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THE SOCIETAL VALUE OF PRESCRIPTION DRUG ADVERTISEMENTS IN THE NEW MILLENNIUM: TARGETED CONSUMERS BECOME THE LEARNED

Caroline L. Nadal*

INTRODUCTION

In a majority of jurisdictions throughout the United States, a prescription drug manufacturer will not be liable to the ultimate drug consumer when it has heavily advertised its product to that consumer yet failed to provide adequate warnings of the dangers associated with its use.¹ Under the learned intermediary doctrine,² the manufacturer absolves itself from liability by providing

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¹ See, e.g., *In re Norplant Contraceptive Prod. Litig.*, 165 F.3d 374 (5th Cir. 1999) (affirming summary judgment for defendant manufacturer despite its aggressive marketing of contraceptive devices to consumers); *Skill v. Martinez*, 91 F.R.D. 498 (D.N.J. 1981) (holding that the court properly instructed the jury that the prescription drug manufacturer's duty did not extend to the consumer of oral contraceptives); *Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352 (Ill. 1996) (affirming summary judgment for the defendant drug manufacturer when the plaintiff argued that the manufacturer had a duty to warn consumers directly); *Doe v. Alpha Therapeutic Corp.*, 3 S.W.3d 404 (Mo. App. 1999) (holding that, despite advertising in *Newsweek* magazine, a pharmaceutical manufacturer did not have a duty to warn consumers directly). The same rule equally applies to medical implants. See, e.g., *Rosci v. AcroMed, Inc.*, 669 A.2d 959 (Pa. 1999) (applying learned intermediary doctrine when the plaintiff brought suit against the manufacturer of surgically implanted bone plates and screws).

² The phrase, "learned intermediary," was coined in *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966). The Eighth Circuit stated that "the purchaser's doctor is a *learned intermediary* between the purchaser and the manufacturer." *Id.* (emphasis added).

adequate warnings to the prescribing physician, i.e. the “learned intermediary.”³ Thus, the physician is left bearing the legal obligation to adequately warn of the dangers and various side effects of prescription medication.⁴ This doctrine operates under the assumption that the prescribing physician makes an informed decision for the patient by balancing her medical diagnosis and history with the benefits and risks of the chosen drug.⁵ Prescription drugs and their associated side effects, according to the doctrine, are complicated beyond the average consumer's comprehension.⁶ As such, the physician, and not the patient, appropriately chooses the prescription medication and thus bears the legal burden to warn patients of associated dangers.⁷

Recently, however, prescription drug manufacturers have undertaken multi-million dollar ad campaigns to promote their products to the public-at-large.⁸ Clearly, prescription drug manufacturers feel that consumers are playing important roles in deciding the prescription drugs they take.⁹ For the pharmaceutical companies, these direct-to-consumer (“DTC”) advertisements serve

³ See *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974) (“Pharmaceutical companies . . . in selling prescription drugs are required to warn only the prescribing physician, who acts as the ‘learned intermediary’ between manufacturer and consumer.”).

⁴ *Id.*

⁵ See *infra* notes 56-57 and accompanying text (discussing assumption that learned physicians make informed choices concerning prescription drugs).

⁶ See *infra* notes 53-55 and accompanying text (describing the complications of the average patient trying to comprehend the complexities of prescription medications); see also *infra* note 169 (parleying various medical terminology used in describing side effects and contraindications associated with prescription drugs).

⁷ See *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974) (holding that the physician is best situated to warn patients of risks associated with prescription medications); see also *infra* notes 54-59 (discussing the rationale behind the learned intermediary doctrine).

⁸ See *infra* notes 145-63 and accompanying text (observing the recent increases in money spent on prescription drug advertisements).

