

Reimagining the Learned Intermediary Rule for the New Pharmaceutical Marketplace

Timothy S. Hall*

ABSTRACT

For the past decade, the learned intermediary rule—the rule of tort law that provides that drug manufacturers may satisfy their duty to warn of a drug’s dangers by warning the prescribing physician rather than the end user of the drug—has been the subject of vigorous academic debate. That debate has been largely moot, however, as the courts have proven reluctant to make significant inroads on the protection offered by the Rule to drug manufacturers. This Article proposes a new approach to the Rule. Part I discusses the history and overwhelming adoption of the Rule pursuant to the Restatement (Second) of Torts. Part II argues that changes in the health care delivery system have resulted in a legal system that introduces market distortions by effectively immunizing the pharmaceutical industry from the legal and social consequences of its own actions. Part III then sets forth a reconceptualization of the Rule, which preserves the Rule’s benefits with respect to the drug industry, the health care system, and the goals of tort law, while also strengthening the protection the tort system offers to individuals injured by prescription drugs.

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* Assistant Professor of Law, Louis D. Brandeis School of Law at the University of Louisville. J.D. *magna cum laude* 1993, Cornell Law School. Thanks to the participants in the 2003 Central States Law Schools Association Annual Meeting, the Winter 2004 meeting of the Ohio Legal Scholarship Workshop, and the 2004 Southeastern Association of Law Schools Annual Meeting for their willingness to listen to and comment on this article, to Ron Eades, Grace Giesel, Jim Jones, David Leibson, Bob Stenger, Elizabeth Pendo, Kathy Cerminara and Rick Bales for reading and providing critical comment on early drafts, and to my research assistants Chris Curran, Jason Lacy and Karen Paulin for their assistance.

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INTRODUCTION

As this Article is being written, the fortieth anniversary of the learned intermediary rule¹—the rule of tort law which provides that drug manufacturers may satisfy their duty to warn of a drug’s dangers by warning the prescribing physician rather than the end user of the drug—is two years away. In 1966, when the United States Court of Appeals for the Eighth Circuit coined the term “learned intermediary rule” in the case of *Sterling Drug v. Cornish*,² President Lyndon Johnson was in the White House³ and *Dr. Kildare* was on television.⁴ *Dr. Kildare*, like Marcus Welby, who followed him,⁵ remains an icon of the traditional American health care system: a primary care physician devoted to his patients. A vast literature chronicles the change (some would say the decline) from the fee-for-service health care system of that time with its emphasis on the dyadic, paternalistic physician–patient relationship, to the modern, twenty-first century health care system with its triadic managed care relationships and uncertain authority structure.⁶ Strangely, in the face of these revolutionary changes in medical practice, as well as a substantial critical scholarly literature, the learned intermediary rule as applied by courts has remained virtually unchanged from its first articulation in 1966 until the present day. Simply stated, and subject to a few

¹ References to “the Rule” in this Article, unless otherwise specified, are to the learned intermediary rule.

² 370 F.2d 82, 85 (8th Cir. 1966). Although the phrase “learned intermediary rule” was coined by the *Sterling Drug* court, the concepts behind the Rule predate its naming. See, e.g., *Magee v. Wyeth Labs., Inc.*, 29 Cal. Rptr. 322, 350-51 (Ct. App. 1963).

³ THE PRESIDENTS OF THE UNITED STATES, at <http://www.whitehouse.gov/history/presidents/index2.html> (last visited Aug. 25, 2004).

⁴ TIM BROOKS & EARLE MARSH, THE COMPLETE DIRECTORY TO PRIME TIME NETWORK AND CABLE TELEVISION SHOWS: 1946-PRESENT 268 (7th ed. 1999).

⁵ *Dr. Kildare* was broadcast from 1961 to 1966. *Id.* *Marcus Welby, M.D.*, premiered in 1969 and ran until 1976. *Id.* at 627-28.

⁶ See generally PETER D. JACOBSON, STRANGERS IN THE NIGHT: LAW AND MEDICINE IN THE MANAGED CARE ERA (2002); E. HAAVI MORREIM, BALANCING ACT: THE NEW MEDICAL ETHICS OF MEDICINE’S NEW ECONOMICS (1995); Carl F. Ameringer, *Devolution and Distrust: Managed Care and the Resurgence of Physician Power and Authority*, 5 DEPAUL J. HEALTH CARE L. 187, 187-93 (2002); Dionne Koller Fine, *Physician Liability and Managed Care: A Philosophical Perspective*, 19 GA. ST. U. L. REV. 641, 644-53 (2003); Joseph Gottfried & Frank A. Sloan, *The Quality of Managed Care: Evidence from the Medical Literature*, 65 LAW & CONTEMP. PROBS. 103, 103-29 (2002); Thomas L. Greaney, *From Hero to Goat: Managed Care in the 1990s*, 47 ST. LOUIS U. L.J. 217, 217-19 (2003); Russell Korobkin, *The Failed Jurisprudence of Managed Care, and How to Fix It*, 51 UCLA L. REV. 457, 462-64 (2003); Daniel P. Maher, *Managed Care and Undividing Loyalties*, 18 J. CONTEMP. HEALTH L. & POL’Y 703, 703-05 (2002).

narrowly applied exceptions, the mere fact that a prescription drug is at issue⁷ in a failure-to-warn tort case automatically vitiates the manufacturer's duty to warn the end user of dangers posed by the product. Courts almost unanimously apply a virtually irrebuttable presumption that the end user's physician is the only appropriate source for warnings of a drug's potential dangers. As Part II of this Article will show, the current state of the American health care system no longer permits such an unreflective assumption.

This Article proposes a reworking of failure-to-warn doctrine and the learned intermediary rule more suited to the changed health care marketplace faced today by patients, physicians, pharmacists, and pharmaceutical manufacturers. In the twenty-first century American managed health care system, patients receive far less personalized attention from their physicians, and are seen by a greater variety and diversity of physicians, than in the past. The average length of an office visit is shorter under aggressive managed care cost containment structures,⁸ providing less time for personal interaction and fewer opportunities for physicians to educate and inform their patients. Additionally, managed care organizations ("MCOs") increasingly exert control over the doctor-patient relationship, including the choice of prescription drugs, through the use of pre-authorization requirements, formularies, and pharmacy benefit managers.⁹

At the same time, the opportunities for successful medical treatment, including pharmacological treatment, are more extensive

⁷ Although the learned intermediary rule has been applied to medical devices as well as prescription drugs, *see, e.g.*, *Johnson v. Zimmer, Inc.*, No. Civ. 02-1328, 2004 WL 742038, at *9-10 (D. Minn. Mar. 31, 2004) (prosthetic femoral hip stem); *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 594-96 (Ga. 2003) (spinal plate); RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(c) (1997) [hereinafter THIRD RESTATEMENT], this Article will focus on the Rule in the prescription drug context. The process of development, approval, promotion, and sale of medical devices is materially different from that of prescription drugs, and analysis of whether a conclusive presumption of a learned intermediary is appropriate in the medical device context is reserved for another day.

⁸ R. Balkrishnan et al., *Capitation Payment, Length of Visit and Preventive Services: Evidence from a National Sample of Outpatient Physicians*, 8 AM. J. MANAGED CARE 332, 337 (2002); Peifeng Hu & David B. Reuben, *Effects of Managed Care on the Length of Time That Elderly Patients Spend with Physicians During Ambulatory Visits*, 40 MED. CARE 606, 610-12 (2002). Both of these articles point out that the length of office visits appears to be more closely related to the type of reimbursement than the type of insurance. For a report reaching the opposite conclusion, that managed care does not seem to have altered the length of office visits, see David Mechanic et al., *Are Patients' Office Visits with Physicians Getting Shorter?*, 344 NEW ENG. J. MED. 201-03 (2001).

⁹ For a discussion of the rise of managed care's control over the distribution of prescription drugs, see Sharlow Johnson, *PBMs: Ripe for Regulation*, 57 FOOD & DRUG L.J. 323, 328-31 (2002).

than they have ever been, and drug manufacturers' research and development budgets have increased commensurately. In addition to medically necessary drugs, drug manufacturers have increasingly turned their attention to producing therapies for conditions that would not have been considered suitable candidates for medical intervention forty years ago. Products such as Viagra, Rogaine, Botox, and others¹⁰ have proven to be lucrative products for their manufacturers, despite the sometimes questionable necessity for these so-called "lifestyle" drugs.

Finally, the modern medical marketplace focuses on the patient as consumer to an extent unimaginable forty years ago. In 1966, the paternalistic relationship between doctor and patient precluded any direct communication between the manufacturer of a drug and end users of that drug. Opportunities to learn about available treatments, except from one's physician in the context of a face-to-face consultation, were virtually nonexistent.¹¹ Today, by contrast, the Internet supplies voluminous information on virtually every drug and alternative therapy on demand to one's desktop or living room.¹² In addition to this wealth of information available for the asking, pharmaceutical products are routinely touted in television, print, and Internet advertisements. Direct-to-consumer advertising occupies an ever-growing percentage of drug companies' vast promotional budgets, and studies show that such advertisements are effective in creating demand for specific brand-name drugs.¹³ With the advent of Internet-based pharmacies, it is even possible (though illegal)¹⁴ for

¹⁰ Such pharmaceuticals developed and marketed primarily for their cosmetic effects, rather than for the treatment of a traditional medical "illness," will be referred to in this Article as "lifestyle" drugs. For a discussion of the difficulty of definitively classifying a particular drug as a "lifestyle" drug, see *infra* Part II.A.3.

¹¹ The only prescription pharmaceutical advertisements undertaken by drug companies in the 1960s were targeted directly to physicians or other health care professionals through medical and other industry journals unlikely to be accessible to the average patient. See *infra* notes 193–95 and accompanying text.

¹² Studies consistently show a large percentage of American Internet users search for health information online, and several companies have started high-profile Internet medical information resource websites. See, e.g., <http://www.drkoop.com> (last visited Aug. 27, 2004); <http://www.webmd.com> (last visited Aug. 27, 2004).

¹³ See, e.g., Simon Gilbody et al., *Direct-to-Consumer Advertising of Psychotropics: An Emerging and Evolving Form of Pharmaceutical Company Influence*, 185 BRIT. J. PSYCHIATRY 1, 1-2 (2004); Barbara Mintzes et al., *How Does Direct-to-Consumer Advertising (DTCA) Affect Prescribing? A Survey in Primary Care Environments with and without Legal DTCA*, 169 CAN. MED. ASS'N. J. 405, 408-09 (2003); Elizabeth Murray et al., *Direct-to-Consumer Advertising: Physicians' Views of Its Effects on Quality of Care and the Doctor-Patient Relationship*, 16 J. AM. BOARD FAM. PRAC. 513, 513-24 (2003).

¹⁴ For an excellent discussion of the legal limits on Internet pharmacies and the extent to which existing Internet pharmacies disregard or operate beyond the reach

consumers to purchase prescription drugs in the absence of a meaningful physician–patient relationship; indeed, without any contact with a licensed physician.¹⁵ Doctors Welby and Kildare would be shocked and bewildered by the sheer volume and diversity of information and alternatives available to today’s patients.¹⁶

This Article surveys these and other changes in the health care marketplace in the past forty years and critically examines the continued vitality of the learned intermediary rule in light of these changes. I conclude that the learned intermediary rule in its current form does not adequately reflect the realities of the modern health care system and I propose reworking the Rule to better regulate today’s pharmaceutical marketplace and better accomplish the main goals of tort law: compensation, deterrence, and cost allocation.¹⁷

The diversity of the modern health care system, recent changes in the development and marketing of prescription drugs, and the increased ethical emphasis on the autonomy and responsibility of the patient lead to the conclusion that the learned intermediary rule should no longer be applied as a bright-line exception for prescription drugs in modern failure-to-warn jurisprudence. Rather, courts should undertake a fact-based inquiry to determine whether the drug in question was in fact sold in the absence of an effective intermediary. The focus should not be on the type of product being sold, but rather on the quality of the doctor–patient interaction that results in the prescription and use of the drug.

In fact, tort law already uses such a rule, but not in the prescription drug context. Manufacturers selling products other than drugs through intermediaries have also argued that the duty to warn the ultimate user of the product should be delegable to the intermediary and, in appropriate cases, courts have been willing to allow manufacturers to satisfy their duty to warn by simply warning an intermediary. The major difference between this “sophisticated user doctrine” and the learned intermediary rule is the level of analysis that courts are willing to undertake to determine whether delegation of the duty to warn to an intermediary is appropriate.

Part I of this Article begins with a brief history and description of the learned intermediary rule as currently applied. Part II then

of those legal limits, see John Blum, *Internet Medicine and the Evolving Legal Status of the Physician–Patient Relationship*, 24 J. LEGAL MED. 413, 439-48 (2003).

¹⁵ See *id.*; see also *infra* Part II.A.4.

¹⁶ Cf. *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245, 1246 (N.J. 1999) (“Our medical-legal jurisprudence is based on images of health care that no longer exist.”).

¹⁷ Stanley Ingber, *Rethinking Intangible Injuries: A Focus on Remedy*, 73 CAL. L. REV. 772, 772 (1985).

surveys the ways in which the Rule as it exists fails to reflect modern medical practice, pharmaceutical marketing, and medical ethics. Part III concludes that the Rule should, rather than merely being abrogated for some or all categories of drug sales, be reformed to reflect the fact that in today's health care delivery environment, not all prescription drug sales occur in the presence and with the assistance and protection of an effective learned intermediary. I propose changes in the application of the learned intermediary rule to bring the law's presumptions into line with the modern health care marketplace and to provide an incentive to drug manufacturers and the health care delivery system to improve the lines of communication between health care providers and patients.

I. THE LEARNED INTERMEDIARY RULE

Prescription drugs have long held a special place in American products liability law, having been singled out as "unavoidably unsafe" by the *Restatement (Second) of Torts*.¹⁸ The law has struggled with the proper balance between the interests of individuals harmed by unavoidably unsafe products¹⁹ and the interest of society in encouraging the development and marketing of innovative pharmaceutical products in the face of the undeniable risk posed by those products.²⁰ The standard formula of strict products liability is widely, and correctly, regarded as unworkable in the prescription

¹⁸ Comment k to section 402A of the *Restatement (Second) of Torts* states in relevant part:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . [B]oth the marketing and the use of [prescription drugs] are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous.

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

¹⁹ Although eager plaintiffs' attorneys occasionally forget, injury is a prerequisite to maintenance of an action for failure to warn. *See Heindel v. Pfizer, Inc.*, No. Civ.A. 02-3348, 2004 WL 1398024, at *1 (D.N.J. June 7, 2004) (granting defendant's motion for summary judgment where plaintiffs alleged no actual injury from taking prescription drugs, but only claimed "economic injuries" they suffered due to [d]efendants' failure to publicize the results of two clinical studies that revealed possible risks associated with the use of the drugs").

²⁰ *See generally* *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1195-96 (Alaska 1992); *Gaston v. Hunter*, 588 P.2d 326, 339-40 (Ariz. Ct. App. 1978); *Bennett v. Madakasira*, 821 So. 2d 794, 809 (Miss. 2002); *Pollard v. Ashby*, 793 S.W.2d 394, 399-400 (Mo. Ct. App. 1990); *Glass v. Ford Motor Co.*, 304 A.2d 562, 563-65 (N.J. Super. Ct. App. Div. 1973); *Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1387 (Pa. 1991).

drug context²¹ because of the uncertainty and complexity attendant on medical treatment and the possibility that strict tort liability might chill research and development of new pharmaceutical products. The precise parameters of the law's treatment of these products, however, are no longer adequately calibrated to give effect to the purposes behind tort law.

A. *Safe Harbor for Manufacturers*

According to the principles of strict liability, the predominant American products liability doctrine,²² a manufacturer or seller of a defective product is liable to the product's end user for injuries caused by that product without regard to whether the manufacturer or seller was negligent in the manufacture or sale of the product.²³ The drafters of the *Second Restatement*, however, noted a different rule for "[u]navoidably unsafe" products.²⁴ Imposition of strict liability for injuries caused by such products would impair an industry's ability to market a socially desirable product and would deprive society of the benefit of that product.²⁵ Therefore, injury resulting from the use of these products generates tort liability for manufacturers only when the products are "unreasonably dangerous."²⁶ Generally speaking, unavoidably unsafe products are unreasonably dangerous when the end user of the product does not know of, or has no reason to know of, the dangers presented by the product and so is unable to take

²¹ See, e.g., *Hahn v. Richter*, 673 A.2d 888, 889-90 (Pa. 1996); T. Leigh Anenson, *Great Expectations: The Role of the Consumer in Determining Effective Design*, 38 TORT TRIAL & INS. PRAC. L.J. 963, 986 (2003). Not all courts recognize this, however. See *Foister v. Purdue Pharma, L.P.*, 295 F. Supp. 2d 693, 705 (E.D. Ky. 2003) ("As this action involves a dangerous prescription drug, it is governed by the rules of strict liability.").

²² See THIRD RESTATEMENT, *supra* note 7, § 1 cmt. a (describing the historic growth of strict products liability as "a discrete area of tort law which borrows from both negligence and warranty").

²³ Section 402A of the *Second Restatement* states: "One who sells any product in a defective condition unreasonably dangerous to the user or consumer . . . is subject to liability . . . although . . . the seller has exercised all possible care in the preparation and sale of his product . . ." SECOND RESTATEMENT, *supra* note 18, § 402A. This principle of strict liability is reaffirmed in the *Third Restatement*, which provides:

One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm . . . caused by the defect. . . . A product . . . contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product

THIRD RESTATEMENT, *supra* note 7, §§ 1-2.

²⁴ SECOND RESTATEMENT, *supra* note 18, § 402A cmt. k.

²⁵ See *id.*

²⁶ See *id.* § 402A cmt. i.

these dangers into account when making the decision whether to use the product by balancing its expected benefits against its potential harms.²⁷ Thus, manufacturers can avoid liability arising out of the use of unavoidably unsafe products by distributing them with legally adequate warnings and instructions for use. The analysis applicable to unavoidably unsafe products, therefore, carries within it a negligence-based reasonableness inquiry.²⁸

The category of unavoidably unsafe products, as the drafters of the *Second Restatement* recognized, encompasses the vast majority of, if not all, prescription drugs.²⁹ All drugs present potential dangers in addition to their touted benefits.³⁰ Although the manufacturer need not explicitly warn against obvious dangers,³¹ potential drug interactions and side effects are not the sorts of dangers that are obvious upon inspection of the product. Therefore, both instructions as to the correct use of the product and warnings as to the potential consequences of both proper and improper use are necessary.³²

²⁷ *Id.* This analysis mirrors the doctrine of informed consent, in which knowledge of and assent to risk eliminates liability for harms resulting from that risk, and thus demonstrates respect for the autonomy of the patient. Of course, under standard principles of informed consent, a physician can be held liable for failing to transmit adequate warnings to the patient. *See Larkin v. Pfizer, Inc.*, No. 2002-SC-0746-CL, 2004 WL 1361954, at *9-10 (Ky. June 17, 2004). This theory of liability, while providing another source of remedy for the patient injured by a prescription drug, is largely beyond the scope of this Article.

²⁸ *See* THIRD RESTATEMENT, *supra* note 7, § 1 cmt. a (noting that although “many courts insist on speaking of [failure-to-warn and defective design liability] as being ‘strict,’” those theories of liability actually “rely on a reasonableness test traditionally used in determining whether an actor has been negligent”). Prescription drug litigation is virtually never conducted on a defective design theory. *Id.* § 6(c) & cmt. b (discussing the “traditional refusal by courts to impose tort liability for defective designs of prescription drugs”).

²⁹ SECOND RESTATEMENT, *supra* note 18, § 402A cmt. k.

³⁰ *See infra* note 261 and accompanying text (discussing the over-the-counter drug market).

³¹ *Cimino v. Raymark Indus., Inc.*, 151 F.3d 297, 331 n.70 (5th Cir. 1998) (observing that “a product seller is not liable for failure to warn of risks ‘that should be obvious to, or generally known by, foreseeable product users’”) (quoting THIRD RESTATEMENT, *supra* note 7, § 2 cmt. j.).

³² The distinction between instructions and warnings is well-developed in the products liability literature. *See, e.g.,* *Natural Gas Odorizing, Inc. v. Downs*, 685 N.E.2d 155, 161 (Ind. Ct. App. 1997) (noting that Indiana law requires manufacturer to provide both adequate instructions for proper use of product and warnings of dangers from improper use); *see also* THIRD RESTATEMENT, *supra* note 7, § 1 cmt. a (discussing history of products liability as it relates to use of “instructions or warnings”). Following the convention in the literature, however, references to “warnings” in this Article should be read to refer to both warnings and instructions unless otherwise specified.

Since warnings and instructions are necessary to enable the reasonably safe use of prescription drugs, and to allow the manufacturer to avoid liability for those injuries that will unavoidably occur from the use of the product, the manufacturer must determine how to satisfy its legal duty to warn and instruct. Discharge of this duty has two facets: the content of the warning and the means of communicating the warning. In this, the drug manufacturer has a decided advantage over manufacturers of other unavoidably unsafe products. Ordinarily, a legally effective warning must be reasonably designed to capture the attention of the end user of the product. An otherwise unobjectionable warning which is diluted by overly favorable descriptions of the product,³³ not communicated in an efficient manner,³⁴ or hidden from clear view³⁵ is of no use to the consumer and cannot be relied on as a shield against liability.

In stark contrast to this ordinary rule of tort law, an adequate warning of the dangers of a prescription drug need not be communicated to the end user at all, but only to the prescribing physician. The prescribing physician, so the theory goes, acts as a “learned intermediary” between the end user and the drug manufacturer. She is an “intermediary” because a prescription drug cannot be legally obtained without a prescription from a licensed physician.³⁶ She is “learned” because of the extensive medical

³³ For cases recognizing that a warning could be nullified by “overpromotion” of the product, which had the effect of diluting the warning’s effectiveness, see, e.g., *Salmon v. Parke Davis & Co.*, 520 F.2d 1359, 1363 (4th Cir. 1975) (interpreting North Carolina law); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973); *Mahr v. G.D. Searle & Co.*, 390 N.E.2d 1214, 1238 (Ill. App. Ct. 1979); *Baldino v. Castagna*, 478 A.2d 807, 810 (Pa. 1984).

