for breast implants might indeed lead to an atypical situation in which patients visit a physician and request a particular treatment, rather than complain of a malady in hopes that the physician will recommend a suitable treatment. It does not follow, however, that this scenario calls for abandonment of the learned intermediary rule.

As previously discussed,²¹⁰ the mere fact that the patient requests a treatment does not absolve the physician of his or her duty to obtain the patient's informed consent. Doctors are legally bound to exercise independent medical judgment and are not free to acquiesce in a patient's

²⁰⁶ See *supra* notes 170-200 and accompanying text.

²⁰⁷ See *supra* notes 88-142 and accompanying text.

²⁰⁸ *Silicone Breast Implants to Be Restricted*, UPI, Apr. 17, 1992, available in LEXIS, Nexis Library, UPI File.

²⁰⁹ *Id.*

²¹⁰ See *supra* notes 177-78 and accompanying text.

requests for treatment without first weighing the advisability of the treatment and informing the patient of attendant risks.²¹¹ Similarly, a breast implant manufacturer, who is not required to warn patients directly in large part because there is no direct manufacturer-patient contact,²¹² is placed in no better position to warn patients just because patients request the manufacturer's product. Thus, the distinctions relied upon so heavily in the oral contraceptives cases and espoused by the *Hill* court as applied to IUDs not only fail to support abandonment of the learned intermediary rule as applied, but are equally unpersuasive in breast implant cases.

The lack of physician supervision of the "use" of breast implants might also be asserted against application of the learned intermediary rule to breast implants. In the oral contraceptives cases the fact that patients are essentially on their own after receiving the initial prescription/insertion was found to justify an exception to the learned intermediary rule.²¹³ This certainly occurs in breast implant cases, but is qualitatively distinguishable. No amount of knowledge of risks on the part of a woman who has received breast implants can help her eliminate the risks to which she has been exposed. In this regard, it would seem that the warnings applicable to breast implant cases, as with IUDs, are of the informed-choice variety—decreasing risks is not a truly viable objective of such warnings. It follows that another of the objectives attributed to requiring manufacturer-to-patient warnings with oral contraceptives—providing written warnings that the patient can digest over time—is largely misplaced in breast implant cases. The value of written warnings is drastically lessened in the case of informed consent warnings, particularly those regarding medical devices, because the time to weigh the costs and benefits of a medical device is *before* having the device implanted, not afterward.

The lack of physician supervision also relates to the issue of the physician's and the manufacturer's relative abilities to provide effective warnings. Some commentators calling for abandonment of the learned intermediary rule point to the need for written warnings and the manufacturer's supposed greater capacity to provide them as justification for abandonment of the rule.²¹⁴ However, in medical device cases the nature of the risks and, hence, the warnings are such that oral communication is probably an

²¹¹ See *supra* note 51 and accompanying text.

²¹² See Paul Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947, 987 (1964) ("It would be virtually impossible for a manufacturer to comply with the duty of direct warning, as there is no sure way to reach the patient."); *infra* note 235.

²¹³ See *supra* notes 98, 119, 126 and accompanying text.

²¹⁴ See *supra* note 183.

adequate means of conveying the warnings. The typical risks associated with breast implants are rupture and leakage,²¹⁵ events simple enough to explain to the average patient. If, indeed, it is true that the complexity of the information regarding oral contraceptives is too great to communicate briefly and through oral communication, it has yet to be proven that the same situation exists with breast implants. Mere conclusory statements to the contrary should not be taken at face value and should not result in a breast implant exception to the learned intermediary rule.

Potential challenges to the learned intermediary rule in implant cases might place great weight on the fact that breast implants are not only elective, as are IUDs, but are perhaps more often than not used for cosmetic purposes wholly independent of any medical or functional need.²¹⁶ However, just as the increased role of the patient in deciding to seek birth control and in choosing which form to use does not justify an exception to the learned intermediary rule, the heightened elective nature of breast implant treatment does not detract from the need for the learned intermediary rule. In the final analysis, it is the existence of the physician-patient relationship that makes manufacturer-to-patient warnings impractical and, in many respects, inadvisable. The exact nature of the treatment is irrelevant.

C. Other Medical Devices

Courts have generally continued to apply the learned intermediary rule in cases involving medical devices other than IUDs and breast implants.²¹⁷ In general, the application of the learned intermediary rule in such cases is immune to the principal challenges set forth in the oral contraceptive, IUD, and breast implant cases (i.e., elective nature of treatment, decreased physician involvement in decision-making process) due to the nature of the treatment involved.²¹⁸ In this respect, cases involving more traditional implants and devices do not present as fertile ground for challenges to the learned intermediary rule as do IUD and breast implant cases.