⁹ *Experimenting with Direct-to-Consumer Advertising*, LANCET, Aug. 19, 2000 (noting the recent increase in the sales of prescription drugs, especially those heavily advertised); see also *infra* notes 145-63 (discussing the increase in funds spent on direct-to-consumer advertising).

financial purposes by encouraging patients to ask their physicians for the marketed products.¹⁰ For consumers/patients, such marketing suggests a movement in an evolving health care system where patients are making decisions that doctors used to make for them.¹¹ Patients are now receiving the information, formerly sent only to physicians, via print ads, television and radio commercials, and Internet sites.¹² As a result, they are taking charge of their own personal health care and are more often choosing the prescription drugs they take.¹³

In light of these recent changes, courts and scholars have begun questioning whether the learned intermediary doctrine should be strictly applied when a drug manufacturer engages in DTC marketing.¹⁴ A number of courts have already recognized exceptions to the doctrine when the drug in question was distributed for mass immunizations or contraception.¹⁵ An exception, courts have reasoned, is warranted when the physician and patient are not able

¹⁰ See Tamar V. Terzian, Note, *Direct-to-Consumer Prescription Drug Advertising*, 25 AM. J.L. & MED. 149, 157 (1999) (noting that “physicians state that they are increasingly asked and pressured by their patients to prescribe drugs that the patient has seen advertised”); see also *infra* note 147 (likening DTC advertising to the promotion of toys and cereal to children).

¹¹ See *infra* notes 122-44 and accompanying text (discussing recent changes in the American health care system).

¹² See *infra* notes 145-63 and accompanying text (explaining how pharmaceutical manufacturers are now reaching out to consumers directly); see also *infra* notes 147-48 and accompanying text (discussing how patients now ask physicians for specific prescription medications as a result of these advertisements).

¹³ See *infra* notes 195-208 and accompanying text (describing the benefits of DTC advertisements on consumers' awareness).

¹⁴ See, e.g., Yonni D. Fushman, Comment, *Perez v. Wyeth Labs., Inc.: Toward Creating a Direct-to-Consumer Advertisement Exception to the Learned Intermediary Doctrine*, 80 B.U. L. REV. 1161, 1183 (2000) (noting that an exception to the learned intermediary doctrine is warranted when the manufacturer has engaged in DTC because the manufacturer can reach the masses with warnings); Nancy K. Plant, *The Learned Intermediary Doctrine: Some New Medicine for an Old Ailment*, 81 IOWA L. REV. 1007, 1078 (1996) (advocating abrogation of the learned intermediary doctrine in favor of a informed consent approach in light of health care changes in society).

¹⁵ See *infra* notes 65-118 and accompanying text (listing and discussing the cases that have allowed for such exceptions).

to develop a strong relationship and when the patient has exercised independent judgment in choosing the drug he or she takes.¹⁶ In its 1999 decision, *Perez v. Wyeth Laboratories*,¹⁷ the New Jersey Supreme Court was the first to create an exception to the learned intermediary doctrine when a pharmaceutical manufacturer has engaged in DTC advertising.¹⁸ The *Perez* Court, like the courts adopting exceptions for mass immunization and contraceptives, found an exception warranted because under the current health care system physicians are spending less time with patients.¹⁹ Further, patients are receiving more information directly from the pharmaceutical manufacturers, and are becoming empowered to ask their physicians for specific drugs.²⁰ The *Perez* decision, however, is only a limited victory for future plaintiffs.²¹ The New Jersey Supreme Court places the burden on the plaintiff to prove that the defendant manufacturers blatantly disregarded the guidelines of the

¹⁶ See *infra* notes 65-118 and accompanying text (explaining the rationale that has led courts to adopt exceptions to the learned intermediary doctrine).

¹⁷ 734 A.2d 1245 (N.J. 1999).

¹⁸ *Id.* The New Jersey Supreme Court stated the following:

We believe that when mass marketing of prescription drugs seeks to influence a patient's choice of a drug, a pharmaceutical manufacturer that makes direct claims to the consumer for the efficacy of its product should not be unqualifiedly relieved of a duty to provide proper warnings of the dangers or side effects of the product.

Id. at 1247.

¹⁹ *Id.* at 1256-57.

²⁰ *Id.*

²¹ *Id.* at 1259 (holding that plaintiff can only rebut this presumption by demonstrating deliberate non-compliance or concealment by the defendant manufacturer); see also William A. Dreier, *Direct-to-Consumer Advertising Liability: An Empty Gift to Plaintiffs*, 30 SETON HALL L. REV. 806, 825 (2000) (opining that, because under *Perez v. Wyeth Laboratories* New Jersey requires a plaintiff to prove that the pharmaceutical manufacturer blatantly disregarded FDA regulations in DTC advertisements, plaintiffs will have difficulties getting past defendants' summary judgment motions).