³⁴ For cases finding that a warning not adequately communicated to prescribing physicians is not legally effective, see, e.g., *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 657 (1st Cir. 1981) (interpreting New Hampshire law); *Ortho Pharm. Corp. v. Chapman*, 388 N.E.2d 541, 549 (Ind. Ct. App. 1979); *Baker v. St. Agnes Hosp.*, 421 N.Y.S.2d 81, 85-86 (App. Div. 1979).

³⁵ *Wright ex rel. Trust Co. of Kan. v. Abbott Labs.*, 62 F. Supp. 2d 1186, 1201 (D. Kan. 1999) (finding a warning adequate because, *inter alia*, it was “not concealed or hidden on some remote part of a large piece of machinery... [but] clearly emblazoned on the package label and repeatedly stated on the package insert”).

³⁶ Restrictions on the legal sale of prescription drugs are contained in the Food, Drug, and Cosmetics Act. Specifically, 21 U.S.C. § 353(b) provides that drugs, which are approved by the FDA as prescription drugs:

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist.

training that enables her to comprehend the content of a complete and necessarily technical and complex warning about the drug. Training and experience allow the physician to translate the technical details concerning the potential therapeutic benefits and known risks of the drug into specific recommendations and instructions for use by the individual patient. In the absence of either of these factors, the Rule should not apply.³⁷

The first mention of the learned intermediary rule by that name occurred in 1966 in the case of *Sterling Drug v. Cornish*.³⁸ From that beginning, the Rule was quickly and widely adopted by state and federal courts.³⁹ In *Sterling Drug*, the plaintiff alleged that a warning given to her physician by the drug manufacturer was inadequate because it did not disclose a known, although rare, side effect of the drug prescribed for her.⁴⁰ The *Sterling Drug* court distinguished prescription drugs from “normal consumer item[s],”⁴¹ holding that the law required a warning to the prescribing physician, but the court gave no rationale for an accompanying exemption from the duty to warn the consumer directly.⁴²

Moreover, comment k to section 402A of the *Second Restatement*

21 U.S.C. § 353(b) (2000).

³⁷ This is an application of the familiar legal maxim of *cessante ratiōe legis cessat et ipsa lex*, translated as, “Where the reason for the law itself also ceases.” BLACK’S LAW DICTIONARY app. B at 1708 (8th ed. 2004). As will be shown in Part I.C, *infra*, however, courts have not heeded this rule of construction in the prescription drug context.

³⁸ 370 F.2d 82, 85 (8th Cir. 1966). The *Sterling Drug* court stated: “In [a prescription drug] case the purchaser’s doctor is a learned intermediary between the purchaser and the manufacturer. If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms . . . there is an excellent chance that injury to the patient can be avoided.” *Id.* The court made this statement in the context of distinguishing the case at bar, in which plaintiff suffered a known but rare side effect, from cases holding that a manufacturer has no duty to warn of risks to hypersensitive or allergic plaintiffs. *Id.* The purposes behind the rule are clearly apparent in the *Sterling Drug* court’s statement of the rule.

³⁹ See *Vitanza v. Upjohn Co.*, 778 A.2d 829, 838 n.11 (Conn. 2001) (listing forty-four state and federal jurisdictions that have adopted the Rule); *Larkin v. Pfizer, Inc.*, No. 2002-SC-0746-CL, 2004 WL 1361954, at *8 & n.3 (Ky. June 17, 2004) (listing thirty-four states that have adopted the Rule); see also 2 FRANK C. WOODSIDE, III, M.D., J.D., DRUG PRODUCT LIABILITY § 14.02[2][b][i], at 14-39 (“The learned intermediary doctrine is nearly universally accepted with respect to warnings for prescription drugs . . .”).

⁴⁰ *Sterling Drug*, 370 F.2d at 83-84.

⁴¹ *Id.* at 85.

⁴² In fact, the *Sterling Drug* court did not expressly state that the warning given to the physician stands in place of a legally adequate warning to the consumer, but merely stated that, if a warning is given to the physician, “there is an excellent chance that injury to the patient can be avoided.” *Id.*

does not expressly support the corollary that the duty to warn the prescribing physician supersedes, rather than supplements, a duty to warn the user of the product.⁴³ That corollary was soon firmly established, however. In the 1973 case of *Gravis v. Parke-Davis & Co.*,⁴⁴ the plaintiff alleged injury from the use of novocain as a spinal anesthetic, and sought damages from the drug's manufacturer under a failure-to-warn theory.⁴⁵ The manufacturer had provided a warning to the physician but not to the patient.⁴⁶ The Court dispensed with the plaintiff's failure-to-warn claim by stating: "We believe that it was unreasonable to suppose that a drug manufacturer must go beyond the physician and give actual warnings to the patient. Once the physician has been warned, the choice of which drugs to use, and the duty to explain the risks involved, is his."⁴⁷ The *Gravis* court gave three justifications for not requiring a drug manufacturer to warn the patient directly: (1) "The entire system of drug distribution in America is set up so as to place the responsibility of distribution and use upon professional people"; (2) "professionals are in the best position to evaluate the warning put out by the drug industry"; and (3) "[g]enerally speaking, only a physician would understand the propensities and dangers involved."⁴⁸ Today, it is clear that the Rule consists of two parts: (1) the manufacturer's provision of a legally adequate warning to the prescribing physician and (2) the accompanying exemption from the duty to warn the end user.⁴⁹ As

⁴³ Comment k to section 402A of the *Second Restatement* states in relevant part that an unavoidably unsafe product, "properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous." SECOND RESTATEMENT, *supra* note 18, § 402A cmt. k. Section 402A, however, does not answer the question of to whom "proper directions and warning[s]" must be given. *Id.*

⁴⁴ 502 S.W.2d 863 (Tex. Civ. App. 1973); *see also* *Davis v. Wyeth Labs.*, 399 F.2d 121, 130 (9th Cir. 1968). Although *Gravis* cites to a 1955 case for the proposition that there is no duty to warn the patient directly, the cited case does not stand for the proposition that a drug manufacturer has no duty to warn the patient directly, but rather that a physician's failure to disclose the known dangers of a particular anesthetic was not negligence because the patient had impliedly consented to the administration of an anesthetic during childbirth. *See Hall v. United States*, 136 F. Supp. 187, 193 (W.D. La. 1955).

⁴⁵ *Gravis*, 502 S.W.2d at 869-70. The *Gravis* case was a particularly apt one for the application of the learned intermediary rule, since the drug at issue was a surgical anesthetic, and one would ordinarily not expect a patient to concern himself with the details of this choice. In *Gravis*, the drug in question was not itself the treatment, but merely a means to effecting the surgical treatment sought by the plaintiff.

⁴⁶ *See id.* at 870.

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *See generally* *Goodson v. Searle Labs.*, 471 F. Supp. 546, 549 (D. Conn. 1978); *Ortho Pharm. Corp. v. Chapman*, 388 N.E.2d 541, 548 (Ind. Ct. App. 1979); *Whitley v. Cubberly*, 210 S.E.2d 289, 292 (N.C. Ct. App. 1974); *McEwen v. Ortho Pharm.*

Parts II and III of this Article will show, however, the justifications offered for the learned intermediary rule have changed very little since 1973, despite vast changes in the health care delivery system.⁵⁰

B. *Recognized Exceptions*

Even the learned intermediary rule in its current form acknowledges that in some situations prescription drugs are dispensed in circumstances which do not permit delegation of the duty to warn to the prescribing physician. The few recognized exceptions to the learned intermediary rule each attempt to identify a category of prescription drug use in which there is no effective intermediary to intercede between the manufacturer and the consumer of prescription drugs. While these exceptions have been somewhat successful in identifying common situations in which drugs are dispensed outside the doctor–patient relationship, in practice they are both underinclusive and overinclusive, and thus fail to adequately police the pharmaceutical marketplace. For example, because of the rapid pace of change in the health care market, there are now more drug sales than ever occurring outside the context of the doctor–patient relationship, and many of these sales are not captured by the current exceptions.⁵¹ Furthermore, the mechanistic application of the exceptions by most courts may in some cases remove the protections of the learned intermediary rule even though a drug was in fact dispensed in the context of a doctor–patient relationship. Thus, in their current form, the generally recognized exceptions fail to carry out the purposes of the Rule.

1. Mass Vaccines

The most widely recognized exception to the learned intermediary rule is the mass immunization exception under which vaccinations delivered in a clinic without significant participation by a physician do not qualify for the protection of the learned intermediary rule.⁵² Warnings of the risks attendant on such vaccines

Corp., 528 P.2d 522, 529 (Or. 1974).

⁵⁰ See *infra* Parts II & III.B.

⁵¹ See *infra* notes 185–86 and accompanying text (describing online sales of prescription drugs without a prescription).

⁵² The learned intermediary rule, and the tort system generally, have been significantly altered in the childhood vaccine area by the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, tit. III, 100 Stat. 3743, 3755 (codified as amended at 42 U.S.C. §§ 300aa-1 to -34 (2000)). This Act was passed by Congress in 1986 in response to a growing number of lawsuits alleging injury from childhood vaccinations. It essentially establishes a national compensation fund, the National Vaccine Injury Compensation Program, for injuries from such vaccinations, without

must therefore be delivered and tailored to the vaccine's recipient.⁵³ This exception is explicitly grounded in the lack of physician participation in the medical decision-making process. Since the patient does not have an opportunity to receive the benefit of a physician's individualized judgment as to the desirability of the vaccine, the manufacturer of the vaccine cannot expect a physician to deliver a suitable warning to the patient or to exercise independent medical judgment in helping the patient make a decision whether or not to use the product.⁵⁴ Significantly, the same vaccine, administered under a physician's direction during an office visit, is subject to the learned intermediary rule, and assuming a legally adequate warning to the physician, an injured patient cannot look to the vaccine manufacturer for compensation.⁵⁵

The mass vaccine exception was the first exception to the

regard to negligence or fault. It also limits tort lawsuits against vaccine manufacturers for injuries which are compensable from the Program. *See, e.g.*, 42 U.S.C. § 300aa-11(a)(2) (barring some civil lawsuits against vaccine manufacturers until after a petition for compensation is filed with the Program), § 300aa-21 (providing that, after a judgment is entered on a petition filed with the Program, the petitioner may elect to receive the compensation (if any) awarded under the Program or else file a civil suit for damages). The Act, however, does not bar all such lawsuits. *See Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 5-7 (1st Cir. 1994) (holding that parents' claims for loss of consortium are not barred). Therefore, the Act does not render the tort system, or the learned intermediary rule, entirely obsolete in this area.

⁵³ *See generally* *Petty v. United States*, 740 F.2d 1428, 1436 (8th Cir. 1984); *Reyes v. Wyeth Labs., Inc.*, 498 F.2d 1264, 1275 (5th Cir. 1974); *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 131 (9th Cir. 1968); *Allison v. Merck & Co.*, 878 P.2d 948, 957-58 (Nev. 1994); *Cunningham v. Charles Pfizer & Co.*, 532 P.2d 1377, 1381 (Okla. 1974).

⁵⁴ In cases of unavoidably unsafe products, unlike other products which carry warnings, the purpose of the warning is not to enable the consumer to use the product more safely (although certain warnings may in fact serve that purpose in the prescription drug context, such as a warning that the drug will make the user drowsy and should not be used while operating heavy machinery). Rather, such warnings are used solely to allow the user to make an informed decision whether or not to use the product at all, since many of the risks of these products are not avoidable, no matter how safely the product is used. *See, e.g.*, *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 813 (5th Cir. 1992) ("[T]here are two very different types of warnings that might be associated with a particular product: (1) an unavoidable risk warning; and (2) a preventable risk warning."). Thus, courts have required plaintiffs to show, in cases of unavoidable risks, that the requested warning would have changed their behavior instead of establishing the issue via the presumption that a preventable risk warning would have been heeded. *Id.* at 814 (declining to adopt the presumption under Mississippi law). *But see Reyes*, 498 F.2d at 1281 (adopting the presumption of causation in an unavoidable risk case under Texas law).

⁵⁵ *See, e.g.*, *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1178 (5th Cir. 1989). To the extent that this represents an effort by the courts to tailor the application of the learned intermediary rule to specific circumstances of the drug's use, this is entirely consistent with the thesis of this Article.

learned intermediary rule to be articulated. In *Reyes v. Wyeth Laboratories*,⁵⁶ a plaintiff allegedly injured by the polio vaccine⁵⁷ sued the vaccine's manufacturer. The vaccine had been administered by a registered nurse as part of a clinic-based childhood immunization program.⁵⁸ Although Wyeth, the manufacturer, had provided package insert warnings with the vaccine to the nurses administering the injections, neither the nurses nor the consent form signed by plaintiff's parent conveyed any of the warning information to the patient.⁵⁹

The jury found for the plaintiff.⁶⁰ On appeal, Wyeth argued that the trial court had erred in not applying the learned intermediary rule to the case.⁶¹ In fact, the appellate court could have resolved this case in Wyeth's favor under the learned intermediary rule. Wyeth had provided full disclosure of the risks of the vaccine to the health care providers involved,⁶² and the health care providers had at least two opportunities to convey those warnings to the patient's parent, but chose not to do so.⁶³ The court could have concluded that responsibility for the failure to warn rested with the health care professional and not the drug manufacturer. The court, however, chose instead to articulate an exception to the Rule for mass vaccinations.

The mass vaccine exception is the clearest and most widely accepted exception to the learned intermediary rule. In cases like *Reyes*, there is no intermediary, or at least no effective intermediary, between the patient and the manufacturer. Although there is a health care professional administering the vaccine, that professional is usually not a licensed physician.⁶⁴ Furthermore, the vaccine is

⁵⁶ 498 F.2d 1264 (5th Cir. 1974).

⁵⁷ Although defendant Wyeth Laboratories ("Wyeth") contested the issue at trial by claiming that the plaintiff's polio was in fact a "wild" strain not present in its vaccine, the jury rejected this theory by holding Wyeth responsible for the plaintiff's injuries. *Id.* at 1271.

⁵⁸ *Id.* at 1270.

⁵⁹ *Id.*

⁶⁰ *Id.* at 1269.

⁶¹ *Id.* at 1277 (rejecting Wyeth's argument that prior cases should be distinguished).

⁶² For a discussion of the status of nurses and other non-physician health care workers under the learned intermediary rule, see *infra* note 64 and accompanying text.

⁶³ The patient's mother had signed a consent form allowing the administration of the vaccine, which made no mention of any of the risks of the vaccine. *Reyes*, 498 F.2d at 1270. Nor did she receive any information about risks directly from the nurse administering the injection. *Id.* at 1270-71.

⁶⁴ Although the *Reyes* court held that the registered nurse who administered the

administered outside the context of a doctor–patient relationship and there is thus no opportunity for individualized consideration of whether the vaccine is appropriate for the patient.

2. Oral Contraceptives

A second exception, recognized only by a minority of jurisdictions, is the oral contraceptive exception. This exception is grounded in part on an extension of the reasoning in the mass vaccine cases. In those cases, the exception was justified on the grounds that a physician does not act as an intermediary between the patient and the vaccine manufacturer.⁶⁵ In the contraceptive cases, plaintiffs similarly argue that although physicians must be consulted in order to obtain the drug in question, they do not in fact play their traditional role of advisor and decision maker, but are much more likely to simply defer to the wishes of the patient and prescribe the drug.⁶⁶

The contraception exception was articulated by the Supreme Judicial Court of Massachusetts in 1985 in the case of *MacDonald v. Ortho Pharmaceutical Corp.*⁶⁷ The plaintiff in *MacDonald* was prescribed

polio vaccine was not a learned intermediary, some courts have held that, in certain circumstances, a non-physician health care worker can perform the function of a learned intermediary. *See Rohrbough v. Wyeth Labs., Inc.*, 719 F. Supp. 470, 478 (N.D. W. Va. 1989) (holding that nurse who administered DPT vaccine in public clinic was learned intermediary since she discussed medication with patient and made considered medical judgment before administering vaccine); *Walker v. Merck & Co.*, 648 F. Supp. 931, 934 (M.D. Ga. 1986), *aff'd without opinion*, 831 F.2d 1069 (11th Cir. 1987); *Singleton v. Airco, Inc.*, 314 S.E.2d 680, 682 (Ga. Ct. App. 1984) (holding that nurse anesthetist qualified as learned intermediary because she was familiar with side effects of medication); *Wyeth-Ayerst Labs. Co. v. Medrano*, 28 S.W.3d 87, 93 (Tex. App. 2000) (holding, *inter alia*, that nurses as well as doctors can be learned intermediaries for purposes of the doctrine). If a non-physician health care worker has the appropriate training to evaluate the warning and make a medical judgment as to the effectiveness and desirability of the treatment for the particular patient before her, she should be considered an effective intermediary, because the policies behind the Rule will be advanced by applying the Rule in that setting. That determination, however, should not be made lightly. The Rule should only be applied after a full consideration of the status and relevant training of the health care worker and after proper exercise of individualized medical judgment by that health care worker on behalf of the patient.

⁶⁵ *See supra* notes 54-55 and accompanying text.

⁶⁶ *See, e.g., Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379, 380 (E.D. Mich. 1985). *But see Allen v. Searle*, 708 F. Supp. 1142, 1147-48 (D. Or. 1989) (holding that learned intermediary rule would apply to an intrauterine contraceptive device (“IUD”) because of participation of prescribing physician in selection and insertion of device, despite the “greater degree of patient participation” in the decision to use the device).

⁶⁷ 475 N.E.2d 65 (Mass. 1985).

oral contraceptives by her physician and later suffered a stroke.⁶⁸ She alleged that the stroke was caused by blood clotting, a known side effect of the contraceptive.⁶⁹ Although the manufacturer's warning material, which described the potential for abnormal blood clotting and brain damage, was provided to the patient, it did not mention the word "stroke."⁷⁰ A jury agreed that this omission rendered the product unreasonably dangerous and returned a verdict for the plaintiff and against the manufacturer.⁷¹ The trial judge, however, granted defendant's motion for judgment notwithstanding the verdict based on the learned intermediary rule's exemption of drug manufacturers from the duty to warn the patient directly.⁷²

On appeal, the manufacturer argued that Massachusetts should accept the reasoning of other jurisdictions that had applied the learned intermediary rule to prescription contraceptives.⁷³ The Supreme Judicial Court, however, identified several characteristics of contraceptives that, it concluded, justified the creation of an exception to the learned intermediary rule. These included: the active involvement of the patient in the decision to use the drug; the relatively passive role of the physician; the status of "the pill" as "a convenience, rather than a traditional medication";⁷⁴ the relative lack of post-prescription involvement by the physician; and the existence of FDA regulations requiring direct warnings to the patient.⁷⁵ The court concluded that the learned intermediary rule should be abrogated for oral contraceptive drugs and that the manufacturer's duty to deliver a legally adequate warning runs directly to the patient.

This exception stretches the mass vaccine rationale. The most significant change is that, in the typical oral contraceptive fact pattern, the drug is actually dispensed within the context of a doctor-patient relationship.⁷⁶ Despite this, the other factors identified by the

⁶⁸ *Id.* at 67.

⁶⁹ *Id.* at 67 n.4.

⁷⁰ *Id.* at 67.

⁷¹ *Id.* at 68.

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *MacDonald*, 475 N.E.2d at 69 n.10 (quoting Statement of American Medical Association in March 14, 1970 issue of *Science News*, quoted in Comment, *Liability of Birth Control Pill Manufacturers*, 23 HASTINGS L.J. 1526, 1532 (1972)).

⁷⁵ *Id.* at 69. For further discussion of the relationship between the FDA mandate and the learned intermediary rule, and the current debate over preemption in this context, see *infra* Part III.D.

⁷⁶ See *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379, 380 (E.D. Mich. 1985); *Ogders v. Ortho Pharm. Corp.*, 609 F.Supp. 867, 874-75 (E.D. Mich. 1985); *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961 (E.D. Wis. 1981); *MacDonald*,

MacDonald court, such as increased patient involvement in the treatment decision-making process and the relatively passive role of the physician, justify abrogation of the learned intermediary rule in the contraceptive context.⁷⁷ Since the rationale behind the learned intermediary rule requires not only that the prescribing physician be present, but that she also be in a position to act as an effective intermediary between the patient and the drug manufacturer, jurisdictions which have adopted this exception recognize that the mere presence of a prescribing physician does not offer adequate protection to the patient in the circumstances described above.⁷⁸

3. FDA-Mandated Patient Warnings

Where the FDA requires specific information to be furnished to the patient,⁷⁹ in addition to the warnings furnished to the physician, the learned intermediary rule may not apply.⁸⁰ The leading case on

475 N.E.2d at 70.

⁷⁷ Fewer courts have extended this exception to encompass contraceptive devices such as IUDs. *See, e.g., Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1148 (D. Or. 1989) (declining to apply contraceptive exception in case involving a Cu-9 contraceptive device because “although a greater degree of patient participation may be involved in the choice of a prescription contraceptive than in some other prescription drugs, the physician makes the ultimate decision as to whether a particular contraceptive requested by the patient is appropriate”). In cases where courts have been willing to make this extension, the rationale for the exception is the same—the fact that the patient makes the decision to use the product, the fact that the product is not being used in a medical context but rather for the patient’s convenience, and the fact that there is essentially no significant follow-up care by the physician, are held to justify abrogation of the learned intermediary rule.

⁷⁸ *See supra* note 77. It may be true that in cases of surgically implantable devices, the physician assumes the role of an intermediary; however, to the extent that the *Allen* court and other courts refuse to recognize an exception because of the mere presence of a physician in the chain of distribution, this is inadequate reasoning. *See Wyeth-Ayerst Labs. Co. v. Medrano*, 28 S.W.3d 87, 92 (Tex. App. 2000) (refusing to recognize exception for prescription contraceptives “even when a physician makes no individualized judgment in prescribing and administering a prescription drug”).

⁷⁹ In the 1980s, there was a brief move toward requiring patient warnings for all prescription drugs. Although that initiative was rescinded in 1982, patient package inserts are still required for certain drugs. Drugs for which a patient package insert is required include estrogens, 21 C.F.R. § 310.515 (2004), oral contraceptives, 21 C.F.R. § 310.501 (2004), and nicotine, *Edwards v. Basel Pharms.*, 933 P.2d 298, 299-300 (Okla. 1997). Such inserts are required “only when there is a need to communicate detailed risk information about a drug product or instructions for using the product.” Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use, 68 Fed. Reg. 6062, 6072 (Feb. 6, 2003) (to be codified at 21 C.F.R. pt. 201).