²¹⁵ *Silicone Breast Implants to Be Restricted*, UPI, Apr. 17, 1992, available in LEXIS Library, UPI File.

²¹⁶ See *supra* note 209 and accompanying text.

²¹⁷ *E.g.*, *Bravman v. Baxter Healthcare Corp.*, 984 F.2d 71 (2d Cir. 1993) (heart valve); *Phelps v. Sherwood Medical Indus.*, 836 F.2d 296 (7th Cir. 1987) (heart catheter); *Brooks v. Medtronic, Inc.*, 750 F.2d 1227 (4th Cir. 1984) (pacemaker); *Bukowski v. Coopervision Inc.*, 592 N.Y.S.2d 807 (App. Div. 1993) (contact lens).

²¹⁸ In carving out an exception to the learned intermediary rule, IUD and breast implant decisions focus on the patient's increased role in the decision-making process and the elective nature of the treatment. See *Hill*, 884 F.2d at 1071 (citations omitted).

In *Brooks v. Medtronic, Inc.*,²¹⁹ appellant-plaintiff challenged the application of the learned intermediary rule to a failure to warn of the dangers associated with the pacemaker he had received. The court rejected appellant's attempt to invoke the rationale of the mass immunization exception, finding that "pacemakers are not dispensed indiscriminately in mass clinics, but instead are prescribed only after a physician balances the individual's needs against the known risks."²²⁰ The court likewise rejected "[a]ppellant's attempt to tread his way around"²²¹ the rule on the ground that the manufacturer "had advance notice of his surgery and therefore had ample opportunity to provide him with a warning."²²² The court found that the physician-patient relationship warranted the application of the learned intermediary rule, noting that in some cases additional warnings from the manufacturer to the patient could pose "unwanted, unsettling and potentially harmful risks" to the patient.²²³

A similar attempt to distinguish device cases from prescription drug cases was rejected in *Phelps v. Sherwood Medical Industries*.²²⁴ In *Phelps*, a patient who had received a heart catheter urged an exception to the learned intermediary rule based on distinctions between medical devices and prescription drugs. However, the court could "find no principled basis for such a distinction"²²⁵ and held that the learned intermediary rule was applicable to medical devices.²²⁶

As *Brooks* and *Phelps* indicate, courts have generally been unreceptive to asserted grounds for distinguishing prescription drug cases from cases involving medical devices. As between traditional medical devices and those devices considered more elective in nature, such as IUDs and breast implants, the former obviously leaves less room for the distinctions relied upon in carving out exceptions for oral contraceptives and IUDs. Nonetheless, even where the medical device is entirely elective, or even cosmetic, if such a device is implanted by a physician treating his patient, the application of the learned intermediary rule best recognizes the respective capabilities of manufacturer and physician and best facilitates adequate and effective warning to patients. At the heart of the learned

²¹⁹ 750 F.2d 1227 (4th Cir. 1984).

²²⁰ *Id.* at 1232.

²²¹ *Id.*

²²² *Id.*

²²³ *Id.*

²²⁴ 836 F.2d 296 (7th Cir. 1987).

²²⁵ *Id.* at 303.

²²⁶ *Id.*

intermediary rule is a respect for the physician-patient relationship. In those rare cases, such as mass immunization programs, where such a relationship is not established, it is proper to ignore the learned intermediary rule. However, once the physician-patient relationship is established the rule should be applied, be it in the context of a life-saving heart valve transplant or a breast augmentation for purely aesthetic purposes.

D. The Costs and Benefits of the Learned Intermediary Rule

One of the chief systemic benefits of the learned intermediary rule is its tendency to reinforce expected results and thus provide relevant parties—particularly physicians and drug and medical device manufacturers—prior notice of the duties expected of them.²²⁷ Ad hoc departures from the rule necessarily upset these expectations. Nevertheless, such departures can, and do, occur. Armed with what might have seemed an exhaustive list of factors supporting its decision, the court in *Hill v. Searle Laboratories*²²⁸ was apparently comfortable with its decision to require manufacturers of IUDs to warn consumers directly, despite the fact that when the manufacturer in that case sold its product it had every reason to believe that its duty to warn had been discharged by physicians. While in the abstract the court could, and did, quite naturally conclude that requiring manufacturer-to-consumer warnings could only help matters, in practice the decision is misguided. The problem with the result in *Hill*, and other calls for abandonment of the learned intermediary rule, is that they overlook significant benefits achieved through use of the learned intermediary rule, misconstrue the central justifications for the rule, and drastically underestimate the practical difficulties manufacturers would face if they were required to provide legally sufficient warnings directly to patients.