FDA.²² This places a great burden on a plaintiff and renders an outcome in her favor unlikely.²³

Although the standard set forth in *Perez* creates an exception to the learned intermediary doctrine, like New Jersey, other courts will increasingly face the issue of whether the learned intermediary doctrine should apply when a prescription drug manufacturer has engaged in heavy DTC marketing. Courts should give considerable weight to the social benefits and harms of DTC marketing. Advocates of DTC argue that such marketing increases consumer awareness, reduces disease-associated stigmas, and enables patients to take charge of their own health care.²⁴ Critics, on the other hand, believe that the ads provide complicated and misleading information to patients who are not medically trained to weigh the risks and benefits of specific prescription drugs.²⁵ Courts viewing DTC marketing as ultimately beneficial should either refuse to create an exception to the learned intermediary doctrine or should create only a limited exception in order not to dissuade manufacturers from advertising.²⁶

This Note outlines four options for courts to consider when facing the difficult question of whether to adopt an exception to the learned intermediary doctrine. Courts can take one of the four following approaches: (1) reject creating an exception to the learned intermediary doctrine; (2) allow an exception to the learned intermediary doctrine, but create a strong rebuttable presumption requiring a plaintiff to prove that the manufacturer intentionally failed to comply with FDA guidelines through conscious concealment or failure to disclose subsequently acquired harmful product information;²⁷ (3) allow an exception to the learned intermediary

²² *Id.* FDA Guidelines regulating DTC advertising of prescription drugs falls under 21 C.F.R. § 202.1 (2000); see also *infra* notes 164-74 and accompanying text (detailing this regulation).

²³ See Dreier, *supra* note 21, at 825.

²⁴ See *infra* notes 195-208 and accompanying text (setting forth the social benefits of DTC marketing).

²⁵ See *infra* notes 209-27 and accompanying text (setting forth the social harms of DTC marketing).

²⁶ See *infra* notes 260-61 and accompanying text (opining that an open-ended exception to the learned intermediary doctrine would dissuade DTC advertising).

²⁷ This is the resolution New Jersey adopted in *Perez*, 734 A.2d at 1259.

doctrine, but create a weaker rebuttable presumption requiring plaintiff only to show that the manufacturer did not comply with FDA guidelines; or (4) create an exception to the learned intermediary doctrine regarding noncompliance with FDA regulations as presumptive but not determinative of liability. In weighing all the factors, courts should conclude that the third option presents the optimal results. In holding manufacturers to the standards that the FDA has set forth, courts will not dissuade DTC advertising but will encourage pharmaceutical manufacturers to advertise more responsibly within the guidelines the FDA has set forth.²⁸

Part I of this Note discusses the background of the learned intermediary doctrine to include the underlying rationale behind the doctrine and the exceptions that courts have recognized over the years. Part II discusses the changes that have occurred in health care over the past two decades and the impacts these changes have had on the physician-patient relationship. Moreover, this section addresses the massive boom of DTC marketing by pharmaceutical manufacturers and the different advertisement mediums, including the governing FDA regulations. Finally, Part III of this Note considers the social benefits and harms of the existing DTC advertisements in conjunction with the policy arguments behind the four approaches laid out above to conclude that the third approach, creating a weak rebuttable presumption against the plaintiff, is the optimal choice for courts to adopt.

I. THE LEGAL BACKGROUND AND EVOLUTION OF THE LEARNED INTERMEDIARY DOCTRINE

A majority of courts have embraced the learned intermediary doctrine, setting forth the rule that manufacturers of prescription drugs are shielded from liability when they have adequately warned the prescribing physician.²⁹ This is a departure from the general products liability principle that manufacturers owe a duty to reasonably warn consumers of dangers associated with the products

²⁸ See *infra* notes 269-71 and accompanying text (explaining why the third option presents the optimal solution for courts to follow).