⁸⁰ *See, e.g., Alexander v. Smith & Nephew, PLC*, 98 F. Supp. 2d 1276, 1286 n.10 (N.D. Okla. 2000); *Hatfield v. Sandoz-Wander, Inc.*, 464 N.E.2d 1105 (Ill. App. Ct. 1984); *McKee v. Am. Home Prods. Corp.*, 782 P.2d 1045 (Wash. 1989). *Contra In re Norplant Contraceptive Prods. Litig.*, 165 F.3d 374, 379 (5th Cir. 1999) (stating that,

this exception is *Edwards v. Basel Pharmaceuticals*.⁸¹

In *Edwards*, the widow of a long-time smoker brought an action against the manufacturer of a nicotine patch that had been prescribed to her husband.⁸² The plaintiff's husband had died from a heart attack resulting from a nicotine overdose incurred from using the product while still smoking.⁸³ Although the manufacturer specifically warned the prescribing physician of the risk of death by overdose if the patient smoked cigarettes while using the patch, the warning provided by the manufacturer to the patient only stated, "an overdose might cause you to faint."⁸⁴ The manufacturer argued that it had satisfied both its tort duty to warn the prescribing physician under the learned intermediary rule and its separate duty, imposed by the FDA,⁸⁵ to directly warn the patient. After the district court granted defendant's motion for summary judgment,⁸⁶ the issue framed for the United States Court of Appeals for the Tenth Circuit was the effect of FDA approval of a patient warning⁸⁷ on that warning's adequacy under principles of tort law.⁸⁸

The *Edwards* court noted that there are two lines of cases on the issue of the relationship between FDA regulation and tort regulation of the adequacy of a patient warning. Under one line of cases, the FDA mandate eliminates the learned intermediary rule from the analysis, and state tort principles are used to determine the adequacy of the warning.⁸⁹ Under the second line of cases, the FDA mandate merely carves out an exception to the learned intermediary rule as delineated by the specific mandate.⁹⁰ Only under the first line of

under Texas law, existence of FDA-mandated patient warning would not preclude application of learned intermediary rule).

⁸¹ *Edwards v. Basel Pharms.*, 116 F.3d 1341 (10th Cir. 1997).

⁸² *Id.* at 1342.

⁸³ The deceased was actually wearing two nicotine patches, and smoking a cigarette, at the time of his fatal heart attack. *Id.*

⁸⁴ *Id.*

⁸⁵ The content of the warning given by Basel Pharmaceuticals to the patient, although alleged to be defective by plaintiff due to its failure to disclose the risk of death from an overdose of nicotine, had been approved by the FDA. *Id.*

⁸⁶ *Id.*

⁸⁷ Although no evidence was actually adduced that the FDA had in fact approved the content of Basel's patient warning, the allegation of FDA approval was uncontested and so taken as true by the Tenth Circuit and the Oklahoma Supreme Court. See *Edwards*, 116 F.3d at 1343 n.1; *Edwards v. Basel Pharms.*, 933 P.2d 298, 299-300 (Okla. 1997).

⁸⁸ *Edwards*, 116 F.3d at 1343.

⁸⁹ See, e.g., *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 69-70 (Mass. 1985); *McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522, 532-35 (Or. 1974).

⁹⁰ See, e.g., *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024, 1032 (D.N.J. 1988); *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 399 (Del. 1989).

cases—the stronger version of the exception—would a court engage in independent analysis of the adequacy of the FDA-mandated warning. Under the second, weaker version, only failure to deliver the specific FDA-mandated text would result in tort liability.⁹¹

Since the tort standard is a matter of state law, and since the issue was one of first impression in Oklahoma, the Tenth Circuit certified the question of which version of the exception to use to the Oklahoma Supreme Court for an advisory opinion regarding Oklahoma law.⁹² The Oklahoma court held that the strong exception should apply, and that compliance with a specific FDA mandate does not preclude examination of the adequacy of the warning under state tort law principles.⁹³ This is the position taken by the reporters of the *Third Restatement* as well, who state in the comments to section 6: “[The *Third Restatement*] recognize[s] common-law causes of action for defective drug design and for failure to provide reasonable instructions or warnings, even though the manufacturer complied with governmental standards.”⁹⁴

The justification for the FDA-mandate exception is on its face somewhat different than either the mass vaccine or oral contraceptive exception. On closer examination, however, they are related. Under the strong version of the FDA exception, unlike the mass vaccine exception, the context in which the drug is prescribed does not enter into the analysis. The principal justification for the exception seems

⁹¹ In 1993, I argued that compliance with an FDA mandate should not preempt analysis of the adequacy of a warning under state tort law—a position consistent with the first line of cases. See generally Timothy S. Hall, *Bypassing the Learned Intermediary: Potential Liability for Failure to Warn in Direct-to-Consumer Prescription Drug Advertising*, 2 CORNELL J. L. & PUB. POL'Y 449, 466-73 (1993) [hereinafter Hall, *Bypassing*]. I continue to believe that independent review of the adequacy of warnings is the better analysis. This is consistent with the approach taken by the *Third Restatement*, which concludes that “a product’s compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective . . . but such compliance does not preclude as a matter of law a finding of product defect.” THIRD RESTATEMENT, supra note 7, § 4(b). For more on the preemption debate, see *infra* Part III.D.

⁹² *Edwards*, 116 F.3d at 1343.

⁹³ *Edwards v. Basel Pharms.*, 933 P.2d 298, 303 (Okla. 1997). Although the Oklahoma Supreme Court spoke in terms of whether compliance with the FDA mandate “reinstates” the Rule, *id.* at 301-03, this is not quite accurate. The issue is not whether the learned intermediary rule is “reinstated,” but whether the Rule exempts the manufacturer from state tort analysis of the quality and content of the warning provided to the patient.

⁹⁴ THIRD RESTATEMENT, supra note 7, § 6 cmt. b. Furthermore, section 4 of the *Third Restatement* provides: “[A] product’s compliance with an applicable . . . regulation is properly considered in determining whether the product is defective . . . but such compliance does not preclude as a matter of law a finding of product defect.” *Id.* § 4(b).

to be that, since the FDA has made an independent decision that direct warnings to the patient are (for whatever reason) necessary, tort law should act to regulate the content of those warnings. Thus, the existence of the FDA mandate itself is enough to trigger the exception to the learned intermediary rule and an independent examination of the content of the patient warning.

In order to appreciate the relationship between the exceptions, one must consider the FDA's decision to mandate direct warnings to patients for particular categories of prescription drugs. To the extent that the rationales for the FDA's decision to mandate direct warnings to patients mirror the justifications used in the mass vaccine or oral contraceptive cases, the courts in applying this exception are simply deferring to the FDA's judgment that, in these cases, there is sufficient risk that the physician in the doctor-patient relationship is not an effective intermediary.

4. Direct-to-Consumer Advertising

The final exception to the learned intermediary rule has been argued largely in theory,⁹⁵ with only one court to date adopting it as a matter of positive law.⁹⁶ The direct-to-consumer ("DTC") advertising exception holds that the learned intermediary rule should not apply when a plaintiff is led to seek a prescription for the drug by direct-to-consumer advertising sponsored by the drug manufacturer. Proponents of this exception argue that by inserting itself into the medical decision-making process, formerly the sole province of the doctor and patient, the drug manufacturer is detracting from the authority of the physician as intermediary.⁹⁷ The proponents further

⁹⁵ See generally Mitchell S. Berger, *A Tale of Six Implants: The Perez v. Wyeth Laboratories Norplant Case and the Applicability of the Learned Intermediary Doctrine to Direct-to-Consumer Drug Promotion*, 55 FOOD & DRUG L.J. 525 (2000); Ozlem A. Bordes, *The Learned Intermediary Doctrine and Direct-to-Consumer Advertising: Should the Pharmaceutical Manufacturer Be Shielded from Liability?*, 81 U. DET. MERCY L. REV. 267 (2004); April L. Foreman, *Web of Manipulation: The Learned Intermediary Doctrine and Direct-to-Consumer Advertising on the World Wide Web*, 35 J. MARSHALL L. REV. 97 (2001); Bradford B. Lear, *The Learned Intermediary Doctrine in the Age of Direct Consumer Advertising*, 65 MO. L. REV. 1101 (2000); Patrick Cohoon, Comment, *An Answer to the Question Why the Time Has Come to Abrogate the Learned Intermediary Rule in the Case of Direct-to-Consumer Advertising of Prescription Drugs*, 42 S. TEX. L. REV. 1333 (2001).

⁹⁶ See *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245 (N.J. 1999).

⁹⁷ This effect is noted in other areas of the law as well. See W.E. 'Ted' Afield, Note, *The New Drug Buyer: The Changing Definition of the Consumer for Antitrust Enforcement in the Pharmaceutical Industry*, 2001 COLUM. BUS. L. REV. 203, 209-10 (arguing that for purposes of defining the "consumer" of prescription drugs in antitrust cases, DTC advertising undermines traditional view that prescribing physician is the consumer).

contend that, by voluntarily assuming the role of provider of information regarding the drug, the manufacturer should also assume the legal duty to provide an adequate warning about the dangers of the drug.⁹⁸ In 1995, users of the contraceptive implant known as Norplant sued the manufacturer, alleging harm arising from side effects of the medication as well as difficulties in removing the implants.⁹⁹ Although a prescription contraceptive, Norplant had been extensively marketed directly to consumers as a more convenient alternative to daily-dose oral contraceptives.¹⁰⁰ However, the advertisements, although in compliance with FDA rules governing direct-to-consumer advertising of prescription drugs,¹⁰¹ did not mention the potential for pain and scarring associated with the removal of the device.¹⁰²

Wyeth Laboratories, the manufacturer of Norplant, argued that the warnings of the risk of such adverse effects given to the plaintiffs' physicians should preclude liability under the learned intermediary rule. In 1999, however, the New Jersey Supreme Court held that that state's learned intermediary doctrine did not apply to drugs which were marketed directly to consumers.¹⁰³ The court held that drug manufacturers that advertised to consumers directly were legally required to provide an "adequate warning of the product's dangerous propensities,"¹⁰⁴ and that compliance with FDA guidelines on direct-to-consumer marketing of prescription drugs created a *prima facie* presumption that such a warning had been given.¹⁰⁵ While the New

⁹⁸ Foreman, *supra* note 95, at 114 ("[T]he drug manufacturer has advertised itself into the role of the Learned Intermediary, and must accept responsibility of warning the end consumer."); Lear, *supra* note 95, at 1115 (under the learned intermediary rule, "drug manufacturers can hide behind the learned intermediary doctrine and continue to present information regarding the benefits of their products without being required to inform the consumer of the risks").

⁹⁹ *Perez*, 734 A.2d at 1248.

¹⁰⁰ *Id.*

¹⁰¹ A full discussion of the regulation of direct-to-consumer advertisement of prescription drugs is outside the scope of this Article. Commentators have argued that existing FDA regulation of direct-to-consumer advertising in fact does not adequately protect consumers of prescription drugs. For more on this subject, see Timothy S. Hall, *The Promise and Peril of Direct-to-Consumer Prescription Drug Promotion on the Internet*, 7 DEPAUL J. HEALTH CARE L. 1 (2003) [hereinafter Hall, *Promise and Peril*].

¹⁰² *Perez*, 734 A.2d at 1248.

¹⁰³ *Id.* at 1254-57.

¹⁰⁴ *Id.* at 1257.

¹⁰⁵ *Id.* at 1257-59. Although this ruling is at least consistent with the holding in *Edwards*—that compliance with an FDA-mandated warning does not wholly preempt application of state tort law to determine the adequacy of a warning—it in fact provides the manufacturer a substantial shield from liability. Because of the lack of

Jersey Supreme Court in *Perez* was the first court to adopt a DTC exception to the learned intermediary rule,¹⁰⁶ other jurisdictions have not followed New Jersey's lead,¹⁰⁷ nor have there been further reported cases in New Jersey alleging injury from failure to warn in DTC advertisements.

The *Perez* case involved a nexus between the DTC and contraception exceptions to the learned intermediary rule.¹⁰⁸ The outcome in *Perez* could thus be read as merely another contraception case. The *Perez* court, however, clearly did not intend it that way and explicitly declined to analyze the case in the context of other cases creating an exception to the learned intermediary rule for prescription contraceptives.¹⁰⁹ In a subsequent Norplant class action, a federal district court analyzed the learned intermediary rules of all fifty states and agreed that the DTC exception articulated by the New Jersey court was not the same as the contraceptive exception articulated by the Massachusetts courts. In the Norplant class action, the United States District Court for the Eastern District of Texas held that, as a matter of choice of law doctrine, the Massachusetts rule would not prohibit the application of the learned intermediary rule to Norplant cases governed by Massachusetts law.¹¹⁰

The *Perez* case identified several theoretical justifications for a DTC exception to the learned intermediary rule. These include:

litigation on point, it is not clear what evidence would suffice to overcome the presumption that compliance with FDA regulations satisfies the duty to warn. This issue will be important in determining the viability of future failure-to-warn claims based on direct-to-consumer advertising. In fact, the reason for the lack of subsequent litigation alleging direct-to-consumer advertising as an exception to the learned intermediary rule may be the perceived strength of the presumption that compliance with FDA regulations satisfies the tort duty as well. See THIRD RESTATEMENT, *supra* note 7, § 4(b) (providing that compliance with regulatory requirements should not preclude finding that a product is defective).

¹⁰⁶ Although the *Perez* court was the first to hold that a DTC exception exists, the first suggestion of such an exception by a court appears to have come eight years earlier. In 1991, the United States District Court for the District of Massachusetts noted in a footnote that “[i]n an appropriate case, the advertising of a prescription drug to the consuming public may constitute a third exception to the learned intermediary rule. By advertising directly to the consuming public, the manufacturer bypasses the traditional physician–patient relationship, thus lessening the role of the ‘learned intermediary.’” *Garside v. Osco Drugs, Inc.*, 764 F. Supp. 208, 211 n.4 (D. Mass. 1991). Despite the *Garside* court’s recognition in *dicta* of the theoretical grounds for such an exception, that case did not involve DTC advertising, so the learned intermediary rule was held to apply. *Id.*

¹⁰⁷ See *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 806-12 (E.D. Tex. 2002) (providing summary of state laws regarding this exception).

¹⁰⁸ See *Perez*, 734 A.2d at 1247.

¹⁰⁹ *Id.* at 1256.

¹¹⁰ *Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d at 810-11.

1. The drug manufacturer, having undertaken to provide information about the drug to the consumer, should have the corresponding duty to ensure that the information provided is complete and accurate.¹¹¹

2. Abolition of the learned intermediary rule in cases of DTC advertising recognizes the increasing importance of the patient's role in choosing medical treatment rather than having it chosen for him by the physician.¹¹²

3. Abolition of the Rule recognizes that DTC advertising, by providing information directly to the patient, "encroaches on [the doctor-patient] relationship by encouraging consumers to ask for advertised products by name."¹¹³ In addition, advertising of prescription drugs aimed directly at the consumer may create the mistaken impression in the mind of the consumer that the products are safe or that the FDA has approved the advertisement.¹¹⁴

The existing exceptions to the learned intermediary rule fail to adequately give effect to the purposes behind the Rule. By merely establishing categories of exceptions to the blanket exemption from the duty to warn the end user,¹¹⁵ the Rule fails to adequately address the rapid pace of change in the modern health care marketplace. When combined with judicial reluctance to embrace new exceptions, this creates a market distortion in which drug manufacturers have the ability and resources to communicate effectively with end users, but are not given legal incentives to do so in a responsible manner.

C. *The Learned Intermediary Rule as a Blanket Exemption*

The learned intermediary rule is properly thought of as an

¹¹¹ *Perez*, 734 A.2d at 1257 ("When a patient is the target of direct marketing, one would think, at a minimum, that the law would require that the patient not be misinformed about the product.")

¹¹² *Id.* at 1256-57 ("Patient choice is an increasingly important part of our medical-legal jurisprudence.")

¹¹³ *Id.* at 1256 (quoting Susan A. Casey, Comment, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 WM. MITCHELL L. REV. 931, 956 (1993)) (internal quotation marks omitted).

¹¹⁴ See *supra* note 111; see also Michelle Andrews, *Money & Medicine: Risky Turn on Madison Avenue*, N.Y. TIMES, Jan. 19, 2003, at 9 (discussing advertisements for medical devices, and noting that "Consumers, accustomed to the Food & Drug Administration's rigorous approval process for drugs, may assume that the same applies to medical devices. It doesn't. . . . In the absence of clinical trials data, people don't have the information they need to evaluate whether one product is better than others") (internal quotation marks omitted).

¹¹⁵ See, e.g., *Kennedy v. Merck & Co., Inc.*, No. 19591, 2003 WL 21658613, at *5 (Ohio Ct. App. July 3, 2004) ("Absent a recognized exception, [the] learned intermediary doctrine controls this case . . .").

exception to the general rule of law that product warnings, to be legally effective, must be given to the end user of a product.¹¹⁶ This exception, in keeping with its rationale, should apply only when an effective intermediary exists.¹¹⁷ As currently implemented by the courts, however, the learned intermediary rule constitutes a blanket exemption from a duty to warn the consumer of a prescription drug of the potential dangers of the drug. The vast majority of courts apply a virtually irrebuttable presumption¹¹⁸ that, absent one of a few narrowly drawn exceptions, an effective intermediary exists. Courts generally do not engage in an analysis of the facts of each case to determine whether the Rule should apply.¹¹⁹

A few plaintiffs have challenged this conception of the Rule and have argued that courts should engage in fact-specific reasoning in determining whether the learned intermediary rule should apply, but have met with little success. In *Swayze v. McNeil Laboratories, Inc.*,¹²⁰ the plaintiff alleged that the defendant drug manufacturer should have known that there was a pervasive practice in Mississippi by which physicians in fact did not exercise independent medical judgment in making drug-prescription decisions with respect to a certain narcotic anesthetic, and that this drug was in fact administered without adequate supervision by licensed medical professionals.¹²¹ The court dismissed the plaintiff's concerns, as well as plaintiff's analogy to non-pharmaceutical case law,¹²² holding that the classification of the drug

¹¹⁶ See *Cottam v. CVS Pharmacy*, 764 N.E.2d 814, 820 (Mass. 2002) (observing that the Rule "is an exception to the general rule that a manufacturer or retailer of an unavoidably dangerous product must directly warn all foreseeable consumers of the dangers of its product"); *Edwards v. Basel Pharms.*, 933 P.2d 298 (Okla. 1999).

¹¹⁷ See *supra* note 37 and accompanying text.

¹¹⁸ In fact, this presumption most often goes undiscussed by courts, most of which do not even recognize the possibility of the absence of an effective intermediary. See, e.g., *Hall v. Elkins SINN, Inc.*, No. 03-31030, 2004 WL 1418787, at *3 (5th Cir. June 22, 2004) (per curiam) ("[T]he 'learned intermediary doctrine' applies in this case, because it involves a prescription drug."). Note that the possibility of a lack of an effective intermediary is at least recognized by the *Third Restatement*. See *infra* notes 139-143 and accompanying text.

¹¹⁹ *Larkin v. Pfizer, Inc.*, No. 2002-SC-0746-CL, 2004 WL 1361954, at *10 (Ky. June 17, 2004) (Wintersheimer, J., dissenting) (expressing belief that learned intermediary rule "provides a type of summary immunization for pharmaceutical manufacturers and makes the adequacy of warnings to the ultimate consumer a question of law for the court and not a question of fact for the jury").

¹²⁰ 807 F.2d 464 (5th Cir. 1987).

¹²¹ *Id.* at 470. The drug in question was a surgical anesthetic, which plaintiff alleged was administered by medical technicians without adequate training, thus giving rise to plaintiff's injury. See *id.* at 465, 471.

¹²² Plaintiff made reference to *Gordon v. Niagara Machine & Tool Works*, 574 F.2d 1182 (5th Cir. 1978), in which the court held that a warning given to plaintiff's employer was inadequate, and that the warning should have been given to individual

as a prescription drug controlled, and that as a result, plaintiff had not raised any material issue of fact sufficient to overcome a motion for summary judgment.¹²³

The plaintiff also attempted to overcome the presumption that a warning to the prescribing physician was adequate in *Bacardi v. Holtzman*.¹²⁴ In *Bacardi*, the plaintiff argued that summary judgment as a matter of law was inappropriate because factual issues still remained regarding the manner in which he gained access to the drug (namely, outside of a physician–patient relationship). The *Bacardi* court stated, “It is the general rule that in the case of prescription drugs warnings of potential adverse effects to the prescribing physician is [sic] sufficient.”¹²⁵ The court rejected plaintiff’s appeal from the grant of summary judgment in favor of the defendant, holding that only in cases falling within a recognized exception to the learned intermediary rule would concerns about the lack of a physician–patient relationship be heard.¹²⁶

Another excellent example of the approach taken by courts to the learned intermediary rule is *Vitanza v. Upjohn Co.*¹²⁷ In *Vitanza*, plaintiff’s decedent was a 34-year-old male with a history of allergies to aspirin and non-steroidal anti-inflammatory drugs, who died after taking a tablet of Ansaid.¹²⁸ Although the drug had not been prescribed for him, but for his wife,¹²⁹ Mr. Vitanza, knowing of his allergy, attempted to ascertain whether the drug was safe for him to take. After examining the drug’s packaging, as well as reference materials, and finding no express statement warning him against taking the drug,¹³⁰ he took one tablet and died several hours later of a severe allergic reaction.¹³¹

Vitanza’s widow sued Upjohn, the manufacturer of the drug,

operators of the machinery in question. *Swayze*, 807 F.2d at 471 (citing *Gordon*, 574 F.2d at 1192). This supports the thesis that courts apply different analyses in prescription drug cases than in other cases involving intermediaries, and that the analysis in the prescription drug cases is far more conclusory than that applied in other industries.

¹²³ *Swayze*, 807 F.2d at 469.

¹²⁴ 442 A.2d 617 (N.J. Super. Ct. App. Div. 1981).

¹²⁵ *Id.* at 619; see also *Stanback v. Parke, Davis & Co.*, 657 F.2d 642, 644 (4th Cir. 1981) (“[T]he duty an ethical drug manufacturer owes to the consumer is to warn only physicians . . .”).

¹²⁶ *Bacardi*, 442 A.2d at 620.