It is intuitive that the more warnings available to a patient, the better off the patient will be. Thus, in requiring manufacturers to warn IUD recipients directly, courts like *Hill* see themselves as furthering such admirable goals as patient autonomy and safe and effective use of prescription drugs and devices. In reality, manufacturers are unable to tailor warnings to patients and must therefore provide standardized warnings to all patients, risking both dilution and unnecessary hysteria due to the need to adequately warn all potential patients of all potential hazards.²²⁹

²²⁷ See *supra* notes 48-66 and accompanying text.

²²⁸ 884 F.2d 1064 (8th Cir. 1989); see *supra* notes 170-200 and accompanying text.

²²⁹ See *supra* notes 86-87 and accompanying text.

The need to reduce warnings into layman's terms is a virtually insurmountable task manufacturers would face in attempting to satisfy a duty to warn all patients directly. Whereas the lexicon of medicine is universal among physicians, regional and demographic differences among the populace in general make effective standardized warnings impossible. This factor is exacerbated by the heretofore painfully uncertain science of failure-to-warn litigation. *MacDonald v. Ortho Pharmaceutical*²³⁰ is an excellent case-in-point.

In *MacDonald*, FDA-required inserts accompanying oral contraceptive pills warned patients of the risk of "[b]lood clots [that] occasionally form in the blood vessels . . . and may threaten life if the clots break loose and then lodge in the lung or if they form in other vital organs, such as the brain."²³¹ Despite the apparent clarity of this warning, the court ruled that it was for a jury to decide whether the company should have explicitly warned of the risk of a "stroke," which the plaintiff asserted would have caused her to forgo use of the product.²³²

Obviously, holdings such as *MacDonald* pose serious threats to physicians as well as manufacturers. But physicians, at least, have the advantage of knowing their patients and thus some opportunity to ensure that the patients comprehend warnings. Manufacturers have no similar opportunity.²³³ Forced not only to warn each patient but also to satisfy a fact-finder's hindsight estimation of what an appropriate warning would have been, a manufacturer would be subject to potentially crippling liability with no real means of meeting its duty. The inevitable result of such a predicament is the exodus of manufacturers from the market.²³⁴

²³⁰ 475 N.E.2d 65 (Mass.), cert. denied, 474 U.S. 920 (1985); see *supra* notes 89-107 and accompanying text.

²³¹ *MacDonald*, 475 N.E.2d at 67 n.4.

²³² *Id.* at 71.

²³³ See Carole A. Cheney, Comment, *Not Just for Doctors: Applying the Learned Intermediary Doctrine to the Relationship Between Chemical Manufacturers, Industrial Employers, and Employees*, 85 NW. U. L. REV. 562, 567 (1991) (noting that the distribution systems for prescription drugs may cause a manufacturer to become "separated from the users of its products," leaving the manufacturer "unable to anticipate and meet its user's informational needs" (citing Clarke E. Khoury, Note, *Warning Labels May be Hazardous to Your Health: Common-Law and Statutory Responses to Alcoholic Beverage Manufacturers' Duty to Warn*, 75 CORNELL L. REV. 158, 185 (1989))).

²³⁴ See Flannagan, *supra* note 39, at 420 & n.90 (discussing the risk that the vague standard applied in *MacDonald* could "prompt oral contraceptive manufacturers to withdraw their product from the market" and comparing the situation to vaccine manufacturers' reluctance to produce swine flu vaccine until the government accepted liability).

In essence, the sort of protracted inquiry undertaken in *Hill* defeats the purpose of the learned intermediary rule. The rule, as originally adopted and generally still applied, recognizes the respective roles of physician and manufacturer and actually ensures that useful warnings reach the consumer. In other words, the original justifications for the learned intermediary rule justify its continued application and its extension to medical device cases.

Abrogation of the rule not only contradicts the objectives of providing adequate warnings in the most effective manner, but also upsets established expectations. Manufacturers such as the defendant in *Hill* and the defendants in the oral contraceptive cases had directed warning information to physicians because established legal principles indicated that it was their duty to direct the information to the physician, not the patient. Holding such manufacturers liable, after the fact, for inadequately warning the patient directly blatantly upsets the manufacturer's reasonable expectations. The manufacturer in these cases had no direct contact with the patient and reasonably relied on the established rule that its duty to warn was discharged by warning the treating physician. In essence, then, the mere *existence* of the learned intermediary rule, because the manufacturer is expected to conform its behavior to that rule, provides considerable weight against further *ad seriatim* abandonment such as that undertaken in *Hill*.²³⁵