²⁹ See *supra* note 1.

they place on the market.³⁰ The learned intermediary doctrine has been rationalized on several grounds.³¹ First, prescription drugs are complex and idiosyncratic in how they react to the human body, and consumers can only acquire them through physicians' prescriptions.³² Thus, physicians and not consumers are better suited to weigh the risks and benefits of the medications and provide necessary warnings to patients.³³ Courts, however, have recognized an exception to the learned intermediary doctrine in mass immunization settings where consumers do not have the opportunity to receive adequate warnings from physicians.³⁴ A smaller number of court have allowed for an exception for contraceptives, reasoning that a healthy patient chooses her method of contraception independent of a physician's input.³⁵ The New Jersey Supreme Court is the first court to recognize an exception when the pharmaceutical company has engaged in DTC marketing.³⁶

A. *General Tort Principles and the Rationale Behind the Learned Intermediary Doctrine*

Manufacturers have a duty to warn consumers about possible risks associated with the products they place in the market.³⁷ The

³⁰ See *infra* notes 37-48 and accompanying text (detailing general products liability principles).

³¹ See *infra* notes 53-59 and accompanying text (discussing the rationale behind the doctrine).

³² See *infra* notes 53-55 and accompanying text (describing the complications of the average patient in trying to comprehend the complexities of prescription medications).

³³ See *Reyes*, 498 F.2d at 1276 (holding that the physician is best situated to warn patients of risks associated with prescription medications).

³⁴ See *infra* notes 65-77 and accompanying text (discussing the exception for mass immunizations).

³⁵ See *infra* notes 78-79 and accompanying text (discussing the exception for contraceptives).

³⁶ *Perez*, 734 A.2d at 1259.

³⁷ The *Restatement (Third) of Torts: Products Liability* § 2(c) (1998) states the following:

purposes behind warnings are twofold.³⁸ First, they instruct consumers on proper use of a product to reduce the risks of injuries resulting from misuse.³⁹ Second, they enable the consumer to make an informed choice to use the product and face exposure to the risks.⁴⁰ Prescription drugs fall into a special class of products

[A product] is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.

Id.

One uncertainty that courts have faced is whether failure to warn claims sound in strict liability or negligence. *See Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal. 3d 987 (1991) (holding that under strict liability failure to warn, plaintiffs must show that the defendant manufacturer knew or should have known of the unwarned risks). *Cf. Beshada v. Johns-Manville Products Corp.*, 447 A.2d 539 (N.J. 1982) (holding manufacturers strictly liable for failing to warn of risks that were scientifically unknowable at the time of manufacture). Many courts recognize the confusion generated between negligence and strict liability principles that manufacturers should only be liable for those risks it knew or should have known; however, the *Restatement (Third)* and most courts require the plaintiffs to prove that manufacturers knew or should have known of the associated risks. *See* RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. §2 cmt. m; *see also Vassallo v. Baxter Health care Corp.*, 696 N.E.2d 909, 923 (Mass. 1998) (adopting the approach of the *Restatement (Third)* in holding that manufacturer could not be held liable for unforeseeable hazards).

Furthermore, under common law tort doctrine, courts do not hold manufacturers liable for warning against obvious dangers associated with a product. *See, e.g., Jamieson v. Woodward & Lothrop*, 247 F.2d 23 (D.C. Cir. 1957) (holding that manufacturer of a rubber exercise rope did not have a duty to warn plaintiff of the rope snapping back and causing injury).

³⁸ *See* JAMES A. HENDERSON & AARON D. TWERSKI, PRODUCTS LIABILITY PRODUCTS AND PROCESS 337 (4th ed. 2000) (introducing distinctions between warnings and instructions manufacturers provide consumers).

³⁹ *Id.*

⁴⁰ *Id.*; *see also*, RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. §2 cmt. i (1998).

Such warnings allow the user or consumer to avoid the risk warned against by making an informed decision not to purchase or use the product at all and hence not to encounter the risk. In this context, warnings must be provided for inherent risks that reasonably foresee-

deemed “unavoidably unsafe” under the *Restatement (Second) of Torts*.⁴¹ All prescription drugs pose hazards, whether minute or great, to consumers.⁴² However, these same drugs cure life-threatening diseases, remedy crippling mental-illnesses, alleviate physical aches, pains, and provide numerous other benefits.⁴³ Our society has come to accept the bad with the far-surpassing good.⁴⁴ Both *Restatement (Second) of Torts* and the *Restatement (Third) of Torts: Products Liability* recommend that prescription drug manufacturers not be held strictly liable for failing to warn of

able product users and consumers would reasonably deem material or significant in deciding whether to use or consume the product. Whether or not many persons would, when warned, nonetheless decide to use or consume the product, warnings are required to protect the interests of those reasonably foreseeable users or consumers who would, based on their own reasonable assessments of the risks and benefits, decline product use or consumption.