¹²⁷ 271 F.3d 89 (2d Cir. 2001).

¹²⁸ *Id.* at 91. Ansaid is prescribed to treat arthritis. *Id.* at 90.

¹²⁹ *Id.*

¹³⁰ Perhaps Mr. Vitanza should have realized that the name of the drug, Ansaid, “is an acronym for A Non Steroidal Anti Inflammatory Drug.” *Id.*

¹³¹ *Id.* at 91.

alleging that the failure to label the drug as a non-steroidal anti-inflammatory drug (“NSAID”) constituted a failure to warn, rendering the drug unreasonably dangerous.¹³² Upjohn, moving for summary judgment, asserted the learned intermediary rule as a defense, claiming that its warning to prescribing physicians of the nature of the drug discharged its duty, and that it owed no duty to warn Vitanza.¹³³ Vitanza argued that the learned intermediary rule should no longer be applied automatically, but instead should trigger an inquiry into whether in fact an effective intermediary existed.¹³⁴ The United States Court of Appeals for the Second Circuit initially expressed some doubt about whether Connecticut law would recognize the learned intermediary rule as a defense as a matter of law.¹³⁵ The court noted that Connecticut’s recently adopted Products Liability Act might give support to Vitanza’s argument, and that recent changes in the health care marketplace might justify a more fact-based approach to the Rule. The Second Circuit therefore certified to the Connecticut Supreme Court the question of whether the learned intermediary rule should bar Vitanza’s claim as a matter of law.¹³⁶

The Connecticut Supreme Court soundly affirmed the traditional approach to the learned intermediary rule,¹³⁷ holding that no fact-based inquiry was needed to grant Upjohn’s motion for summary judgment and that Vitanza’s claim was barred as a matter of law. In reaching this conclusion, the court merely repeated the boilerplate defenses of the Rule, including the legal requirement of a prescription to obtain the drugs. The court expressly approved of the use of categorical exceptions to take account of changes in the prescription drug marketplace.

The treatment of the learned intermediary rule as a bright-line exception was perhaps justifiable in 1966, when the rule was first articulated. At that time, the health care market was simpler, and a paternalistic doctor–patient relationship was more firmly established as the dominant paradigm of health care delivery. Today’s health care system, however, no longer permits the unexamined

¹³² *Id.*

¹³³ *Id.*

¹³⁴ *Vitanza v. Upjohn Co.*, 214 F.3d 73, 76 (2d Cir. 2000).

¹³⁵ *Id.* at 78-79.

¹³⁶ *Id.* at 74.

¹³⁷ *Vitanza v. Upjohn Co.*, 778 A.2d 829, 847 (Conn. 2001) (“[W]e see no reason to create an entirely new exception on the facts of the present case, where the traditional doctor–patient relationship existed, there were no communication problems, and adequate warnings were provided to the prescribing physician.”).

presumption that prescription drugs are dispensed in the context of an ideal doctor–patient relationship.¹³⁸ In contrast to courts’ overwhelmingly reflexive and uncritical application of the Rule to virtually all prescription drug cases, this Article proposes a more nuanced application of the Rule that (1) recognizes that the Rule is an exception to the primary doctrine that warnings run to the ultimate consumer of a product; (2) takes into account developments in the health care marketplace; and (3) establishes an approach capable of adapting to future changes in the development, marketing and use of prescription drugs.

D. The Third Restatement—A Step in the Right Direction

In 1998, the American Law Institute approved a new and controversial¹³⁹ revision of the *Restatement (Third) of Torts: Products Liability*.¹⁴⁰ Although section 6(d) of the *Third Restatement* appears to recognize the diminishing utility of the traditional learned intermediary rule, ultimately, the Comments and Reporter’s Notes to that section reveal that the *Third Restatement* continues to rely on identification of categorical exceptions to the Rule rather than revision of the Rule itself.

The approach of the *Third Restatement* to failure-to-warn claims involving prescription drugs is contained in section 6, which provides in pertinent part:

(d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

(1) prescribing and other health care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or

(2) the patient when the manufacturer knows or has reason to know that health care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.¹⁴¹

The *Third Restatement* thus explicitly recognizes that in certain

¹³⁸ See *infra* Part II (describing changes in the health care marketplace since 1966).

¹³⁹ See generally Michael J. Wagner & Laura L. Peterson, *The New Restatement (Third) of Torts—Shelter from the Product Liability Storm for Pharmaceutical Companies and Medical Device Manufacturers?*, 53 FOOD & DRUG L.J. 225 (1998).

¹⁴⁰ THIRD RESTATEMENT, *supra* note 7, § 6.

¹⁴¹ *Id.* § 6(d).

circumstances, health care providers may not be in a position to act as effective intermediaries. The approach of the *Third Restatement*, however, is flawed in two respects. The first flaw is apparent from the Comments and Reporter's Note to section 6. Comment e, "Direct Warnings to Patients," makes reference to the existing mass vaccine, FDA mandate, and DTC advertising exceptions. The Reporter's Note to comment e restates the vaccine exception and notes that "[t]he Institute has left to developing case law whether other exceptions . . . should be recognized."¹⁴² Thus, although the language of subsection (d)(2) itself could be read to support a case-by-case determination of whether a learned intermediary exists, as proposed in this Article, this is not borne out in the Comments or Reporter's Notes, which continue to espouse an analysis based on identification and mechanical application of categorical exceptions.

Furthermore, despite the recognition in the *Third Restatement* that in certain circumstances health care providers may not be in a position to act as effective intermediaries, to date, few courts have accepted this invitation to refine the learned intermediary rule to reflect modern health care trends.¹⁴³ The time has come both to recognize the changed health care marketplace and to move beyond the categorical exception model which has characterized the learned intermediary rule to date. In this proposed evolution of the Rule, it is hoped that the *Third Restatement's* treatment of the traditional Rule will provide impetus for courts to further reconsider the learned intermediary doctrine along the lines advanced in this Article.

E. *The Sophisticated User Doctrine*

1. Description of the Doctrine

Drug companies are not the only product manufacturers that sell products into a chain of distribution, rather than directly to end users. Although standard tort doctrine provides that a

¹⁴² *Id.* § 6 cmt. e, reporter's note.

¹⁴³ *See, e.g.,* *Pumphrey v. C.R. Bard, Inc.*, 906 F. Supp. 334, 337-39 (N.D. W. Va. 1995) (holding that where manufacturer provided legally adequate warning of dangers of medical device directly to physician, manufacturer had no further duty to warn patient directly); *Hansen v. Baxter Healthcare Corp.*, 764 N.E.2d 35, 46 (Ill. 2002) (declining to apply standard from *Third Restatement* because it was not raised at trial or appropriately briefed). *Pumphrey* cited to a provision in a tentative draft of the *Third Restatement*. 906 F. Supp. at 338. *See also* *Transue v. Aesthetech Corp.*, 341 F.3d 911 (9th Cir. 2003) (evaluating medical device claim under standards of *Second Restatement* rather than *Third Restatement*); *Larkin v. Pfizer, Inc.*, No. 2002-SC-0746-CL, 2004 WL 1361954 (Ky. June 17, 2004) (adopting *Third Restatement* version of learned intermediary rule, but as a blanket exemption).

manufacturer's duty to warn extends through the chain of distribution to the end user,¹⁴⁴ the sophisticated user doctrine operates to relieve that duty in certain cases by reason of the characteristics of a particular market.

The sophisticated user doctrine looks superficially like the learned intermediary rule. As summarized in comment n to section 388 of the *Second Restatement*, under proper circumstances, an adequate warning given to a third party, not the end user, will be sufficient to discharge the manufacturer's duty to warn despite the fact that the warning was not in fact passed on to the end user by the intermediary.¹⁴⁵ This rule is typically invoked in situations where there is little communication, if any, between the manufacturer and the end user of the goods, such as when component parts are supplied for incorporation into a finished product,¹⁴⁶ or when products are sold to an employer for use by its employees.¹⁴⁷ In these circumstances, the *Second Restatement* concludes, it is reasonable for the manufacturer to rely on the intermediary to convey the warning to the end user and the manufacturer should suffer no legal liability for the intermediary's failure to do so.¹⁴⁸ The similarity of the circumstances involved in a sophisticated-user situation to the

¹⁴⁴ See, e.g., SECOND RESTATEMENT, *supra* note 18, § 388 cmt. l (“The supplier’s duty is to exercise reasonable care to inform *those for whose use the article is supplied* of dangers which are peculiarly within his knowledge.”) (emphasis added).

¹⁴⁵ *Id.* § 388 cmt. n.

¹⁴⁶ See, e.g., *Donahue v. Phillips Petroleum Co.*, 866 F.2d 1008 (8th Cir. 1989) (odorizing agent added to propane used in residential hot water heater); *Parker v. E.I. Du Pont de Nemours & Co.*, 909 P.2d 1, 7 (N.M. 1995) (component substances of dental implants); see also *Lee v. Butcher Boy*, 215 Cal. Rptr. 195 (Ct. App. 1985) (addressing issue of injury caused by defective motor used to power meat grinder); *infra* note 150 (discussing the related “bulk seller doctrine”). Despite occasional confusion by some courts, *Union Carbide Corp. v. Kavanaugh*, No. 4D03-2956, 2004 WL 1393537 (Fla. Dist. Ct. App. June 23, 2004) (applying the sophisticated user defense of § 388 but using the terminology of the learned intermediary rule), or litigants, *Bremer v. Egan Healthcare Corp.*, No. Civ.A. 03-1418, 2004 WL 1396314, at *4 (E.D. La. June 21, 2004) (“As the walker in this litigation was dispensed to the plaintiff by doctor prescription, the defendant argues that the learned intermediary or sophisticated user doctrine applies.”), these are two distinct doctrines of law.

¹⁴⁷ See, e.g., *Swope v. Columbian Chems. Co.*, 281 F.3d 185, 205-11 (5th Cir. 2002) (holding that manufacturer must establish that employer knew or reasonably should have known of product’s dangers to trigger sophisticated user doctrine). The sophisticated user doctrine is most often used in lawsuits by employees injured by products sold to the employer in bulk, but has also been used in cases brought by the retail purchaser of those products. See Richard C. Ausness, *Learned Intermediaries and Sophisticated Users: Encouraging the Use of Intermediaries to Transmit Product Safety Information*, 46 SYRACUSE L. REV. 1185, 1220-21 (1996) (describing cases brought by retail purchasers of products which were decided using the sophisticated user doctrine).

¹⁴⁸ SECOND RESTATEMENT, *supra* note 18, § 388 cmt. n.

tripartite relationship between a drug manufacturer, physician, and patient is obvious. As the next section will demonstrate, however, the details of the sophisticated user doctrine vary in material respects from the learned intermediary rule.

2. Sophisticated Users and Learned Intermediaries

Both the sophisticated user doctrine and the learned intermediary rule allow the manufacturer of a dangerous product to delegate to others the duty to warn the product's end users of its dangers.¹⁴⁹ Despite the superficial similarities, however, courts have approached the two doctrines in very different ways.¹⁵⁰

A good example of the application of the sophisticated user doctrine is found in *Smith v. Walter C. Best, Inc.*¹⁵¹ In *Smith*, the plaintiffs were employees of Valley Mould, which purchased sand from defendant Walter C. Best, Inc.¹⁵² In the course of their employment, plaintiffs came into contact with the sand and

¹⁴⁹ There are actually two “sophisticated user” issues in products liability law. The first merely provides that there is no duty to warn of a risk of which the user of a product is already aware. Therefore, courts have held that a “sophisticated user” who is aware of the risks of a product cannot complain of the seller’s failure to deliver a warning. See *Matherne v. Poutrait-Morin/Zefal-Christophe, Todson, Inc.*, 868 So. 2d 114, 120-21 (La. Ct. App. 2003) (finding actual knowledge on part of plaintiff). The second doctrine applies where, as discussed in this Article, a manufacturer sells a product to a third party who makes the product available to end users. The issue in these cases is to what extent the manufacturer can rely on the intermediary—the so-called “sophisticated user”—to deliver adequate warnings about the safe use of the product. See, e.g., *Mohr v. St. Paul Fire & Marine Ins. Co.*, 674 N.W.2d 576, 584 (Wis. Ct. App. 2003). It is this second doctrine which is the subject of this discussion. For a discussion of potential jury confusion between the two doctrines, see *Mozeke v. International Paper Co.*, 933 F.2d 1293 (5th Cir. 1991).

¹⁵⁰ There is a third doctrine relevant to this discussion called the “bulk seller doctrine.” Much like the learned intermediary and sophisticated user doctrines, the bulk seller doctrine provides that when a manufacturer provides dangerous products in bulk to a third party for repackaging and sale to end users, the manufacturer may only warn the intermediary and is not required to ensure that a warning makes its way to every end user. See, e.g., *Humble Sand & Gravel, Inc. v. Gomez*, No. 01-0652, 2004 WL 2090592, at *1 (Tex. Sept. 17, 2004). However, courts have generally held that, as with the sophisticated user doctrine and unlike the application of the learned intermediary rule, the bulk seller doctrine only shields a manufacturer from liability if the reliance on the intermediary was reasonable in the circumstances. See, e.g., *Little v. Liquid Air Corp.*, 952 F.2d 841, 850-51 (5th Cir. 1992) (“The bulk seller, therefore, fulfills its duty to the ultimate consumer only if it ascertains (1) that the distributor to which it sells is adequately trained, (2) that the distributor is familiar with the properties of the product and the safe methods of handling it, and (3) that the distributor is *capable of* passing this knowledge to the consumer.”) (emphasis added).

¹⁵¹ 927 F.2d 736 (3d Cir. 1990).

¹⁵² *Id.* at 737-38.

eventually developed silicosis, a respiratory disease.¹⁵³ Plaintiffs sued, alleging that their injuries were caused by defendants' failure to provide them with warnings of the dangerous nature of their product.¹⁵⁴ The district court granted summary judgment for the defendants pursuant to the sophisticated user doctrine, and plaintiffs appealed.¹⁵⁵

The United States Court of Appeals for the Fifth Circuit reviewed the district court's findings of fact and noted:

The district court focused on whether Valley Mould was a knowledgeable purchaser of silica sand and upon whether the sand suppliers failed to exercise reasonable care in relying upon Valley Mould to provide appropriate employee warnings. The [district] court [found] ample record evidence to support the conclusion that Valley Mould was a knowledgeable industrial purchaser of silica sand, familiar with the dangers associated with inhaling silica dust and with proper dust control methods. The court also concluded that Valley Mould was in a superior position to supply effective employee warnings.¹⁵⁶

The contrast between the district court's analysis of whether the sophisticated user doctrine should insulate the manufacturer from liability and the typical learned intermediary analysis could not be more stark. The sophisticated user analysis is a fact-based, circumstance-sensitive inquiry¹⁵⁷ into the reasonableness of the manufacturer's behavior and the relationships among the manufacturer, the intermediary, and the injured party.¹⁵⁸ In contrast, the typical learned intermediary case focuses solely on whether or not the facts fit one or more predefined exceptions.¹⁵⁹ The result is that learned intermediary cases (i.e., prescription drug cases) tend to be

¹⁵³ *Id.* at 738.

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ *Id.* at 740.

¹⁵⁷ See also *Case v. Merck & Co.*, No. Civ. A. 02-1779, 2002 WL 31478219, at *5 (E.D. La. Nov. 5, 2002) (declining to grant summary judgment without specific evidence as to whether an effective intermediary existed because "there [was] no factual record before the Court upon which to base a finding that the vaccine manufacturers were sophisticated users").

¹⁵⁸ This is the analysis contemplated by the *Second Restatement*. Comment n to section 388 of the *Second Restatement* provides a set of factors for courts to apply in deciding whether a manufacturer's behavior was reasonable in the circumstances. These include: (1) the degree of harm posed by the product; (2) the "known or knowable character of" the intermediary relied on by the manufacturer; (3) the burden which would be imposed on the manufacturer by requiring direct warnings; and (4) the practicality of having the goods themselves carry the warning to the end user. SECOND RESTATEMENT, *supra* note 18, § 388 cmt. n.

¹⁵⁹ See *supra* part I.C.

disposed of by summary judgment while sophisticated user cases tend to reach a jury for determination of the reasonableness of the warning given.¹⁶⁰

The Reporters of the *Third Restatement* recognized the difference between the application of the sophisticated user doctrine and the learned intermediary rule. Unlike the learned intermediary rule, they wrote that under the sophisticated user doctrine, “There is no general rule as to whether one supplying a product for the use of others through an intermediary has a duty to warn the ultimate product user directly or may rely on the intermediary to relay warnings. The standard is one of reasonableness in the circumstances.”¹⁶¹ This is obviously very different from the learned intermediary rule, which has developed as a bright-line rule of exemption from the duty to warn the end user.

Recall the case of *Vitanza v. Upjohn Co.*¹⁶² In *Vitanza*, the Second Circuit asked the Connecticut Supreme Court to decide the issue of whether the learned intermediary rule was a bar to liability or a defense to be considered by the fact finder.¹⁶³ Although the Second Circuit noted that Connecticut courts had in previous cases been willing to treat the learned intermediary rule as a case-by-case defense, in part due to “changed conditions in the health care industry, including direct marketing . . . and increased patient choice,”¹⁶⁴ the Connecticut Supreme Court chose to reaffirm the bright-line nature of the learned intermediary rule, concluding that “[t]he learned intermediary doctrine stands for the proposition that, as a matter of law, the prescribing physician . . . is the person best able

¹⁶⁰ Compare *Conwed Corp. v. Union Carbide Chems. and Plastics Co., Inc.*, 287 F. Supp. 2d 993 (D. Minn. 2001) (denying summary judgment to manufacturer of asbestos), and *Natural Gas Odorizing, Inc. v. Downs*, 685 N.E.2d 155 (Ind. Ct. App. 1997) (precluding summary judgment in favor of defendant due to fact issue as to reasonableness of odorant supplier’s reliance on intermediary), with *Wright ex rel. Trust Co. of Kan. v. Abbott Labs., Inc.*, 259 F.3d 1226 (10th Cir. 2001) (affirming grant of summary judgment in learned intermediary rule case).

¹⁶¹ THIRD RESTATEMENT, *supra* note 7, § 2 cmt. i; see also SECOND RESTATEMENT, *supra* note 18, § 388 cmt. n (“[I]t is obviously impossible to state in advance any set of rules which will automatically determine in all cases whether one supplying a chattel for the use of others through a third person has satisfied his duty . . . by informing the third person of the dangerous nature of the chattel . . .”); *Hoffman v. Houghton Chem. Corp.*, 751 N.E.2d 848, 856 (Mass. 2001) (“[I]n certain *limited circumstances*, ‘a manufacturer may be absolved from blame [for failure to warn] because of a *justified reliance* upon . . . a middleman,’ so long as such *reliance is reasonable*.”) (quoting *Carter v. Yardley & Co.*, 64 N.E.2d 693, 697 (Mass. 1946)) (emphasis added) (alterations in internal quotation in original).

¹⁶² 271 F.3d 89 (2d Cir. 2001); see *supra* notes 127–37 and accompanying text.

¹⁶³ See *Vitanza v. Upjohn*, 778 A.2d 829 (Conn. 2001).

¹⁶⁴ *Vitanza*, 271 F.3d at 92.

to take or recommend precautions against the harm.”¹⁶⁵ This formula, which is accepted without question by a significant majority of courts, encapsulates the difficulty with applying the Rule in the context of the modern health care market.

II. PROBLEMS WITH THE LEARNED INTERMEDIARY RULE

A. *The Rule Fails to Reflect Modern Medical Practice*

1. Diminution of the Authority of the Physician

When the learned intermediary rule was first articulated, the doctor–patient relationship was very different than the relationship which exists today. In 1966, physicians were substantially autonomous in their role as medical advisors and decision makers for their patients.¹⁶⁶ A patient’s health insurer, if he had one, did not exercise any meaningful oversight over a physician’s spending or practice patterns, and physicians were almost certainly paid on a fee-for-service basis. In contrast, today, 78 million Americans under the age of 65 receive health insurance and health care through some form of managed care organization.¹⁶⁷ Managed care is defined by the convergence of health insurance and the delivery of health services,¹⁶⁸ and is characterized by significant oversight of and limitation on the independent authority of the physician.¹⁶⁹ The growth of managed care is explained in large part as a market reaction in the 1970s and 1980s to the dramatic increases in the cost

¹⁶⁵ *Vitanza*, 778 A.2d at 841 (emphasis added). Unfortunately, the Connecticut court in *Vitanza* failed to take account of two things. First, the radical changes in the health care marketplace since the articulation of the learned intermediary rule, and second, the fact that the rule is in fact not, as the court stated “a rule of law stating a duty,” *id.* at 840, but is rather an exception to the general rule that warnings are owed to the end user of an unavoidably unsafe product. See *supra* note 116 and accompanying text.

¹⁶⁶ For an excellent discussion of the lack of meaningful communication in the traditional, fee-for-service doctor–patient relationship, see JAY KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* (1984).

¹⁶⁷ NAT’L CENTER FOR HEALTH STAT., U.S. DEP’T OF HEALTH & HUMAN SERVS., HEALTH, UNITED STATES, 2003, WITH CHARTBOOK ON TRENDS IN THE HEALTH OF AMERICANS 339 tbl.132, available at <http://www.cdc.gov/nchs/data/hus/tables/2003/03hus132.pdf> (last visited Oct. 13, 2004). For a more complete description of the managed care revolution and its effect on the doctor–patient relationship, see Timothy S. Hall, *Bargaining with Hippocrates: Managed Care and the Doctor–Patient Relationship*, 54 S.C. L. REV. 689 (2003) [hereinafter Hall, *Bargaining with Hippocrates*].

¹⁶⁸ Hall, *Bargaining with Hippocrates*, *supra* note 167, at 692-94.

¹⁶⁹ *Id.* at 694-99.

of health care under a fee-for-service system, and one of the principal goals of managed care has been to deliver medical services as efficiently as possible.¹⁷⁰ Unfortunately, one of the casualties of this drive for efficiency has been the quality of the physician–patient interaction, as physicians are pressured by financial incentives to perform more services in less time.¹⁷¹ These circumstances allow physicians little time to process warnings provided by drug manufacturers into forms in which they will be heard, understood, and heeded by patients. Although the physician still performs a gatekeeping function, since even in the modern doctor–patient relationship physicians can refuse to prescribe drugs that they believe to be unhelpful or contraindicated,¹⁷² this gatekeeping function is less concerned with patient education and empowerment than it is an exercise of a physician’s clinical judgment. Simply put, the structure of the modern doctor–patient relationship does not allow the physician to occupy the ideal ethical role which underlies the learned intermediary doctrine—that of collaborative decision making and tailoring the technical warnings delivered by the drug company into a form suitable for the patient.