E. A Legislative Approach

Two cases that have thus far been treated more or less as anomalies might, in fact, provide guidance in reconciling demands for greater patient warnings with the policy objectives embodied by the learned intermediary rule. The first of these cases is *Lukaszewicz v. Ortho Pharmaceutical Corp.*,²³⁶ which allowed a failure-to-warn claim to proceed on a negligence per se theory based on a violation of federal regulations.²³⁷ The second case is *Desmarais v. Dow Corning Corp.*,²³⁸ which found that state failure-to-warn claims concerning

²³⁵ See Henderson & Twerski, *supra* note 33, at 302-03 (describing "seriatim effect" as a weakness of failure-to-warn jurisprudence due to a poor fit between case-by-case adjudication system and the need to consider a broad range of factors in determining the adequacy of warnings).

²³⁶ 510 F. Supp. 961, *modified*, 532 F. Supp. 211 (E.D. Wis. 1981).

²³⁷ See *supra* notes 133-38 and accompanying text.

²³⁸ 712 F. Supp. 13 (D. Conn. 1989).

breast implants were preempted by federal regulation.²³⁹ Simply put, the advantage in each case is that determination of what constitutes adequate warning and, more importantly in this context, to whom such warning should extend was made in advance by a legislative or quasi-legislative body capable of considering a more expansive range of facts than that presented in a single lawsuit.

In *Lukaszewicz*, the cause of action was based on the manufacturer's failure to comply with federal labeling requirements.²⁴⁰ The court did not, on its own, decide that the particular facts of the case before it warranted direct manufacture-to-patient warnings. Instead, a fact-finding body—the Food and Drug Administration—determined that such warnings were necessary and dictated the content of the warnings. Such an agency determination is typically made after consideration of a more comprehensive set of factors than can properly and effectively be considered in a judicial setting. Moreover, the legislative and rule-making processes are equipped to resist the natural tendency to assume that one more warning is almost always cost-justified without considering the hidden costs of piling on warnings.²⁴¹

Likewise, the *Desmarais* court's finding that state failure-to-warn claims are preempted by federal regulation recognizes the relative strengths of legislative and judicial bodies in determining proper warnings. Courts are designed to resolve particular disputes. Courts are not equipped to set particularized standards, the establishment of which often entails minutiae such as phraseology and placement. The "empty shell of failure to warn"²⁴² is plagued by after-the-fact determinations and demands legislative, rather than judicial, law making. The determinations of what constitutes adequate warning and to whom such warning should be extended cannot fairly and responsibly be made on an ad-hoc basis.

For these reasons, *Desmarais* and *Lukaszewicz* might be indicative of the ideal course for failure-to-warn cases in that pre-determined legislative standards represent the best hope for a proper balance. Once such standards have been set, the courts should respect the balance that the legislature or administrative body has struck. In any event, the default

²³⁹ See *supra* note 168.

²⁴⁰ *Lukaszewicz*, 510 F. Supp. at 964-65 (requiring the labeling of oral contraceptives).

²⁴¹ See *Henderson & Twerski*, *supra* note 33, at 296-303 (generally discussing the risk-utility balancing of warnings); *supra* notes 85-87 and accompanying text.

²⁴² See *Henderson & Twerski*, *supra* note 33, at 265 (referring to the decreased effectiveness of the failure to warn doctrine in influencing manufacturer's conduct because courts have diluted the doctrine through overuse).

position—applicable when no legislative or administrative determination has been made—should be continued reliance on the learned intermediary rule.

CONCLUSION

Consideration of IUD and breast implant cases perhaps best underscores the basis for the continuing need for the learned intermediary rule: regardless of the motivation behind the treatment, regardless of the elective nature of the treatment, and regardless of the physician's degree of participation in the decision-making process, the intervention of the physician-patient relationship between manufacturer and patient puts all parties on notice that the doctor has fully assumed the role of adviser and counselor. This allows for effective, unobstructed warning on the physician-patient end of the transaction, and allows the manufacturer to fulfill its duty to warn by warning the only party it can warn effectively—the treating physician. Increasing the number of warnings to patients and the number of parties required to warn the patient does not facilitate more effective warnings, and can actually hinder such warnings. Moreover, requiring direct manufacturer-to-patient warnings, except in situations where more responsive fact-finding bodies predetermine the nature of such a duty, risks placing manufacturers in a hopelessly untenable position. Piecemeal abrogation of the learned intermediary rule only serves to increase the cost of doing business for all parties, without a corresponding return on the consumer's investment, and creates untold costs in the form of unheeded and unheedable warnings.

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