Id.

⁴¹ RESTATEMENT (SECOND) OF TORTS §402A cmt. k (1965).

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 Such a product, properly prepared, and accompanied by proper directions and warnings, is not defective, nor is it unreasonably dangerous.

Id.

⁴² Penicillin, the antibiotic heralded as one of the greatest medical discoveries of the twentieth century, has a number of dangers associated with its use. *Penicillin, The Wonder Drug*, at <http://www.botany.hawaii.edu/faculty/-wong/BOT135/Lect21b.htm> (last visited on Feb. 6, 2001). Among listed potential hazards is a proportionately rare occurrence of shock and/or seizures, and more common side effects of nausea, vomiting, or diarrhea. See OnHealth, *What Are the Possible Side Effects of Penicillin V?*, at <http://www.onhealth.webmd.com/-conditions/resource/pharmacy/multum8/item,73027.asp> (last visited Sept. 16, 2000).

⁴³ See RESTATEMENT (SECOND) OF TORTS §402A cmt. k (1965) (“An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified.”).

⁴⁴ *Id.*

unknown, potential dangers,⁴⁵ and most jurisdictions follow this guidance.⁴⁶ Recognizing that imposing strict liability would likely curb manufacturers' research and development of new and valuable drugs, courts have adopted a negligence standard, imposing liability only when prescription drug manufacturers have acted unreasonably in failing to warn of dangers they knew or should have known.⁴⁷ Further, courts have also extended a manufacturer's duty to warn only to the prescribing physician and not the ultimate consumer.⁴⁸

With the birth of the learned intermediary doctrine, prescription drug manufacturers have become insulated from numerous liabilities.⁴⁹ The California appellate courts were among the first to create a "no duty" rule for prescription drug manufacturers, holding that the manufacturers did not have a legal obligation to

⁴⁵ *Id.*; see also RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 cmt. m (1998).

The issue of foreseeability of risk of harm is more complex in the case of products such as prescription drugs, medical devices, and toxic chemicals. Risks attendant to use and consumption of these products may, indeed, be unforeseeable at the time of sale. Unforeseeable risks arising from foreseeable product use or consumption by definition cannot adequately be warned against. Thus, in connection with a claim of inadequate design, instruction, or warning, plaintiff should bear the burden of establishing that the risk in question was known or should have been known to the relevant manufacturing community.

Id.

⁴⁶ See, e.g., *Vassallo v. Baxter Healthcare*, 696 N.E. 909 (Mass. 1998) (embracing the position of the *Restatement (Third)* in joining the majority of jurisdictions that foreseeability is relevant to a failure to warn claim).

⁴⁷ *Id.* Dean Prosser aptly stated the following:

The argument that industries producing potentially dangerous products should make good the harm, distribute it by liability insurance, and add the cost to the price of the product, encounters reason for pause, when we consider that two of the greatest medical boons to the human race, penicillin and cortisone, both have their dangerous side effects, and that drug companies might well have been deterred from producing and selling them.

JOHN W. WADE ET. AL., PROSSER, WADE AND SCHWARTZ'S CASES AND MATERIALS ON TORTS 749 (9th ed. 1994).

⁴⁸ See *supra* note 1 (listing supporting cases).

⁴⁹ See *supra* note 1 (listing supporting cases).

warn consumers of the hazards associated with their products.⁵⁰ Doctors who prescribe the drugs and who have direct patient contact are in a superior position to provide necessary information and warnings.⁵¹ The reporters of the *Restatement (Third) of Torts: Products Liability* also recognize the learned intermediary rule as a sound products liability doctrine.⁵²

The rationale behind the learned intermediary doctrine is best illustrated in the oft-quoted passage from *Reyes v. Wyeth Laboratories*:

Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is a task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.⁵³

Furthermore, courts have universally embraced the learned intermediary doctrine for four reasons.⁵⁴ First, the complexities of

⁵⁰ See *Love v. Wolf*, 38 Cal. Rptr. 183, 193 (1964) (“[I]f adequate warning of potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to insure that the warning reaches the doctor’s patient for whom the drug is prescribed.”); *Magee v. Wyeth Labs., Inc.*, 29 Cal. Rptr. 322 (1963) (holding that adequate warning to a physician relieves the manufacturer of liability).