Managed care is also characterized by increased control over the doctor–patient relationship by third party payors. In the pharmaceutical context, managed care companies exert control over drug choices in three ways: by use of pre-authorization requirements, through use of formularies, and by using prescription benefit managers (“PBMs”). Formularies are lists of covered drugs for which the MCO will pay or which will be subject to lower co-payment and deductible costs than non-formulary drugs. These formulary drugs are often chosen, not solely on the basis of therapeutic benefit, but also on the basis of cost discounts negotiated between the managed care company and the manufacturer of the drug.¹⁷³ Prescription

¹⁷⁰ *Id.* at 690. There is substantial debate, however, whether cost savings seen in the early years of managed care penetration are sustainable, as medical cost increases are once again far outpacing the level of inflation in the economy as a whole. *Id.* at 693.

¹⁷¹ For a more complete discussion of financial incentives in managed care, see generally Timothy S. Hall, *Third-Party Payor Conflicts of Interest in Managed Care: A Proposal for Regulation Based on the Model Rules of Professional Conduct*, 29 SETON HALL L. REV. 95 (1998).

¹⁷² Today’s health care market, however, provides patients with opportunities to obtain drugs even without their physicians’ consent. See *infra* Part II.A.4 (discussing the rise of Internet pharmacies which will provide prescription drugs outside the context of a doctor–patient relationship).

¹⁷³ GEN. ACCT. OFF., PRESCRIPTION DRUG BENEFITS: IMPACT OF MEDICARE HMOs’ USE OF FORMULARIES ON BENEFICIARIES 5-6 (1999).

benefit managers are firms employed to reduce the cost of prescription drug coverage to MCOs, often through programs to encourage the use of generic alternatives and cheaper drugs within the same therapeutic class.

2. Increased Importance of Drug Therapies

The twentieth century saw the greatest expansion of the knowledge and power of medicine in history. Much of this expansion came in the form of pharmaceutical therapies, resulting in more effective treatments for scores of diseases. These advances in drug therapies also fueled a dramatic increase in pharmaceutical spending,¹⁷⁴ and the resulting rise in prescription drug costs still reverberates through American health policy debates.¹⁷⁵ It is no exaggeration to say that drug therapies are now at the core of American medical practice, and that few Americans leave a doctor's appointment without a prescription.

This increased emphasis on pharmacology in modern medicine, however, also has its downside. With the increased efficacy of modern medicines has come an increased demand for medication, even in situations where the medication is contraindicated or unhelpful.¹⁷⁶ This can be harmful both to the individual patient as well as to the public health. The literature is replete with descriptions of overuse and misuse of antibiotic drugs, to the extent that many microbial diseases once successfully treated with antibiotics have developed resistance to the commonly used drugs, and are once again spreading relatively unchecked.¹⁷⁷ Patient demand for drugs can lead both to doctor-shopping and, more recently, to patients obtaining medication themselves entirely outside the doctor-patient relationship.

¹⁷⁴ Thomas R. McLean & Edward P. Richards, *Health Care's "Thirty Years' War": The Origins and Dissolution of Managed Care*, 60 N.Y.U. ANN. SURV. AM. L. 283, 392 (2004) (noting that spending on prescription drugs increased 300% from 1991 to 2001).

¹⁷⁵ See H. Jeffrey Lawrence, M.D., *The High Cost of Prescription Drugs: The Price of Success?*, 4 YALE J. HEALTH POL'Y L. & ETHICS 165, 165-67 (2004).

¹⁷⁶ See Murray et al., *supra* note 13, at 521 (reporting that physicians found forty-nine percent of specific drug requests from patients to be clinically inappropriate).

¹⁷⁷ See, e.g., Oliver T. Rutschmann & Marisa Elena Domino, *Antibiotics for Upper Respiratory Tract Infections in Ambulatory Practice in the United States, 1997-1999: Does Physician Specialty Matter?*, 17 J. AM. BOARD FAM. PRAC. 196 (2004); U.S. FOOD & DRUG ADMIN., ANTIBIOTIC RESISTANCE, at

http://www.fda.gov/oc/opacom/hottopics/anti_resist.html (last visited Oct. 16, 2004).

3. Increased Emphasis on “Lifestyle” Drugs

At the same time as advances in pharmaceutical science were expanding the physician’s abilities to cure, drug companies were also expanding into new markets and redefining the concepts of sickness and of medical intervention. In 1998, Pfizer obtained FDA approval for a new drug for the treatment of erectile dysfunction. The new drug, Viagra, was a runaway bestseller for Pfizer¹⁷⁸ and arguably ushered in a new era of “lifestyle” drugs.¹⁷⁹ While the application of medical science to cosmetic enhancement is not new, the development and use of so-called “lifestyle drugs” has boomed in the past few years,¹⁸⁰ and the onslaught of such products and therapies shows no signs of abating.¹⁸¹

The increased availability of “lifestyle” drugs has caused problems for the health care system, raising questions about the appropriateness of coverage for purportedly medically unnecessary treatments.¹⁸² Particularly in light of the extremely high cost of many prescription drugs and many needy individuals’ inability to pay for medically necessary drugs, the ethics of spending millions of dollars on the development, marketing, and sale of non-medically-necessary therapies is debatable.

One might argue that the purchase of a “lifestyle” drug such as Viagra shares several of the characteristics of previously recognized exemptions to the learned intermediary rule, and that the Rule should therefore simply not apply to such drugs. This analysis, however, is overly simplistic and would be unworkable in practice.

¹⁷⁸ See *Viagra: \$1 Billion in Sales Expected in First Year on the Market*, CHI. TRIB., July 10, 1998, at C7; *A Record Pace for Viagra Sales*, N.Y. TIMES, July 7, 1998, at D6.

¹⁷⁹ Although certainly some “lifestyle” products such as Rogaine pre-dated the Viagra boom, it was Viagra that captured the imagination of the nation. A search of the Nexis “major newspapers” database reveals 1,498 articles with “Viagra” in the title during 1998, the year of its introduction.

¹⁸⁰ See *Visage in a Bottle—Bespoke Services Look to the Future*, BRAND STRATEGY, May 12, 2003, at P6, available at 2003 WL 6282132.

¹⁸¹ See Jeffrey P. Kahn, *Raising the Issue of Viagra Costs—Who Should Pay?*, at <http://www.cnn.com/Health/bioethics/9807/viagra.cost/> (last visited Oct. 16, 2004) (“The future will likely offer many new drugs like Viagra: expensive drugs that have lifestyle benefits without actually curing an illness or disease. . . . The case of Viagra represents only the beginning of what will be more difficult decisions about who pays for the promising treatments of the future.”).

¹⁸² See, e.g., *State’s Authority over Drug Coverage Upheld*, L.A. TIMES, May 21, 2003, at B6 (describing disagreement between insurers and state officials over which drugs are medically necessary and which are “nonessential”). For an overview of some of the legal issues arising from the popularity of Viagra, see generally Kim H. Finley, Comment, *Life, Liberty, and the Pursuit of Viagra? Demand for “Lifestyle” Drugs Raises Legal and Public Policy Issues*, 28 CAP. U. L. REV. 837 (2000).

Although it is true in many cases that such drugs are sought by the patient—perhaps after exposure to direct-to-consumer advertising—and that the physician may play a diminished role in the decision to use the drug,¹⁸³ this is not true of all prescriptions for any given “lifestyle” drug. For example, while Viagra is certainly sought, prescribed, and used for lifestyle, cosmetic, or “convenience” purposes, it is also used for the treatment of organic erectile dysfunction.¹⁸⁴ In that latter context, it is far more likely that the drug is being prescribed and used within the context of a doctor–patient relationship, in which case the learned intermediary rule should apply. This inability to clearly distinguish at first glance between “lifestyle” applications and “medical” applications of drugs leads to the conclusion that a categorical exception from the protections of the learned intermediary rule for “lifestyle” drugs is inappropriate, and that a more nuanced approach is required.

4. Increased Availability of Alternate Outlets for Prescription Drugs

One of the consequences of the Internet economy boom of the 1990s has been the rise of Internet-based pharmacy services. While many of these online pharmacies are merely cyber-analogues of brick and mortar pharmacies or cost-saving mail-order pharmacies run by insurance companies, there are Internet pharmacies where prescription drugs can be purchased outside of a doctor–patient relationship. Some of these pharmacies employ licensed physicians to write prescriptions, usually on the basis of an online questionnaire filled out by the customer, while others provide prescription drugs without any prescription.¹⁸⁵ While such pharmacies are illegal under current American drug and physician licensing laws, to date there have been no significant efforts by the Food and Drug Administration (“FDA”) or other regulatory bodies to crack down on such operations. In fact, the international nature of the Internet may make regulation of these “on-line” pharmacies virtually impossible, as

¹⁸³ These characteristics are typically used by courts that recognize the oral contraceptive exception. *See supra* Part I.B.2.

¹⁸⁴ Another example of this difficulty in categorization occurs with cosmetic surgery. For example, breast augmentation is considered a “lifestyle” treatment rather than a medical treatment when used in a purely elective context despite the fact that it can be used in other cases in a medically necessary fashion such as reconstructive surgery after a mastectomy. There are virtually no so-called “lifestyle” drugs or treatments which are not also used for sound medical reasons.

¹⁸⁵ For a typology of Internet pharmacies, see Barbara J. Williams, Note, *On-Line Prescriptions and Drug Sales: An Overview of Emerging Issues*, 1 HOUS. J. HEALTH L. & POL'Y 147 (2001).

sellers can readily set up shop beyond the jurisdiction of American authorities. This is compounded by the fact that mailed packages of prescription drugs are difficult to interdict at the border.¹⁸⁶

If the manufacturer of a prescription drug knows or should know that the product will not be dispensed in the context of a meaningful doctor–patient relationship, then there is already support in the case law¹⁸⁷ and in the *Third Restatement*¹⁸⁸ for not applying the learned intermediary rule. As early as 1974, the Fifth Circuit Court of Appeals, applying Texas law, stated that a drug manufacturer would be held to the knowledge of an expert in the “distribution and administration of pharmaceutical products.”¹⁸⁹ The court further stated that, in the context of the administration of the polio vaccine, it was generally known that “a great majority of [people] receive their . . . vaccine in mass administrations or county clinics manned at least in part by [non-physicians].”¹⁹⁰ Consequently, the Fifth Circuit concluded that the defendant would be presumed to have known that vaccines sold to a state health department would likely be administered in such a context.¹⁹¹ The *Third Restatement* also incorporates this principle in its statement that warnings should be provided to the patient when a drug manufacturer knows or should know that a drug is being sold in a situation where “health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.”¹⁹²

5. Increased Marketing to the Patient as Decision Maker

In the past two decades, there has been a dramatic change in the promotion of prescription drugs. In 1966, when the learned intermediary rule was first articulated, prescription drugs were marketed exclusively at physicians and other health care professionals.¹⁹³ Since that time, marketing materials intended for consumers have become the fastest growing segment of the

¹⁸⁶ Letter from Representatives John D. Dingell and Peter Deutch, to Dr. Mark McLennan, FDA Commissioner (July 14, 2003) (describing inadequate interdiction practices and procedures in the Louisville, Kentucky UPS facility), *available at* http://www.house.gov/commerce_democrats/press/108ltr43.htm.

¹⁸⁷ See *Reyes v. Wyeth Labs.*, 498 F.2d 1264 (5th Cir. 1974).

¹⁸⁸ THIRD RESTATEMENT, *supra* note 7, § 6(d)(2).

¹⁸⁹ *Reyes*, 498 F.2d at 1277.

¹⁹⁰ *Id.* (internal quotation marks omitted).

¹⁹¹ *Id.* (citing *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 131 (9th Cir. 1968)).

¹⁹² THIRD RESTATEMENT, *supra* note 7, § 6(d)(2).

¹⁹³ For a more complete discussion of the phenomenon of direct-to-consumer prescription drug promotion, see generally Hall, *Bypassing*, *supra* note 91; Hall, *Promise and Peril*, *supra* note 101.

pharmaceutical industry's promotional budget.¹⁹⁴ Direct-to-consumer marketing is conducted through print and broadcast media and, most recently, through the new medium of the Internet.

Although direct-to-consumer marketing is a fairly new phenomenon, studies have shown it to be effective in establishing brand name recognition and in creating demand for the advertised product.¹⁹⁵ Direct-to-consumer advertising has been controversial, largely because of perceptions on the part of consumer advocates and others that advertisements do not present a fair balance of promotional and instructional information about the product advertised.¹⁹⁶ Opponents of direct-to-consumer advertising point to numerous instances of misleading or inaccurate statements about advertised products.¹⁹⁷

Despite criticism of direct-to-consumer advertising, such promotional efforts are becoming accepted in the health care marketplace. The FDA has not acted to significantly limit the ability of drug manufacturers to engage in such advertising;¹⁹⁸ and drug manufacturers apparently find them a useful adjunct to the more traditional promotional efforts directed at health care professionals.¹⁹⁹ Some commentators recognize that direct-to-consumer advertisements have potential benefits, including increased awareness on the part of patients of new or innovative treatments.²⁰⁰

¹⁹⁴ *Direct-to-Consumer Advertising Jumps 185%* (Nov. 6, 2003), at http://www.pharmacist.com/articles/h_ts_0409.cfm (last visited Oct. 31, 2004).

¹⁹⁵ MARTA WOSINSKA, COMMENTS ON CONSUMER-DIRECTED PROMOTION, Docket No. 2003N-0344 (Dec. 1, 2003) (summarizing results of empirical research into the effects of DTC advertising), available at <http://www.fda.gov/ohrms/dockets/dailys/03/dec03/120303/03N-0344-emc-000017-01.pdf> (last visited Oct. 31, 2004).

¹⁹⁶ Foreman, *supra* note 95, at 110-14 (describing and critiquing the content of several promotional Web sites).

¹⁹⁷ See, e.g., Jackie Judd, *Truth in Advertising? FDA Says Many Prescription Drug Ads are Deceptive*, Jan. 3, 2001 (on file with author).

¹⁹⁸ See Hall, *Promise and Peril*, *supra* note 101, at 3-8 (discussing history of FDA's regulation of direct-to-consumer advertising).

¹⁹⁹ See Michael Pastore, *Internet Pharmaceutical Ads Prove Effective*, at http://www.cyberatlas.internet.com/markets/advertising/article/0,1323,5941_2941_91,00.html (last visited Oct. 16, 2004) (reporting on study finding that Internet advertising to consumers is more effective than traditional print or broadcast advertisements); Ross Tieman, *Keep Taking the Tablets—Brand Extensions*, FIN. TIMES, Apr. 16, 2003, at 2 (quoting Jo Pisani of consultants PricewaterhouseCoopers as saying, "Increased consumer awareness will lead to more of a 'pull' for pharmaceutical products by patients, requesting drugs by name, rather than traditional 'push' model driven by the pharma sales force."), available at 2003 WL 17852987.

²⁰⁰ STATEMENT OF NANCY M. OSTROVE, PH.D., DEPUTY DIRECTOR, DIV. OF DRUG MKTG., ADVER. & COMMUNICATIONS, DEP'T OF HEALTH & HUMAN SERVS., BEFORE THE

Direct-to-consumer advertisements have the potential to help patients become more educated partners in making their own health care decisions and more likely to follow through with their therapy. Direct-to-consumer advertising thus may improve both the ethical ideal of patient autonomy and the quality of health care outcomes. In any event, the growth of direct-to-consumer advertising clearly signals the recognition by drug manufacturers of the importance of the consumer's desires and brand awareness in the health care decision-making process.²⁰¹ Similarly, the law must recognize the expanded role of the consumer in the modern health care market.

Despite some judicial recognition of the increasingly important role of the health care consumer, courts have generally not applied the same insights to the application of the learned intermediary rule. Only New Jersey has recognized an exception to the Rule for direct-to-consumer promotional activities. Even in New Jersey, however, recognition of this exception has not resulted in subsequent litigation seeking to hold drug manufacturers liable for failure to warn.²⁰²

Some commentators have agreed with the New Jersey Supreme Court that a categorical exception to the learned intermediary rule for drugs advertised directly to consumers is appropriate.²⁰³ Even though the New Jersey Supreme Court is to be commended for its recognition of the potential dangers of direct-to-consumer advertising, its approach to the problem is less than optimal. New Jersey requires that companies marketing prescription drugs to consumers also provide legally adequate warnings to consumers,²⁰⁴

SUBCOMM. ON CONSUMER AFFAIRS, FOREIGN COMMERCE, AND TOURISM, SENATE COMM. ON SCI. & TRANSP. (July 24, 2001) (summarizing potential benefits of DTC advertising), at <http://www.fda.gov/ola/2001/drugpromo0724.html> (last visited Oct. 31, 2004); Hall, *Promise and Peril supra* note 101, at 25-31 (discussing the potential benefits and detriments of direct to consumer advertising on the internet.

²⁰¹ See Tieman, *supra* note 199, at 2 (observing that "increasingly-informed consumers are also contributing to a shift in the way the pharmaceutical industry regards its brands. Today, blockbuster drugs such as Prozac, for depression, or Viagra, for impotence, have become household names. . . . Patients . . . can research treatments from home on the internet . . . and confront their doctor with the fruits of their research").

²⁰² See *supra* Part I.B.4.

²⁰³ George W. Evans & Arnold I. Friede, *The Food and Drug Administration's Regulation of Prescription Drug Manufacturer Speech: A First Amendment Analysis*, 58 FOOD & DRUG L.J. 365, 423 (2003) ("[B]ecause consumers are shielded by learned intermediaries in the selection and use of prescription drugs, it is not essential for DTC advertisements to outline what each and every particular risk of a drug might be. . . . Concerning the drug at issue, doctors can be presumed to act responsibly and with full information from the operative labeling before issuing consumers a prescription.").

²⁰⁴ See *supra* note 104 and accompanying text.

effectively abrogating the learned intermediary rule for heavily advertised drugs. The New Jersey Supreme Court did not establish any procedure for determining whether or not the direct marketing of the drug in fact undermined the existence of a learned intermediary, relying instead on the establishment of a categorical exception.

B. The Rule Reflects an Outdated Ethical View of the Doctor–Patient Relationship

It is no exaggeration to say that the principle of informed consent is the bedrock of modern medical ethics.²⁰⁵ In the past forty years, increased attention to the informed consent doctrine has sparked a revolution in society’s concept of the doctor–patient relationship.

The Hippocratic Oath²⁰⁶ stands as the paradigm of the “traditional” paternalistic doctor–patient relationship. According to the Hippocratic concept of this relationship, doctors should not inform their patients of the nature of their illnesses or of the therapies prescribed for them, as patients were thought to be incapable of understanding the complexities of medical practice.²⁰⁷ This approach, founded on the authority of the physician and the compliance of the patient, has been almost completely replaced by the principle, as articulated in *Canterbury v. Spence*,²⁰⁸ that “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body”²⁰⁹ Although widespread acceptance of this principle by both the law and the medical profession was slow in arriving, patient autonomy is now virtually universally recognized as an ethical goal—some say the primary ethical goal—of modern American medical practice.²¹⁰

Both the principle of autonomy and the related informed consent doctrine envision the patient as an empowered partner in

²⁰⁵ TOM L. BEAUCHAMP & JAMES CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 77-80 (5th ed. 2001).

²⁰⁶ See Nova Online, *The Hippocratic Oath—Classical Version*, at http://www.pbs.org/wgbh/nova/doctors/oath_classical.html (last visited Oct. 16, 2004).

²⁰⁷ See generally SISSELA BOK, LYING: MORAL CHOICE IN PUBLIC AND PRIVATE LIFE 223-24 (1978) (noting absence of obligation of veracity in classical physicians’ oaths); NHSS Tan, *Deconstructing Paternalism*, 43 SINGAPORE MED. J. 148, 148 (2002) (discerning paternalism in original Hippocratic Oath).

²⁰⁸ 464 F.2d 772 (D.C. Cir. 1972).

²⁰⁹ *Id.* at 780 (quoting *Schloendorff v. Soc’y of N.Y. Hosp.*, 185 N.E. 92, 93 (N.Y. 1914)) (internal quotation marks omitted) (alterations in original).

²¹⁰ See BEAUCHAMP & CHILDRESS, *supra* note 205, at 77-80.

making health care decisions. As informed consent doctrine becomes more robust and respect for patient autonomy is more fully recognized in the law, the retention of a learned intermediary rule which presupposes the patient's near total reliance on the physician will become increasingly out of touch with the ethical goals of medicine. The law should provide incentives for the health care system to more completely realize its aspirational goals and not incentives to cut patients out of the decision-making process.

The law has begun to recognize the increased importance of the patient in the health care decision-making process.²¹¹ In 1996, in the context of a trademark infringement lawsuit filed by the Upjohn Company against Wyeth-Ayerst, a rival maker of an estrogen replacement therapy, a federal district court concluded that "physicians, pharmacists *and patients* are the consumers relevant to determining how likely it is that consumers will confuse" the two products.²¹² The court based its conclusion in large part on the extensive efforts by the defendant to target its promotional campaign toward potential patients, as well as by using the more traditional avenue of advertising to physicians.²¹³ The court noted that the likely effect of such direct advertising was to enhance the role of the patient in the health care decision-making process and that the advertisements were designed to promote "alleged advantages to which a lay person is likely to attach some significance: convenient packaging, cost savings and the approval of the FDA."²¹⁴

²¹¹ See, e.g., *Planned Parenthood v. Sanchez*, 280 F. Supp. 2d 590, 607 (W.D. Tex. 2003) (grounding the right to an abortion in, *inter alia*, principles of bodily autonomy); *Pekera v. Purpora*, 836 A.2d 1253, 1256 (Conn. App. Ct. 2003) (ruling that a physician was justified in declining to provide treatment because of his patient's informed refusal to consent to such treatment); *Cohen v. Bolduc*, 760 N.E.2d 714, 721 (Mass. 2002) (finding that a state statute authorizing medical care proxies "ensures that a patient's right of autonomy . . . is respected"); *In re Bronx Psychiatric Ctr.*, 728 N.Y.S.2d 10, 13 (App. Div. 2001) (protecting a patient's right to autonomy in an involuntary commitment case by appointment of counsel); *In re Duran*, 769 A.2d 497, 504-05 (Pa. Super. 2001) (grounding the right to refuse a blood transfusion in principles of autonomy).

²¹² *Upjohn Co. v. Am. Home Prods. Corp.*, No. 1:95CV237, 1996 WL 33322175, at *3 (W.D. Mich. Apr. 5, 1996) (emphasis added).

²¹³ *Id.* at *11 ("While it is true that courts generally do not discuss patients as relevant consumers for trademark purposes when the product is a [prescription drug] requiring a prescription, . . . the marketing of PREMPRO differs from caselaw precedent. . . . [D]efendant . . . has targeted directly existing . . . patients and prospective . . . patients with . . . promotions.").

²¹⁴ *Id.* at *11-12 ("The parties do not dispute that patients as well as physicians and pharmacists can come to recognize a prescription drug by its brand name. . . . Simply because a patient cannot actually purchase PREMPRO without a prescription, does not mean that a patient cannot seek [PREMPRO] from a physician."). For facts disputing the court's assumption that a physician is necessarily required to purchase

In the context of antitrust law, it is also important to properly define the relevant market for a particular type of goods or services.²¹⁵ In this area as well, there has been movement towards including the consumer in the relevant market definition, recognizing the increasing importance of the consumer in the health care decision-making process.²¹⁶

C. The Rule Establishes Improper Incentives for Drug Manufacturers

The learned intermediary rule has provided at least an indirect incentive for drug manufacturers to employ direct-to-consumer advertising and other devices to bypass the learned intermediary. Because the courts treat the learned intermediary rule as a blanket exception to liability for failure to directly warn the consumer,²¹⁷ and do not engage in a case-by-case inquiry as to whether a legally sufficient intermediary actually exists, plaintiffs injured by industry efforts to bypass the learned intermediary have no valid recourse. The learned intermediary rule thus has the effect of creating market distortions.²¹⁸

prescription drugs in today's health care marketplace, see *supra* Part III.A.4, which describes the rise of Internet pharmacies.

²¹⁵ WILLIAM C. HOLMES, ANTITRUST LAW HANDBOOK § 3.2 (2004 ed.) (“[A] key threshold element in a [Sherman Act] Section 2 case will ordinarily be the definition of the ‘relevant market,’ meaning the particular group of products with which, and geographic area within which, the defendant’s product or service effectively competes and the effects of its monopolizing conduct are felt.”); Afield, *supra* note 97, at 205 (“In any antitrust analysis that involves a properly defined relevant market, a plaintiff must establish a relevant geographic market and a relevant product market in order to demonstrate that the defendant possesses market power.”).

²¹⁶ See, e.g., Afield, *supra* note 97, at 207-14.

²¹⁷ See *supra* Part I.C.

²¹⁸ Unfortunately, such legally generated market distortions are not unknown to health law. The most famous such phenomenon is, of course, the doctrine of ERISA preemption under which managed care organizations, especially self-funded managed care organizations, are exempt from much state regulation including state tort liability. This has had the effect of insulating MCOs from the tort law consequences of their cost containment policies and allegedly wrongful denials of care. Although ERISA preemption in recent years has been considerably softened by judicial interpretations, see generally Karen A. Jordan, *Recent Modifications to the Preemption Doctrine & Their Impact on State HMO Liability Laws*, 1 IND. HEALTH L. REV. 51 (2004), the insulation from tort liability afforded by the ERISA preemption doctrine is largely responsible both for the meteoric rise of managed care as the dominant health care delivery paradigm in the 1990s and for the recent managed care backlash in the popular culture and health policy. See Karen A. Jordan, *Coverage Denials in ERISA Plans: Assessing the Federal Legislative Solution*, 65 MO. L. REV. 405, 406-08 (2000). Health law scholars have argued that the exemption from liability granted to managed care organizations by early judicial interpretations of the ERISA statute was partly responsible for the development of many questionable managed care practices. These practices include providing primary care physicians with

First, the current state of the law gives the drug industry a perverse incentive to divert research and development dollars away from development of medically necessary drugs to the development of so-called “lifestyle drugs.” The industry has been criticized in recent years for focusing on “lifestyle” drugs, because of their higher profit margin, to the exclusion of medically necessary drugs, which could save lives lost to disease in underdeveloped nations.²¹⁹ Furthermore, “lifestyle” drugs constitute many, though by no means all, of the drugs that are most heavily marketed directly to consumers in the United States,²²⁰ and consumer demand for these drugs is rising to such an extent that funding for them may supplant other, more medically useful drugs in pharmaceutical formularies.²²¹ To the extent that drug manufacturers are obtaining a “free ride” from liability for lifestyle drugs demanded by consumers, their profits on those drugs do not reflect the true cost of the product; and so tort law should step in to rectify the situation. Lower profit margins on lifestyle drugs might help to reduce the disparity between the attractiveness of these drugs as compared to other, more socially useful drugs.²²²

Second, the exemption from liability created by the Rule for

overreaching financial incentives to limit the amount of care provided and severely limiting physicians’ ability to independently control the care of their patients through aggressive use of pre-authorization requirements. See Hall, *Bargaining with Hippocrates*, *supra* note 167, at 699-705. The managed care literature, both scholarly and popular, is replete with “horror stories” of injury and death caused by industry practices and with allegations that ERISA preemption prevents tort law from operating to curtail the depredations of the unfettered marketplace in a market characterized by unequal knowledge, unequal bargaining power, and particularly vulnerable consumers. *Id.*

²¹⁹ James H. Flory & Philip Kitcher, *Global Health and the Scientific Research Agenda*, 32 PHIL. & PUB. AFF. 36 (2004), available at 2004 WL 69026590; Ralph Nader, *Corporate Supremacy & the Erosion of Democracy*, 64 HUMANIST 7 (March 1, 2004), available at 2004 WL 63557844; Amy Ellis Nutt, *The Next Plague; Killer Bacteria Defeat Toughest Antibiotic*, GRAND RAPIDS PRESS, Jan. 4, 2004, at D1, available at 2004 WL 58532055.

²²⁰ David E. Dukes et al., *What You Should Know About Direct-to-Consumer Advertising of Prescription Drugs*, 68 DEF. COUNS. J. 36, 37 (2001) (“DTC detractors note that most pharmaceutical products promoted to consumers are ‘lifestyle’ drugs and that drugs for more complex conditions and diseases receive less promotion.”).

²²¹ Tamar V. Terzian, Note, *Direct to Consumer Prescription Drug Advertising*, 25 AM J.L. & MED. 149, 160 (1999) (“Potential changes in formularies have raised concerns that improving enrollee satisfaction by including requested drugs on formularies may divert resources from other important areas.”).

²²² But see David Brushwood, *Responsive Regulation of Internet Pharmacy Practice*, 10 ANN. HEALTH L. 75, 102 (2001) (“Mounting a . . . crusade against bad choices that affect nobody other than the person making the choice could have the appearance of economic protectionism, no matter how well intended as a public health measure.”).

information conveyed to consumers in advertisements, combined with drug companies' insulation from the economic effect of increased drug spending on the health care economy as a whole, creates a disproportionate incentive to advertise and thus increase demand without due consideration of the relative value of the drug. This increasing push on the part of drug companies to create consumer demand for the latest drug, which often translates to the most expensive drug, is beginning to create a backlash from employers, insurers, and others who are concerned about the dramatic rise in overall health care costs.²²³ Some go so far as to claim that direct-to-consumer advertisements directly contribute to rising drug costs.²²⁴

A case-by-case approach would give drug companies an additional incentive to take care in their promotional efforts and to more carefully police the channels through which their drugs are distributed. Since a manufacturer would have a defense to a claim for failure to warn if in fact the patient had the benefit of a full disclosure and consultation by a physician, drug companies would naturally disfavor sales through Internet pharmacies that provide prescriptions based on merely a checklist, with no face-to-face interaction or physician-patient relationship.²²⁵

²²³ See, e.g., Thomas M. Burton, *Pushing Pills: Reining in Drug Advertising*, WALL ST. J., Mar. 13, 2002, at B1 (quoting General Motors executives as blaming direct-to-consumer advertising of expensive, unnecessary drugs for a 14% rise in drug expenditures, and reporting that GM spent \$55 million in 2001 to pay for Prilosec, a heavily-advertised heartburn medication, for its workers and retirees).

²²⁴ *Id.* (quoting an insurance company executive as saying, "[d]irect-to-consumer ads make drugs cost more").

²²⁵ This argument has an analogy in current litigation against handgun manufacturers. Cities have attempted to sue handgun manufacturers in tort, claiming that they have been injured by crimes committed with handguns negligently sold in circumstances which the gun manufacturers knew or reasonably should have known would result in those guns being used in illegal activity. See, e.g., *James v. Arms Tech., Inc.*, 820 A.2d 27, 34-35 (N.J. Super. Ct. App. Div. 2003) (denying defendants' motion to dismiss lawsuit because the City of Newark had stated a claim against multiple defendants for negligence in distribution and sale of handguns). Many states and cities plagued by gun violence have passed strict laws barring handgun sales within their jurisdiction. See, e.g., *Quilici v. Vill. of Morton Grove*, 695 F.2d 261 (7th Cir. 1982) (upholding local handgun ban against constitutional challenge). Plaintiffs have alleged, however, that handgun manufacturers knowingly or recklessly sell to dealers in neighboring jurisdictions with lax gun laws, enabling the weapons to be transported and sold illegally in the targeted jurisdictions. See generally Tyrone Hughes, Note & Comment, *Hamilton v. Accutec: Potential Collective Liability of the Handgun Industry for Negligent Marketing*, 13 TOURO L. REV. 287 (1996). The case law described in this section is still in the developmental stages and substantial uncertainties remain. These uncertainties include the strong possibility of Congressional action to prohibit handgun manufacturer lawsuits and to put an end to those lawsuits currently pending. See Andrew Harris, *Court Reinstates Indiana*

As described above, prescription drugs are increasingly being sold through non-traditional channels and increasingly are available outside a meaningful doctor–patient relationship or without a prescription from a licensed physician.²²⁶ These sales, under the current approach to the learned intermediary rule, carry a higher risk of injury or death resulting from improper use of the drug because no actor in the supply chain has a realistic legal incentive to warn the end user of the product’s dangers. Particularly in cases of “lifestyle” drugs, consumers may not be mindful of the dangers posed by those products in the context of their wide availability, and so might not undertake a realistic cost–benefit analysis before deciding whether to use them. The Internet pharmacy and the physician, if any, providing the prescription for the drug may be judgment proof, located outside the jurisdiction of American courts, or otherwise inaccessible. The current learned intermediary rule, however, forces the injured plaintiff to rely on the prescribing physician for legal recourse, even when all actors in the chain know or should know that the prescription is being filled in the absence of an effective doctor–patient relationship, and a reasonable informed consent discussion. The alternative Rule proposed in this Article would protect the consumer by removing the protections of the learned intermediary rule from the drug manufacturer when the manufacturer knows or should know that there is in fact no effective intermediary, and by also providing incentives to drug manufacturers not to sell their products through channels in which no legally effective warning is likely to be given.

III. A PROPOSAL

A. *The Contours of the Proposal*

The proposal advanced in this Article starts from a very basic premise: The learned intermediary rule should not apply when the reasoning behind the rule is not applicable.²²⁷ Because of recent

Gun Suit, NAT’L L.J., Jan. 5, 2004, at 5 (describing the Senate version of the Firearms Manufacturer Protection Bill as “just five [votes] shy of a filibuster-proof majority that would ensure its passage”). Other potential problems include the difficulty of establishing a causal link between an allegedly negligent sale and the injury caused to the plaintiff. Nonetheless, the courts have the opportunity to establish incentives for handgun manufacturers to police the sales practices of those with whom they do business by integrating the social cost of those products into their price. This argument can easily be applied by analogy to prescription drug manufacturers in the modern pharmaceutical marketplace.

²²⁶ See *supra* Part II.A.

²²⁷ See *supra* note 37 and accompanying text.

changes in the pharmaceutical industry,²²⁸ courts should no longer assume that drug sales should be subject to the learned intermediary rule.²²⁹ Instead, courts will need to undertake a fact-based analysis of this issue.²³⁰ The goal of this Article is to give courts a methodology for taking into account the diversity of the modern pharmaceutical marketplace.²³¹

The overwhelming majority of courts have applied the Rule as a blanket exemption from the duty to warn of standard products liability doctrine, without a fact-based inquiry into the necessity or desirability of the rule.²³² While the learned intermediary rule remains a justifiable rule in many instances,²³³ failure by courts to

²²⁸ See *supra* Part II.A.

²²⁹ See, e.g., *Swayze v. McNeil Labs., Inc.*, 807 F.2d 464, 470 (5th Cir. 1987) (construing the mass vaccine exception narrowly as “an exception to the general rule that, where prescription drugs are concerned, a manufacturer’s duty to warn extends only to physicians and not to laymen”). Although the result in *Swayze* was probably correct, this reasoning is a misapplication of the maxim that exceptions to general rules of law are to be construed narrowly. The *Swayze* court failed to account for the fact that the learned intermediary rule is itself a narrow exception from the general rule that the duty to warn runs to the end user of the product. See also *Stanback v. Parke, Davis & Co.*, 657 F.2d 642, 647 (4th Cir. 1981) (describing the mass vaccine exception as “quite narrow and highly fact specific”).

²³⁰ See generally Oona A. Hathaway, *Path Dependence in the Law: The Course and Pattern of Legal Change in a Common Law System*, 86 IOWA L. REV. 601 (2001) (discussing how history shapes legal decisions). Professor Hathaway writes:

Lock-in or inflexibility can, in turn, lead to inefficiency. Early decisions may lead to formation of a legal rule that becomes increasingly inefficient over time. . . . External circumstances may change, causing what was once an efficient rule to become inefficient in light of the changed context. Or what is an efficient rule in one case may be much less efficient in a somewhat different context. Or new information may become available that changes the perception of the legal issue and its correct resolution. Or, finally, courts may take what was an efficient rule in a narrow set of circumstances and broaden it to encompass a set of circumstances in which it is less efficient.

Id. at 631.

²³¹ See, e.g., Afield, *supra* note 97, at 224 (arguing for a flexible approach in antitrust cases, Afield observes that “the variety in prescription drugs today . . . indicates that perhaps pharmaceutical consumers need to be defined on a drug-by-drug basis”). There is no logical reason why this proposed flexibility cannot also be applied to the analysis of prescription drug failure-to-warn claims, allowing the courts to ascertain whether the doctor–patient relationship which stands at the heart of the learned intermediary rule in fact justifies the Rule’s application.

²³² See *supra* Part I.C; see also Mitchell S. Berger, *A Tale of Six Implants: The Perez v. Wyeth Laboratories Norplant Case and the Applicability of the Learned Intermediary Rule to Direct-to-Consumer Drug Promotion*, 55 FOOD & DRUG L.J. 525, 546 n.230 (2000).

²³³ This Article does not argue that drug manufacturers should never be able to delegate their duty to warn to physicians. See, e.g., *supra* text accompanying notes 47–49 (discussing reasons why the traditional doctor–patient relationship stood as a bar to drug manufacturer’s liability for failure to warn).

inquire into the justifications for the rule on a case-by-case basis runs the risk that the Rule will devolve into a convenient fiction that protects drug companies from the consequences of their marketing practices.²³⁴

One approach to known inadequacies of a common law rule (such as the learned intermediary rule) is to adopt a series of exceptions to the rule in order to ameliorate some of the perceived injustices that result from its application.²³⁵ This approach is useful for a time, but eventually, the law must ask whether it would not be more appropriate to revise the rule itself to eliminate the need for the exceptions, rather than continuing to create bright-line exceptions to the rule.²³⁶ This time has now come for the learned intermediary rule. The existing exceptions, though grounded on valid criticisms of the Rule, do not accomplish the goal of

²³⁴ See, e.g., *Larkin v. Pfizer, Inc.*, No. 2002-SC-0746-CL, 2004 WL 1361954, at *11 (Ky. June 17, 2004) (Wintersheimer, J., dissenting) (“Given that the manufacturers are now directly marketing and benefiting by increased sales, they must also assume increased share in the risks and duties pertinent to selling a product.”).

²³⁵ Another example of this type of common law evolution is found in the privity of contract requirement. Originally, claims arising out of injuries caused by defective products required an allegation of privity of contract. See *Winterbottom v. Wright*, 152 Eng. Rep. 402 (Ex. 1842). Perceiving a need to extend a remedy to plaintiffs injured by products purchased by another, the courts created an exception to the privity requirement for products which were “of such a character inherently that, when applied to the purposes for which [they were] designed, [they were] was liable to become a source of great danger to many people” *Statler v. George A. Ray Mfg. Co.*, 88 N.E. 1063, 1064 (N.Y. 1909). Eventually, the difficulty associated with administering the “inherently dangerous” exception led to the elimination of the requirement of privity of contract in negligence actions. *MacPherson v. Buick Motor Co.*, 111 N.E. 1050, 1052 (N.Y. 1916) (“[F]or a neglect of such ordinary care or skill whereby injury happens, the appropriate remedy is an action for negligence. The right to enforce this liability is not to be confined to the immediate buyer.”). For a more in-depth discussion of this doctrinal evolution, see generally Hathaway, *supra* note 230.

²³⁶ The process of carving out exceptions to a common law doctrine in order to rectify its shortcomings has its limits. See, e.g., Melissa A. Waters, *Common Law Courts in an Age of Equity Procedure: Redefining Appellate Review for the Mass Tort Era*, 80 N.C. L. REV. 527, 556 (2002) (criticizing the process of “carving out more and more exceptions to the [common law final judgment] rule,” consequently resulting in the “dizzying array of statutory and judicially-created exceptions . . . that make up modern finality jurisprudence”); The Honorable Francis J. Connolly, Casenote, *Landlord/Tenant Law—Code Violations Under Negligence Per Se and Common Law Negligence Theories: Gradjelic v. Hance*, 29 WM. MITCHELL L. REV. 1013, 1014 (2003) (noting arguments that exceptions to the common law rule of no landlord liability “contribute[] to the ‘erosion of the entire common law rule’”) (citation omitted); Matthew F. McLean, Casenote, *The Impact of the Wyoming Supreme Court’s Decision to Abolish a Portion of the Common Law Status Classifications. Clarke v. Beckwith*, 858 P.2d 293 (Wyo. 1993), 29 LAND & WATER L. REV. 299, 301-11 (1994) (describing evolution of common law of possessor’s duty of care to third parties).

harmonizing the Rule's operation with the realities of the health care marketplace.²³⁷ In fact, the diversity and pace of change in the health care market is such that no set of bright-line rules can hope to adequately police the therapeutic decision-making process.

The determination of whether the learned intermediary rule is appropriate should not turn, as it does now, solely on the type of drug or product being prescribed, but rather on the context of the interaction that produces the prescription. The existing case law establishes exceptions to the Rule based on the specific drug or type of drug at issue. For example, several cases hold that oral contraceptives, as a class, are exempt from the learned intermediary rule.²³⁸ This has the benefit of judicial economy and ease of application,²³⁹ but it does not capture the diversity of contexts in which drugs are prescribed and obtained.

I propose that the learned intermediary rule be transformed from a bright-line rule of exemption from liability for failure to warn the end user of a prescription drug into a multi-element test to determine the presence or absence of a meaningful intermediary in the prescription drug context. Under this revised conception of the Rule, the emphasis should be on a manufacturer's duty to warn an end user of an unavoidably unsafe product, and courts should analyze each particular set of circumstances in evaluating whether a warning to the only intermediary is legally adequate.

I propose that the learned intermediary rule should be recast as follows:

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

In the context of prescription drug failure-to-warn litigation, a court should take into account the following list of factors in determining whether it is appropriate to warn only the intermediary:

1. Was the drug prescribed in the context of a face-to-face doctor-patient interaction?

²³⁷ Cf. Hathaway, *supra* note 230, at 658-61 (arguing for relaxation of *stare decisis* where "underlying conditions have changed markedly since the legal rule's introduction").

²³⁸ See *supra* Part I.B.2.

²³⁹ Ausness, *supra* note 147, at 1235-36.

2. Was the drug specifically requested by the patient?
3. Does the patient have an ongoing opportunity to engage the physician in a dialogue about the efficacy of the treatment prescribed?
4. Did the patient seek the drug to treat a medical condition, or for its convenience or cosmetic enhancement effects?
5. Does relevant regulation require that the patient be directly warned of the risks of the drug?

These factors have the benefit of integrating all of the current exceptions to the learned intermediary rule, as well as focusing the attention of the courts on other aspects of a drug sale that are relevant to the application of the Rule. The fundamental requirement for exemption from the duty to warn the end user is that there is in fact an effective intermediary between the manufacturer and the user of the product.²⁴⁰

This revised learned intermediary rule reflects the reasoning of courts that have considered other exceptions to the rule. The theme underlying those exceptions is the search for circumstances under which the physician does not in fact act as an effective learned intermediary for the patient. These circumstances can be divided into two categories: (1) circumstances in which the physician's prescribing power is bypassed through use of modern sales practices such as Internet prescribing and dispensing of drugs absent physician contact with the patient; i.e., where the physician is not acting as an intermediary at all; and (2) circumstances in which, even though there is physician-patient contact, the physician does not exercise his or her independent judgment or does not in fact provide an adequate set of warnings; i.e., where the "learned" nature of the physician's contribution to the decision-making process is bypassed. This may include situations in which the choice to take the drug is a cosmetic one, not a medical one, and in which the physician is perhaps more likely to merely acquiesce in the patient's demand for the drug,²⁴¹ as well as cases in which a drug company has

²⁴⁰ As with the sophisticated user doctrine, the learned intermediary rule should be applied as a defense to tort liability for failure to warn. Thus, in order to obtain an exception from the general rule of tort law that the duty to warn flows from the manufacturer of the product to the end user of that product, the initial burden should fall on the drug company to bring forward facts indicating that the drug was prescribed and delivered in a context providing for an effective intermediary.

²⁴¹ The phenomenon of physician acquiescence to patient demands is not limited to these "lifestyle" drug cases. *See supra* note 177 and accompanying text (describing the over-prescription of antibiotics and the concurrent rise in drug resistant pathogens).

overpromoted a drug, creating demand in the minds of consumers which overrides the contrary advice of their physicians.