⁵¹ 498 F.2d 1264 (5th Cir. 1974).

⁵² See RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6 (d) (1998) (“A prescription drug or 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 . . . prescribing and other health care providers who are in a position to reduce the risks of harm.”).

⁵³ *Id.* at 1276; see also RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6 cmt. b (1998) (“The rationale supporting this ‘learned intermediary’ rule is that only health care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy.”).

⁵⁴ See Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 156-59 (1997) (discussing the rationale behind the learned intermediary doctrine in arguing that

prescription medications combined with the intricate structure of the human body and the peculiarities of specific diseases and ailments preclude average consumers from fully comprehending manufacturers' warnings.⁵⁵ Physicians, secondly, have technical training and expertise to heed warnings and caution patients of dangers associated with prescription medications.⁵⁶ Moreover, because a physician has direct contact with a patient, he or she can more accurately weigh the risks and benefits of a specific medication with the patient's ailment and medical history.⁵⁷ Third, the learned intermediary doctrine helps to preserve the physician-patient relationship and the important deference and reverence that patients cede to doctors.⁵⁸ Finally, prescription drug manufacturers are unable to reach directly all potential consumers with information about their products and, thus they are incapable of appropriately conveying necessary warnings.⁵⁹

an exception should not be permitted for DTC advertising).

⁵⁵ See, e.g., *Hill v. Searle Labs.*, 884 F.2d 1064, 1070 (8th Cir. 1989) (“[T]he information regarding risks is often too technical for a patient to make a reasonable choice.”); *Reaves v. Ortho Pharm. Corp.*, 765 F. Supp. 1287, 1290 (E.D. Mich. 1991) (“As with other prescription drugs, patients are unlikely to understand technical medical information regarding the nature and propensities of oral contraceptives.”).

⁵⁶ See, e.g., *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1232 (4th Cir. 1984) (“[T]he question of [adhering to the learned intermediary doctrine] turns on who is in a better position to disclose risks.”); *Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352, 357 (Ill. 1996) (“[P]rescribing physicians, and not pharmaceutical manufacturers, are in the best position to provide direct warnings to patients concerning the dangers associated with prescription drugs.”); *Terhune v. A.H. Robins Co.*, 577 P.2d 975, 978 (Wash. 1978) (holding that a physician is better able to provide a patient with a thorough, adequate warning).

⁵⁷ See Noah, *supra* note 54, at 158.

⁵⁸ See, e.g., *Swayze v. McNeil Labs.*, 807 F.2d 464, 471 (9th Cir. 1988) (“In all likelihood, such warnings [directly to consumers] would . . . perhaps undermine the physician-patient relationship. When the physician-patient relationship does exist, as here, we hesitate to encourage, much less require, a drug manufacturer to intervene in it.”); *Dunkin v. Syntax Labs.*, 443 F. Supp. 121, 123 (W.D. Tenn. 1977) (“[A]ttempts to give detailed warnings to patients could mislead patients and might also tend to interfere with the physician/patient relationship.”).

⁵⁹ See, e.g., *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 130 (9th Cir. 1968) (“[I]t is difficult . . . for the manufacturer, by label of direct communications, to

B. Extensions and Exceptions

A number of courts have allowed for some flexibility in the somewhat unyielding learned intermediary doctrine in order to adapt to the changes in health care and prescription drug developments.⁶⁰ A few courts have extended the pharmaceutical manufacturer's duty to warn to other health care professionals such as nurses.⁶¹ Most courts, furthermore, have allowed for an exception for mass immunizations, and many fewer courts have done the same when the drug in question is used for contraceptive purposes.⁶² Only one court to date has created an exception to the learned intermediary doctrine when the manufacturer has engaged in DTC advertising.⁶³ When a court creates such an exception, the manufacturer has a duty to directly warn the consumer.⁶⁴

1. Mass Immunizations

In 1968 the United States Court of Appeals for the Ninth Circuit recognized the first major exception to the learned interme-

reach the consumer with a warning."); *Terhune v. A.H. Robins Co.*, 577 P.2d 975, 978 (1978) ("[I]t is ordinarily difficult for the manufacturer to communicate directly with the consumer."). *But see Perez*, 734 A.2d at 1255-56 ("[H]aving spent \$1.3 billion on advertising in 1998 . . . drug manufacturers can hardly be said to 'lack effective means to communicate directly with patients.'" (quoting Noah, *supra*, note 54, at 158)).