The Rule proposed in this Article is consistent with and builds on the insights of the *Third Restatement*.²⁴² Although the *Third Restatement* preserves the formal separation between the sophisticated user doctrine²⁴³ and the learned intermediary rule,²⁴⁴ it lays the groundwork for collapsing the distinction between them, as advocated in this Article. The *Third Restatement* provides that the duty to warn in prescription drug cases is owed first to the physician, but may be owed to “the patient when the manufacturer knows or has reason to know that health care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.”²⁴⁵ Unfortunately, as described above,²⁴⁶ neither the Restatement²⁴⁷ nor the courts²⁴⁸ have yet taken advantage of the text of section 6(d) to amend the learned intermediary rule to take account of the substantial changes in the health care marketplace. This Article hopes to fill that gap.

B. Arguments for Retaining the Learned Intermediary Rule

The learned intermediary rule has demonstrated remarkable persistence in the courts, despite an extensive body of scholarship identifying the Rule’s shortcomings.²⁴⁹ Those who would retain the Rule in its current form generally make three arguments.²⁵⁰ First, they argue that the drug industry, unlike an individual’s physician, does not have adequate means to identify and communicate with potential consumers of a drug. Second, the current Rule’s advocates maintain that patients with no medical or pharmacological training will be unable to understand an adequate warning, and will either be frightened away from a potentially beneficial drug or will not be able to make an informed choice about the risks and benefits of a drug. The physician, on the other hand, is in a position to “translate” the

²⁴² See *supra* note 141 and accompanying text.

²⁴³ See, e.g., THIRD RESTATEMENT, *supra* note 7, § 2(c) & cmt. i.

²⁴⁴ See, e.g., *id.* § 6(d).

²⁴⁵ *Id.* § 6(d)(2).

²⁴⁶ See *supra* Part I.D.

²⁴⁷ See THIRD RESTATEMENT *supra* note 7, § 6(d) & cmt. e.

²⁴⁸ See *supra* note 143.

²⁴⁹ See generally sources cited *supra* note 95; see also Catherine A. Paytash, Note, *The Learned Intermediary Doctrine and Patient Package Inserts: A Balanced Approach to Preventing Drug-Related Injury*, 51 STAN. L. REV. 1343 (1999).

²⁵⁰ For a complete (and more sympathetic) articulation of the arguments for the retention of the learned intermediary rule, see Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Legal and Regulatory Issues*, 32 GA. L. REV. 141 (1997).

technicalities for the patient, and to assist in the risk-benefit analysis. Finally, advocates of the Rule argue that inserting the drug manufacturer into the therapeutic decision-making process by requiring warnings to be given directly to patients would impermissibly interfere with the doctor–patient relationship.

This section examines the bases of each of these claims and shows that, although each of them can be leveled at the proposal made in this Article, they ultimately fail to justify retention of the current Rule.

1. Inability to Communicate with Patient

The first argument made by advocates of the learned intermediary rule is that, because the physician–patient relationship provides an ideal context for communicating product warnings, and because of the burdens and costs involved in attempting to provide adequate warnings to end users of prescription drugs, manufacturers should be relieved of a duty to warn the end user.²⁵¹

Even under the sophisticated user doctrine, inability to communicate effectively with the end user has been held to abrogate the duty to warn.²⁵² In *House v. Armour of America*,²⁵³ a police officer injured by rifle fire sued the maker of the bulletproof fibers used in his protective jacket, arguing that the fiber maker should have had a duty to warn him about the limitations of the protection offered by its product.²⁵⁴ The court held, as a matter of law, that the lack of a viable means of communication between the component part supplier and the end user of the bulletproof vest made from its materials vitiated the duty to warn the individual user, and that the warning to the police department discharged the manufacturer’s duty.²⁵⁵

If drug manufacturers truly could not effectively communicate with the end users of their products, the retention of the learned intermediary rule as an incentive to make sure adequate warnings

²⁵¹ For a discussion of the use of this justification in the litigation surrounding the Dalkon Shield contraceptive device, see James Ottavio Castagnera & Richard Ryan Gerner, *The Gradual Enfeeblement of the Learned Intermediary Rule and the Argument in Favor of Abandoning It Entirely*, 36 TORT & INS. L.J. 119, 126-28 (2000).

²⁵² This is so because “[t]he goal of products liability law is to ‘induce conduct that is capable of being performed.’” *Hoffman v. Houghton Chem. Corp.*, 751 N.E.2d 848, 857 (Mass. 2001) (quoting *Vassallo v. Baxter Healthcare Corp.*, 696 N.E.2d 909, 922 (Mass. 1998)). If manufacturers truly could not communicate with patients, it would make no sense to impose such a duty. This assertion may have been true in 1966; however, it is no longer the case.

²⁵³ 886 P.2d 542 (Utah 1994).

²⁵⁴ *Id.* at 546.

²⁵⁵ *Id.* at 554.

flowed through the prescribing physician would be justified. The behavior of drug companies, however, belies the argument that effective communication between manufacturers and patients is impossible or impracticable.²⁵⁶ Drug companies routinely communicate with patients through direct-to-consumer print and broadcast advertising, informational Web sites, and other media, and, in some cases when required by the FDA, through patient package inserts distributed with each prescription.²⁵⁷ Each of these means of communication could be adapted to the delivery of legally adequate warnings to the patient, when required by the revised rule.

A more likely scenario is that in some cases, communication between the drug company and patients would be relatively simple, and in other cases, far more complex.²⁵⁸ Assuming this to be the case, it makes sense to have a legal rule that can take account of the diversity of circumstances under which prescription drugs are used. While the learned intermediary rule as currently implemented assumes communication to be impracticable, and abolition of the Rule would assume communication to be feasible, the modified Rule proposed in this Article allows the reasonableness of communication in any given set of circumstances to be weighed by the finder of fact in determining the reasonableness of the drug manufacturer's conduct.²⁵⁹

2. Inability of Patient to Understand Warnings

Pharmacology is a complex field, and there is no doubt that a full understanding of the mechanisms of action and potential for

²⁵⁶ See Castagnera & Gerner, *supra* note 251, at 132 (“Through [] zealous marketing tactics, manufacturers display the means necessary to adequately inform the patient about all product properties necessary to make an informed and educated decision.”).

²⁵⁷ See, e.g., *id.* at 123-24 (advocating that burden be placed on manufacturer to “provide adequate warnings in the form of patient package inserts . . . to the patient with every prescription that is filled”). The authors point out that this is also consistent with modern ethical emphasis on the patient's right to participate fully in decisions concerning his health care. *Id.* at 124; see also *supra* Part II.B.

²⁵⁸ For an example of the latter, recall the facts of *Gravis v. Parke-Davis & Co.*, 502 S.W.2d 863 (Tex. Civ. App. 1973), discussed *supra* notes 44-49 and accompanying text. *Gravis* involved a claim of injury arising from the use of a surgical anesthetic. It seems reasonable to conclude that the drug manufacturer would have fewer channels of communication with the patient than in a case involving a prescription for antibiotic tablets filled at a pharmacy.

²⁵⁹ See, e.g., SECOND RESTATEMENT, *supra* note 18, § 388 cmt. n (“Here, as in every case which involves the determination of the precautions which must be taken to satisfy the requirements of reasonable care, the magnitude of the risk involved must be compared with the burden which would be imposed by requiring them . . .”).

interactions associated with prescription drugs requires advanced study. It is also true that most patients cannot understand the information communicated by drug companies to physicians through sources such as the *Physicians Desk Reference*.²⁶⁰ To claim, however, that drug companies are incapable of delivering adequate risk information to potential patients fails to recognize at least two features of the modern health care market. First, many complex drugs are in fact sold directly to consumers, without recourse to the expertise of the physician.²⁶¹ Second, the success of the pharmaceutical industry in communicating with patients and potential patients through direct-to-consumer advertising channels undercuts the argument that consumers are incapable of understanding the risks and benefits of a particular drug.

3. Interference with the Doctor–Patient Relationship

A third argument advanced in favor of retaining the learned intermediary rule is that direct warnings from the manufacturer would impermissibly interfere with the therapeutic relationship between doctor and patient.²⁶² While it is certainly true that medical decisions are best made in the context of a meaningful, trust-based doctor–patient relationship, the law should also recognize that many medical decisions are in fact not informed by such a relationship. In these cases, the law should not leave consumers of prescription drugs without any remedy against those who had an opportunity, but failed

²⁶⁰ *Foreward* to PHYSICIANS' DESK REFERENCE (58th ed. 2004) ("Each . . . entry provides . . . an exact copy of the product's FDA-approved . . . labeling.")

²⁶¹ The market for over-the-counter ("OTC") drugs is vast, comprising \$11.2 billion in sales and up to an estimated 300,000 products in 1990. GEN. ACCT. OFF., NON-PRESCRIPTION DRUGS: OVER THE COUNTER AND UNDEREMPHASIZED 1 (1992). Despite the fact that OTC drugs are readily available to consumers without the need for the professional intervention of a physician or pharmacist, one should not assume that OTC drugs are free from risk. *See id.* at 2. Manufacturers of OTC drugs do not enjoy the same freedom from liability for failure to warn as do manufacturers of prescription drugs. Nonetheless, manufacturers seem to have adequately discharged their duties to warn consumers of the potential dangers of these products. *See, e.g.,* Reyes v. Wyeth Labs., 498 F.2d 1264, 1275-76 (5th Cir. 1974) (observing that if defendant concedes its product is not a prescription drug, then its sole warning to the health care provider "establishes as a matter of law the defectiveness of the [product] for purposes of a prima facie case in strict products liability"); Torsiello v. Whitehall Labs., 398 A.2d 132, 139-40 (N.J. Super. Ct. App. Div. 1979) ("A consumer of over-the-counter drugs is . . . self-prescribing and is intended, expected, and indeed encouraged by the drug industry to do so. He must, therefore, also be given such information by the manufacturer as will permit him to self-prescribe with a minimum of risk."), *cited with approval by* Larkin v. Pfizer, Inc., No. 2002-SC-0746-CL, 2004 WL 1361954, at *4 (Ky. June 17, 2004)).

²⁶² Noah, *supra* note 250, at 170.

to provide adequate warnings of the dangerous propensities of their products. In fact, some have argued that, if we as a society take the doctor–patient relationship seriously, we should ban drug advertisements altogether. Indeed, it seems somewhat disingenuous for pharmaceutical manufacturers to argue that drug advertisements do not interfere with the doctor–patient relationship, but that drug warnings do.²⁶³

Following the reasoning of the pro-DTC advertisement literature provides another argument for rethinking the learned intermediary rule in this context. If consumer-directed advertising enhances the information available to the consumer and thus makes the consumer a more effective and more informed partner in his own health care decisions, surely legal rules which encourage full and fair disclosure of both the benefits and risks of drug therapies would only further contribute to consumer education and empowerment.²⁶⁴

The proposal set forth in this Article is not necessarily an exclusively pro-plaintiff rule. For example, recall the case of *Edwards v. Basel Pharmaceuticals*.²⁶⁵ In that case, Edwards died from a nicotine overdose after receiving a prescription for a nicotine patch from his personal physician. Absent further evidence of circumstances impairing the effectiveness of the physician–patient relationship, the reworked Rule proposed herein would not change the outcome of the case in favor of Edwards. The existence of the FDA mandate to warn the patient should be considered simply as one factor among many related to Edwards’ decision to use the product, and should not necessarily result in drug company liability. It may be that Edwards’ recourse, if any, should be against his physician for failure to clearly communicate the information contained in the manufacturer’s warning to the physician, which plainly disclosed the risk of cardiac failure from a nicotine overdose.²⁶⁶

²⁶³ Cohoon, *supra* note 95, at 1356-57.

Following the reasoning of the proponents of direct-to-consumer marketing provides another argument for rethinking the learned intermediary rule. If consumer-directed advertising enhances the information available to the consumer, and thus makes the consumer a more effective and more informed partner in his own health care decisions, surely legal rules that encourage full and fair disclosure of both the benefits and the risks of drug therapies would only further contribute to consumer education and empowerment. *See, e.g.*, Castagnera & Gerner, *supra* note 251, at 132-33 (“Rather than undermine the physician-patient relationship, a requirement that manufacturers provide direct-to-consumer warnings in reality encourages the patient to question the doctor, thus improving patients’ ability to make informed decisions and understand their treatment.”).

²⁶⁴ *See supra* note 263.

²⁶⁵ 116 F.3d 1341 (10th Cir. 1997); *see supra* Part I.B.3.

²⁶⁶ *Id.* at 1342 (finding that the warnings given to physicians were “relatively

C. *Benefits of the Proposal*

1. Better Serves the Goals of Tort Law

Treatment of the learned intermediary rule in a case-by-case fashion, instead of as a bright-line exemption from the duty to warn the end user, will result in a rule which is more likely to accomplish the goals of tort law. Tort law is generally understood to have three primary functions: deterrence of socially undesirable conduct, compensation of the injured, and, in the case of product liability, allocation of the true costs of producing a product to the manufacturer of that product.²⁶⁷ The proposed rule accomplishes all three functions better than the existing learned intermediary rule.

First, the proposal would deter certain behavior on the part of drug manufacturers. Under current law, a drug manufacturer is extremely unlikely²⁶⁸ to be held responsible in tort for statements made in consumer advertisement materials that create a false positive expectation about the benefits of a drug, or which downplay the risks of a drug. Despite the existence of some FDA guidance on the content of direct-to-consumer advertisement, many believe that existing FDA rules do not adequately protect the interests of consumers in accurate information about prescription drugs, and that many manufacturers in fact do not adequately comply with even the minimal regulations in place. The potential for tort liability would help ensure that information conveyed to consumers about a prescription drug is accurate and balanced. Furthermore, this rule would give drug manufacturers an incentive to police and prevent the sale of prescription drugs into potentially illegal market channels, where sales would occur without a physician's prescription.²⁶⁹

thorough" but that "a package insert addressed to the patient failed to mention the possibility of any fatal reaction to nicotine overdose").

²⁶⁷ Absent a tort-like mechanism for requiring manufacturers to bear the cost of injuries caused by defective products, manufacturers would have insufficient incentive to police the safety of their products, since the cost of injuries caused by those products would be borne by the injured individuals or the health insurance system. This would constitute an undesirable subsidy for the product manufacturers, and would undesirably lower the cost of dangerous products. SECOND RESTATEMENT, *supra* note 18, § 402A cmt. c ("[P]ublic policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and be treated as a cost of production . . .").

²⁶⁸ Only one reported case has established an exemption from the learned intermediary rule for direct-to-consumer advertising. See *supra* Part I.B.4 (discussing the New Jersey Supreme Court's *Perez* decision).

²⁶⁹ Of course, this presupposes that drug companies are able to identify purchasers who are likely to sell prescription drugs inappropriately. Indications are that manufacturers do in fact have such information at their disposal; for instance,

Second, the proposal would ensure that drug manufacturers bear a greater share of the costs of injuries caused by prescription drugs when those drugs are not dispensed in the context of a strong doctor–patient relationship. Under the existing rule, as long as drug manufacturers provide the FDA-mandated “brief summary” information to prescribing physicians, the only basis of liability for failure to warn is through a challenge to the content of the warning given to the physician. If the drug was in fact purchased outside the context of a physician–patient relationship, or if the physician did not heed the warning provided, there may be no recourse at all.²⁷⁰ This means that a large proportion of the avoidable injuries caused by prescription drugs are beyond the concern of drug companies, who are able to transfer these losses to the injured consumers themselves, or to the physician who prescribed the drug. Since the drug companies have no legal liability in this situation, the true social cost of the drug is not reflected in its price, causing the drug to be overconsumed. This is particularly troublesome in cases of “lifestyle” drugs, which are prescribed and desired for cosmetic or convenience reasons. There is no reason for society to provide a subsidy to the manufacturers and consumers of these drugs in the form of costs borne by injured consumers.

Finally, the proposed rule would increase the availability of tort compensation in cases of injury caused by prescription drugs. In cases in which the drug manufacturer contributed to the demand for the drug by direct-to-consumer advertising, or contributed to the availability of the drug through sales into channels where the manufacturer knew or should have known that the product was likely to be sold to the end user outside the context of a physician–patient relationship, the patient injured by improper use of the drug may

Pfizer recently reacted to the phenomenon of Americans crossing the border into Canada to take advantage of that country’s price controls on prescription drugs by threatening to restrict supply to Canadian pharmacies supplying the American market. *Marketplace*, NPR radio broadcast, July 7, 2004. This tends to show that Pfizer is able to (or would be able to if it chose) track the flow of drugs to Canada and through the pharmacies there back into the United States.

²⁷⁰ See *Motus v. Pfizer, Inc.*, 358 F.3d 659, 661 (9th Cir. 2004) (holding that, if physician did not read warning provided by drug company, then plaintiff cannot establish that injury could have been avoided with a better warning, consequently destroying causation element of plaintiff’s prima facie case). Although there are as yet no reported cases alleging failure to warn where the drug in question was purchased through an Internet pharmacy without a valid prescription, a court might find the same defect in causation to exist in that case. In the absence of a duty to warn the end user, however, merely requiring manufacturers to give better alternative warnings to physicians will not change the outcome or prevent injury. Thus, injured consumers are left without a remedy.

have no legal recourse against the physician or seller of the drug.²⁷¹ In these cases, tort law in its current form fails to adequately protect the injured party. By reaffirming the rule of tort law that, absent a clear justification to the contrary, warnings are owed to the end user of an unavoidably unsafe product, the proposal would protect consumers in two ways. First, it would potentially decrease the overpromotion of drugs encouraged by current law, and make it more likely that a potential consumer of a drug will receive an effective warning.²⁷² Second, in cases of overpromotion, or direct-to-consumer sales, in the absence of a legally effective warning, the rule would provide a source of compensation for avoidable harm suffered.²⁷³

2. Better Reflects Modern Medical Practice and Ethics

In addition to enhancing the socially desirable effects of tort law, the rule proposed in this Article also has the benefit of reforming tort law to more accurately reflect the modern view of the doctor–patient relationship. This section will describe how the reformed rule interacts with medical practice and medical ethics.

The modern doctor–patient relationship is generally considered to be grounded in the autonomy of the patient.²⁷⁴ The physician is not the sole decision maker, but has the role of facilitating and making possible the patient’s exercise of autonomy in choosing from the appropriate range of therapeutic options. In order to exercise his right to make decisions regarding “what shall be done with his own body,”²⁷⁵ the patient requires access to appropriate risk and benefit information. Better information to the patient, from whatever source, translates into better health care decision making, improved patient compliance with treatment protocols, and, ultimately,

²⁷¹ In these cases, the patient may not be able to show causation between the action of the physician and the use of the drug (in cases where the patient engaged in forum-shopping to obtain the drug, for example), or may not be able to obtain jurisdiction over the seller (in cases of offshore Internet pharmacies, for example).

²⁷² See *infra* notes 223–24 and accompanying text.

²⁷³ The major advantage to a bright-line rule in this context is that of judicial economy. In litigating the current learned intermediary rule, defendants need not inquire into the existence of a viable, protective doctor–patient relationship. This judicial economy comes, however, at the expense of plaintiffs who are injured by prescription drugs obtained without the protection of a strong doctor–patient relationship. It is the contention of this Article that the better approach in choosing a legal rule to apply is to privilege patient protection over ease of application.

²⁷⁴ See BEAUCHAMP & CHILDRESS, *supra* note 205, at 57-104

²⁷⁵ *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972) (quoting *Schloendorff v. Soc’y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914)) (internal quotation marks omitted).

improved health outcomes.²⁷⁶ The rule proposed in this Article should have the effect of improving both the amount and the quality of information provided to the patient.

Furthermore, the revision of the learned intermediary rule as a standard-based rather than a bright-line test means that courts can more easily respond to market innovations and new practices on the part of drug manufacturers. Currently, courts are relatively limited in their ability to articulate new exceptions to the default, “no duty to warn the patient,” learned intermediary rule. Part of this limitation springs from the common law doctrine of *stare decisis*; but part also springs from the nature of the articulated exceptions. Under the Rule as currently conceived, exemptions from the duty to warn only the physician create categorical exceptions, which courts may fear will be interpreted too broadly. For instance, the court in *Perez v. Wyeth Laboratories*,²⁷⁷ in articulating an exception to the Rule for direct-to-consumer advertising, potentially opens the door for tort liability in every case in which a directly advertised drug is involved. Because of the categorical nature of the exception to the rule, there is relatively little room for individualized assessments of the effect *on this patient* of the specific advertisement at issue, and of the relationship between that advertisement and other factors, such as the existence of a doctor–patient relationship that might ameliorate the effects of any overpromotion in the advertisement.²⁷⁸

3. Balancing Tests Versus Bright Lines

Even accepting *arguendo* the arguments made in favor of the learned intermediary rule in some instances, it does not follow that there should be an absolute exemption from the duty to warn the end user of prescription drugs. The flexibility provided by the factors enumerated above²⁷⁹ provide sufficient opportunity for a drug manufacturer defendant to argue that the duty to warn in a particular case should run only to the prescribing physician or other learned intermediary. The advantage of the proposal advanced in this Article

²⁷⁶ Increased information to the patient about potential adverse effects could also improve outcomes by making patients more vigilant with respect to drug reactions, leading to faster medical intervention. See 2 WOODSIDE, *supra* note 39, § 14.02[2][iv] (discussing court’s rationale in *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961 (E.D. Wis. 1981), for applying contraceptive exception to learned intermediary rule).

²⁷⁷ 734 A.2d 1245 (N.J. 1999).

²⁷⁸ See *id.* at 1257 (holding that “the learned intermediary doctrine does not apply to the direct marketing of drugs to consumers,” but not encouraging courts to engage in case-by-case analysis of the effect of such marketing on the therapeutic decision-making process).

²⁷⁹ See *supra* Part III.A.

is that, unlike the Rule as it is currently applied, there is no resulting injustice in those cases in which patients are harmed by prescription pharmaceuticals obtained without the assistance and counsel of an effective learned intermediary.

At least one other scholar has recognized the similarities between the learned intermediary rule and the sophisticated user doctrine. Writing in 1996, Professor Richard Ausness compared the two doctrines and concluded: “Notwithstanding the fact that different relationships may exist among the various parties, there is a certain amount of commonality” between the paradigmatic learned intermediary and sophisticated user fact patterns.²⁸⁰ Ausness, however, reaches a very different conclusion than this Article, recommending an expansion of a bright-line, “duty-based” approach in a wider variety of sophisticated user cases.²⁸¹

Ausness identifies three similarities between the learned intermediary rule and the sophisticated user doctrine that justify treating the two rules similarly. First, there is no direct contact between the manufacturer and the user of the product. Second, there are circumstances that make it difficult for the manufacturer to communicate directly with the end user. Finally, the intermediary has an independent legal duty to warn the end user.²⁸² Ausness fails, however, to take into account the fact that modern pharmaceutical marketing and technological tools available to both drug manufacturers and potential consumers of drugs have rendered these factors, if not moot, then at least potentially inapplicable in particular situations. It is the increased diversity of information and means of delivering prescription drugs that creates the necessity for the increased flexibility advocated in this Article.

Courts have generally declined to extend the learned intermediary analysis into sophisticated user territory.²⁸³ In *Hall v. Ashland Oil Co.*,²⁸⁴ plaintiffs’ decedent was, coincidentally, an

²⁸⁰ Ausness, *supra* note 147, at 1225. See also 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, 566 (1991) (advocating application of learned intermediary analysis to the relationship between industrial suppliers and employees of goods’ purchasers).

²⁸¹ Ausness, *supra* note 147, at 1239-41.

²⁸² *Id.*, at 1225-26.

²⁸³ See *Gray v. Badger Mining Corp.*, 676 N.W.2d 268, 276 (Minn. 2004) (declining to apply learned intermediary rule, in favor of sophisticated user doctrine, to relationship between supplier of chemicals and the injured employee of purchaser).

²⁸⁴ 625 F. Supp. 1515 (D. Conn. 1986); see also *Donahue v. Phillips Petroleum Co.*, 866 F.2d 1008 (8th Cir. 1989) (refusing to apply learned intermediary rule in

employee of pharmaceutical manufacturer Pfizer. The decedent had been injured by the industrial chemical benzene, which Pfizer had sold to Ashland Oil. When plaintiffs sued Ashland for failing to warn them of the dangerous properties of the chemical, Ashland asserted a learned intermediary defense for purposes of obtaining summary judgment.²⁸⁵ The court rejected the learned intermediary defense in this context, reasoning that there were significant differences between the doctor–patient relationship and the employer–employee relationship.²⁸⁶ Since Ashland had to rely on the sophisticated user doctrine, with its fact-based inquiry into the reasonableness of reliance on the employer as an intermediary, its motion for summary judgment was denied.²⁸⁷

The proposal set forth in this Article has the dual advantages of increasing the sensitivity of the tort system to the realities of the health care marketplace, and of being relatively easy to implement. It does not require the abrogation of any existing common law doctrine, but merely calls for an adjustment of that doctrine to meet the needs of a changed market. Nor does it depend on political will to enact new statutes or regulations. Although some have called for expanded FDA regulation in this area,²⁸⁸ the FDA has in fact been notoriously slow to react to the new realities of the pharmaceutical marketplace.²⁸⁹

D. *Coda: A Short Note on Preemption*

A final issue facing any prescription drug tort regime is the relationship between state tort law and the extensive federal regulatory system governing the prescription drug industry.²⁹⁰ The

employer–employee context under Missouri law); *Todalen v. U.S. Chem. Co.*, 424 N.W.2d 73 (Minn. Ct. App. 1988), *overruled on other grounds*, *Tyroll v. Private Label Chems., Inc.*, 505 N.W.2d 54 (Minn. 1993) (applying the same analysis as *Hall*).

²⁸⁵ *Hall*, 625 F. Supp. at 1516.

²⁸⁶ *Id.* at 1519-20.

²⁸⁷ *Id.* at 1522. The distinction between the learned intermediary and sophisticated user doctrines was not the only grounds for denial of summary judgment, as other issues of material fact, such as the adequacy of the warning given to Pfizer, existed in this case. *Id.* at 1520.

²⁸⁸ See, e.g., Castagnera & Gerner, *supra* note 251, at 125-26 (arguing for FDA-mandated program of disclosure by drug companies through pharmacists).

²⁸⁹ An instructive example is the FDA's reaction to the onset of direct-to-consumer advertisement in the 1980s. Although the FDA did initially request a moratorium on DTC advertising, it later abandoned that moratorium, claiming that existing regulations written with advertisement to physicians in mind were adequate to control DTC advertising. *Hall, Promise and Peril, supra* note 101, at 4-6.

²⁹⁰ See generally Ronald W. Eades, *Attempts to Federalize and Codify Tort Law*, 36 TORT & INS. L.J. 1 (2000) (describing use of preemption analysis to create "federal

FDA closely regulates virtually every phase of prescription drug development and sale, from research and development through manufacture and testing to labeling and distribution.²⁹¹ Further, federal regulation of prescription drug products is explicitly aimed at ensuring the safety and effectiveness of drugs sold to end users.²⁹² Although courts have traditionally rejected arguments that FDA regulation preempts failure-to-warn cases,²⁹³ such arguments have recently been buttressed by a few recently decided cases and signals from the FDA demonstrating its willingness to support such arguments. In addition, the *Third Restatement* acknowledges uncertainty on this issue.²⁹⁴ This section briefly argues that preemption of tort law by FDA regulation in this area is not a good idea.²⁹⁵ A full discussion of the relationship between tort law and FDA regulation, however, is beyond the scope of this Article.

In 1996, in *Medtronic, Inc. v. Lohr*,²⁹⁶ the United States Supreme Court decided that federal regulation of medical devices does not preempt the application of state tort law²⁹⁷ in cases involving injury caused by those devices. Lora Lohr, the plaintiff/respondent in *Medtronic*, was the recipient of a pacemaker manufactured by

defenses to state tort claims”).

²⁹¹ See Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-99 (2000 & Supp. I 2001).

²⁹² U.S. FOOD & DRUG ADMIN., FDA’S MISSION STATEMENT, at <http://www.fda.gov/opacom/morechoices/mission.html> (last visited Oct. 18, 2004).

²⁹³ See 2 WOODSIDE, *supra* note 39, § 14.04[3][c][iii], at 14-129 to -132; Michael I. Krauss, *Loosening the FDA’s Drug Certification Monopoly: Implications for Tort and Consumer Welfare*, 4 GEO. MASON L. REV. 457, 477 (1996) (citing *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142 (D. Or. 1989); *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65 (Mass. 1985)).

²⁹⁴ THIRD RESTATEMENT, *supra* note 7, § 7 cmt. e.

²⁹⁵ The drafters of the *Third Restatement* have expressed agreement with this concept, in a comment to section 6. That comment states in part:

The doctrine of preemption based on supremacy of federal law should be distinguished from the proposition that compliance with statutory and regulatory standards satisfies that state’s requirement for product safety. [Sections 6(c) and 6(d)] recognize common-law causes of action for defective drug design and for failure to provide reasonable instructions or warnings, even though the manufacturer complied with governmental standards.

Id. § 6 cmt. b.

²⁹⁶ 518 U.S. 470 (1996). For an excellent in-depth analysis of the *Medtronic* decision, see generally Robert B. Leflar & Robert S. Adler, *The Preemption Pentad: Federal Preemption of Products Liability Claims After Medtronic*, 64 TENN. L. REV. 691 (1997).

²⁹⁷ Although the claim in *Medtronic* did not involve failure-to-warn theory, but rather design defect theory, *Medtronic*, 518 U.S. at 481, the type of product liability claim should not have a material effect on the preemption analysis.

petitioners.²⁹⁸ When the product malfunctioned, forcing Lohr to undergo emergency surgery to correct the problem,²⁹⁹ she sought damages in tort under Florida law.³⁰⁰ The Court noted that the production and sale of the pacemaker device was regulated under the Medical Device Amendments (“MDA”) to the Food, Drug and Cosmetics Act (“FDCA”), and that the MDA expressly prohibit any state from “establish[ing] . . . 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 [the Act].”³⁰¹ The Court concluded that, despite this language, the plaintiff’s tort claim was not preempted, since state tort law did not involve a “requirement . . . different from, or in addition to,” the FDA requirements under the MDA.³⁰²

Although *Medtronic* may illustrate a reluctance on the part of the Court to preempt state tort law actions, there are several significant differences between the operation of the MDA (with respect to medical devices) and the FDCA (with respect to prescription drugs), which would distinguish the *Medtronic* case from a potential case arguing preemption in the prescription drug failure-to-warn context. These differences also create substantial uncertainty as to the outcome of a future case arguing preemption in the prescription drug context.³⁰³ First, the FDCA, unlike the MDA, contains no express preemption language.³⁰⁴ This means that a court would have to rely on an implied (conflict) preemption analysis,³⁰⁵ rather than

²⁹⁸ *Id.* at 480.

²⁹⁹ *Id.* at 481.

³⁰⁰ *Id.*

³⁰¹ *Id.* at 481-82 (quoting 21 U.S.C. § 360k(a)) (internal quotation marks omitted).

³⁰² See Leflar & Adler, *supra* note 296, at 701-10 (analyzing in detail the *Medtronic* opinion). Significantly, four of the nine justices (Chief Justice Rehnquist and Justices O’Connor, Scalia, and Thomas) were willing to conclude that state tort law did in fact impose an additional requirement on the manufacturer, and thus should have been preempted. *Medtronic*, 518 U.S. at 509-11 (O’Connor, J., dissenting).

³⁰³ See Eades, *supra* note 290, at 15 (“Surprisingly, [*Medtronic*] has not proven to be the final word on this issue . . .”).

³⁰⁴ Compare 21 U.S.C. § 360k(a) (2000) (expressly preempting state laws “(1) . . . different from, or in addition to, any requirement applicable under [the MDA], and (2) which relate[] to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the MDA]”), with David G. Owen, *Federal Preemption of Products Liability Claims*, 55 S.C. L. REV. 411, 428 (2003) (describing FDCA’s lack of an express preemption clause).

³⁰⁵ See Leflar & Adler, *supra* note 296, at 695 (discussing the distinction between conflict and field preemption and concluding that field preemption is virtually

express preemption analysis, which would make it more difficult for a defendant to claim preemption. Second, the device at issue in *Medtronic* had not been rigorously evaluated by the FDA, but was covered under the “grandfather clause” provisions of the MDA.³⁰⁶ Intended as a temporary pro-competitive measure during the implementation of the MDA, the grandfather clause, which allows the marketing of medical devices substantially equivalent to a pre-MDA device without pre-authorization by the FDA, has become the primary route to market for new medical devices.³⁰⁷ This stands in sharp contrast to the extensive substantive FDA scrutiny of new prescription drugs.³⁰⁸ It is possible that the comparatively heightened FDA scrutiny of new prescription drugs would lead the Court to conclude that it is reasonable to substitute the FDA scrutiny for state tort law regulation with respect to the drug’s safety.

Moreover, two cases decided since *Medtronic*, although not overruling *Medtronic*, are arguably more pro-preemption, and could be used to construct a case for FDA preemption of state law prescription drug claims.³⁰⁹ In 2000, the Court held that common law tort claims were preempted by provisions of the National Traffic and Motor Vehicle Safety Act of 1966,³¹⁰ which required passive restraints in automobiles.³¹¹ Although the Court held that the state law claims were not expressly preempted by the statute’s language,³¹² the tort claim was implicitly preempted because of “actual conflict” between tort standards and the passive restraint regulations written by the Department of Transportation (“DOT”).³¹³ The Court reasoned that because DOT regulations explicitly sought to encourage a variety of passive restraint mechanisms, phased in over time, the plaintiff’s allegations that Honda’s failure to install one particular sort of passive restraint (airbags) would undermine that regulatory

impossible to argue in the products liability context).

³⁰⁶ *Medtronic*, 518 U.S. at 477-78.

³⁰⁷ *Id.* at 479 (finding that 80% of new devices are deemed “substantially equivalent” to a device already on the market and thus receive no independent FDA review for safety and efficacy).

³⁰⁸ See Charles J. Walsh & Alissa Pyrich, *Rationalizing the Regulation of Prescription Drugs and Medical Devices: Perspectives on Private Certification and Tort Reform*, 48 RUTGERS L. REV. 883, 890-930 (1996) (detailing extensive FDA review process that new drugs must undergo).

³⁰⁹ For a brief sketch of the pro-preemption analysis contained in this section, see generally James Dabney Miller, *Blocking Bad Claims*, NAT’L L.J., Nov. 10, 2003, at 31.

³¹⁰ Pub. L. No. 89-563, 80 Stat. 718 (1966), *repealed by* Pub. L. 103-272, § 7(b), 108 Stat. 1379 (1994) (current version at 49 U.S.C. § 30101 (2000)).

³¹¹ *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 874-86 (2000).

³¹² *Id.* at 867-68.

³¹³ *Id.* at 874-75.

objective.³¹⁴

In 2001, the Court revisited the implied preemption debate, again in the context of the MDA. In *Buckman Co. v. Plaintiffs' Legal Committee*,³¹⁵ tort plaintiffs sought to hold the manufacturer of bone screws liable for injuries allegedly caused by those products. Like the pacemaker in *Medtronic*, bone screws are devices which would be required to undergo full pre-marketing approval by the FDA, but for the substantial equivalence exception.³¹⁶ Unlike *Medtronic*, the plaintiffs in *Buckman* alleged that the manufacturer of the device made false statements to the FDA in order to obtain a finding of substantial equivalence and avoid substantive FDA review of the device.³¹⁷ Reasoning that the FDCA already provided statutory procedures for policing and responding to fraudulent applications, the Court held that imposition of state tort law scrutiny of a manufacturer's FDA filings would necessarily conflict with those procedures, and was thus impliedly, even though not expressly, preempted.³¹⁸

The Court also addressed the relationship between *Medtronic* and *Buckman*, since the plaintiffs in *Buckman* argued that *Medtronic* saved their tort claim from preemption.³¹⁹ The Court concluded:

[T]he *Medtronic* claims arose from the manufacturer's failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements. . . . Thus, although *Medtronic* can be read to allow certain state-law causes of action that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.³²⁰

The issue for tort defendants who seek to assert federal preemption of failure-to-warn claims involving prescription drugs will thus be the evolving definitional issue of which state law actions "parallel federal safety requirements."³²¹ Given that state-law failure-to-warn actions implicate the traditional police powers of the State to ensure the safety of its citizens,³²² *Buckman* should not be read as dictating preemption of failure-to-warn claims involving prescription

³¹⁴ *Id.* at 882-83.

³¹⁵ 531 U.S. 341 (2001).

³¹⁶ *Id.* at 341.

³¹⁷ *Id.*

³¹⁸ *Id.* at 353.

³¹⁹ *Id.* at 352-53.

³²⁰ *Id.*

³²¹ *Buckman*, 531 U.S. at 353.

³²² *Medtronic*, 518 U.S. at 475.

drugs, notwithstanding the Court's characterization of the claim in *Buckman* as "policing fraud against federal agencies,"³²³ which gave rise to "no presumption against pre-emption."³²⁴

The current Administration is actively pursuing federal preemption of state tort law in the drug and device context.³²⁵ Current results in the courts are mixed. In the Ninth Circuit case of *Motus v. Pfizer*,³²⁶ plaintiff's decedent committed suicide after being prescribed the antidepressant drug Zoloft, manufactured by Pfizer.³²⁷ The plaintiff did not allege that Pfizer should have warned the patient directly, but alleged that the warning provided to the prescribing physician was inadequate.³²⁸ Pfizer responded by arguing that the warning given to the physician complied with FDA requirements, and that plaintiff's state law tort claim of its inadequacy should be preempted.³²⁹ The FDA filed an amicus brief with the Ninth Circuit Court of Appeals in support of preemption.³³⁰ The court, however, did not reach the preemption issue, holding instead that, since decedent's physician did not read or rely on Pfizer's warning, the inadequacy of that warning cannot have been the legal cause of plaintiff's injuries under controlling California law.³³¹

The FDA had more success in the Third Circuit case of *Horn v. Thoratec Corp.*³³² In that case, plaintiff's decedent died after an alleged malfunction of a heart pump manufactured by defendant. Plaintiff sued on both design defect and failure-to-warn theories, but the district court granted Thoratec's motion for summary judgment on the grounds that "any [state law] judgment that the [pump] was unsafe or otherwise substandard would be in direct conflict [with] . . . the FDA's determination that the product was suitable for use."³³³

³²³ *Buckman*, 531 U.S. at 347.

³²⁴ *Id.* at 348.

³²⁵ See Robert Pear, *In a Shift, Bush Moves to Block Medical Suits*, N.Y. TIMES, July 25, 2004, at 1 (reporting that the "administration contends that consumers cannot recover damages for such injuries if the products have been approved by the Food and Drug Administration").

³²⁶ *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2004).

³²⁷ *Id.* at 660.

³²⁸ *Id.*

³²⁹ Brief for Appellee Pfizer Inc. at 62, *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2004) (Nos. 02-55372 & 02-55498), available at 2002 WL 32303085.

³³⁰ Brief for Amicus Curiae United States, *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2004) (Nos. 02-55372 & 02-55498), available at 2002 WL 32303084.

³³¹ *Motus*, 358 F.3d at 661 (citing *Ramirez v. Plough, Inc.*, 863 P.2d 167, 178 (Cal. 1993)).

³³² 376 F.3d 163 (3d Cir. 2004).

³³³ *Id.* at 165 (third alteration in original) (quoting *Horn v. Thermo Cardiosystems, Inc.*, 229 F. Supp. 2d 381, 390 (M.D. Pa. 2002)).

The Third Circuit affirmed the grant of summary judgment, distinguishing *Medtronic* on the grounds that the pump at issue in *Horn* had been approved by the FDA after a full review of the device, rather than under the limited “substantial equivalence” approval granted to the device in *Medtronic*.³³⁴ The court gave substantial deference to the FDA’s new position in favor of preemption.³³⁵

The preemption issue is an important aspect of failure to warn in the prescription drug context,³³⁶ and the FDA’s position in the *Motus* case, coupled with the slim margin in the *Medtronic* opinion, signals that future failure-to-warn claims will be contested on preemption grounds. Because of the importance and historical prevalence of the state police power in this context,³³⁷ and because of the FDA’s failure to act to ensure adequate warnings in the past,³³⁸ I continue to believe that preemption is not appropriate in state failure-to-warn claims involving prescription drugs.³³⁹ The majority position among state and federal courts is still opposed to preemption in this context,³⁴⁰ and, subject to contrary holdings in the future, this Article assumes that such broad preemption is inappropriate.³⁴¹

³³⁴ *Id.* at 169-73.

³³⁵ *Id.* at 178-79.

³³⁶ The *Third Restatement* recognizes that a judicial finding of broad federal preemption would render moot the precise contours of state common law failure-to-warn claims. See THIRD RESTATEMENT, *supra* note 7, § 6 cmt. b (making the assumption “that the federal regulatory standard has not preempted the imposition of tort liability under state law. When such preemption is found, liability cannot attach if the manufacturer has complied with the applicable federal standard.”).

³³⁷ *Medtronic*, 518 U.S. at 475 (observing that “[t]hroughout our history the several States have exercised their police powers to protect the health and safety of their citizens”).

³³⁸ See Hall, *Promise and Peril*, *supra* note 101, at 3-8 (discussing the FDA’s failure to adequately regulate DTC advertising).

³³⁹ Cf. Owen, *supra* note 304, at 441 (“[T]here is . . . no reason . . . why product safety regulation and products liability litigation cannot comfortably co-exist.”).

³⁴⁰ See, e.g., *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1176-78 (5th Cir. 1988); *Mazur v. Merck & Co.*, 742 F. Supp. 239, 245-47 (E.D. Pa. 1990); *Feldman v. Lederle Labs*, 592 A.2d 1176, 1178 (N.J. 1991); *Kurer v. Parke, Davis & Co.*, 679 N.W.2d 867, 874 (Wis. Ct. App. 2004).

³⁴¹ Other scholars have been critical of broad federal preemption of tort law. See, e.g., Eades, *supra* note 290, at 20-21 (“Tort law works because it is an immediate response to local and even individual needs in a community. Attempts to nationalize or make uniform that law detract from its ability to respond to the needs of individuals in local communities.”). Of course, this does not prevent a state from determining, as a matter of positive law, that compliance with federal standards satisfies that state’s products liability law. See Leflar & Adler, *supra* note 296, at 694 (discussing state laws which give “conclusive effect . . . occasionally to compliance with certain federal standards”); MICH. COMP. LAWS § 600.2946(5) (2004) (establishing a conclusive presumption that compliance with FDA mandates satisfies

CONCLUSION

The law must reflect commercial reality.³⁴² Unfortunately, the pace of change in the health care marketplace over the past decade has made it difficult for the common law, a fundamentally conservative institution, to keep up with new developments. While the modifications to the learned intermediary rule proposed in this Article will make the Rule's application somewhat more complex, they have the advantage of realigning the Rule with the practices of the health care marketplace, and thus enabling the tripartite functions of the tort system—compensation, deterrence, and cost allocation—to operate more efficiently. The marketplace for health care services, including prescription pharmaceuticals, has evolved beyond the point where a simple set of categorical exceptions to the learned intermediary rule can effectively reflect the needs of consumers of prescription drugs.

Where an effective intermediary exists, such as where a drug is prescribed and administered within the context of a robust physician–patient relationship, the purposes of tort law are best served by applying the Rule to safeguard the drug manufacturer from liability. We should recognize, however, that the modern health care market has created several opportunities for a consumer to obtain prescription drugs outside of such a relationship—situations that diminish the role of the physician as educator and undermine the doctor/patient relationship. Absent an effective intermediary, the learned intermediary rule, while protecting the drug manufacturer, fails to adequately protect the drug consumer. Furthermore, the learned intermediary rule insulates drug manufacturers from the incentives the tort system provides to take reasonable steps to ensure that adequate warnings are provided to all users of a drug. By reimagining the learned intermediary rule as a fact-based balancing of interests, rather than a bright-line exemption from the usual duty to warn a product's end user, tort law can balance the interests of drug manufacturers with those of consumers, and create incentives to further reduce the incidence of injuries due to misuse of prescription drugs.

state law regarding the adequacy of the warning given).

³⁴² See, e.g., *MacPherson v. Buick Motor Co.*, 111 N.E. 1050, 1053 (N.Y. 1916) (“Precedents drawn from the days of travel by stage coach do not fit the conditions of travel [by automobile] to-day.”).