⁶⁰ See *infra* notes 65-118 and accompanying text (detailing exceptions to the learned intermediary doctrine).

⁶¹ See, e.g., *Rohrbough v. Wyeth Labs.*, 719 F. Supp. 470, 478 (N.D. W. Va. 1989) (designating registered nurses who administered vaccines as learned intermediaries); *Walker v. Merck & Co.*, 648 F. Supp. 931 (M.D. Ga. 1986) (holding licensed practicing nurses administering vaccinations as learned intermediaries). Predominately, however, the courts have rejected extending the manufacturer's duty to pharmacists. See, e.g., *Ramirez v. Richardson-Merrell, Inc.*, 628 F. Supp. 85 (E.D. Penn. 1986); *Jones v. Irvin*, 602 F. Supp. 399 (S.D. Ill. 1985); *Murphy v. E.R. Squibb & Sons, Inc.*, 40 Cal.3d 672 (1985).

⁶² See *infra* notes 65-96 and accompanying text (detailing these exceptions).

⁶³ See *Perez v. Wyeth Labs.*, 734 A.2d 1245 (N.J. 1999); see also *infra* notes 97-118 (providing the background of this case).

⁶⁴ *Perez*, 734 A.2d at 1259.

diary doctrine.⁶⁵ In *Davis v. Wyeth Laboratories*, the court acknowledged that the manufacturer of the Sabin polio vaccine had a duty to warn directly a recipient of the vaccine at a mass immunization clinic.⁶⁶ Mr. Davis developed polio and became paralyzed from the waist down after receiving the Type III polio vaccine.⁶⁷ He brought suit against the manufacturer of the mass vaccine alleging, *inter alia*, that the manufacturer had a direct duty to warn him of the dangers of resulting paralysis.⁶⁸ The Court agreed, likening mass immunizations at a clinic to the purchasing of over-the-counter medication.⁶⁹ The underlying assumptions of the learned intermediary doctrine were not present in this mass

⁶⁵ *Davis*, 399 F.2d at 121.

⁶⁶ *Id.* at 130. The *Davis* court stated the following:

We conclude that the facts of this case imposed on the manufacturer a duty to warn the consumer (or make adequate provision for his being warned) as to the risks involved, and that failure to meet this duty rendered the drug unfit in the sense that it was thereby rendered unreasonably dangerous.

Id.

⁶⁷ *Id.* at 122-123. The polio vaccine was created to prevent an individual's contraction of paralytic poliomyelitis, a crippling disease causing paralysis primarily in young children. *Id.* The Type III vaccination, licensed in 1962, was the first live-virus polio vaccine administered orally. *Id.*

⁶⁸ *Id.* at 124. The Surgeon General had released a warning to health officials and clinics stating that a higher incidence of paralytic poliomyelitis actually resulted in adults than children receiving the vaccination. *Id.* Thus, the Surgeon General advised that the vaccine not be administered to adults, especially over the age of thirty (Mr. Davis was thirty-nine), unless they fall into a high-risk group. *Id.* While this warning was broadcast on the public news, a sales representative of the manufacturer distributing vaccination information to the immunization clinic which Mr. Davis used failed to provide any warnings associated with the vaccine. *Id.* at 125. The sales representative, in fact, represented the vaccine as entirely safe. *Id.*

⁶⁹ *Id.* at 131.

Here, however, although the drug was denominated a prescription drug it was not dispensed as such. It was dispensed to all comers at mass clinics without an individualized balancing by a physician of the risks involved. In such cases (as in the case of over-the-counter sales of non-prescription drugs) warning by the manufacturer to its immediate purchaser will not suffice.

Id.

immunization setting.⁷⁰ The patient, moreover, did not rely on a doctor's signature in order to get the vaccine.⁷¹ Furthermore, vaccines are typically given in large numbers where individuals do not sit down with a physician one-on-one to hear the dangerous side effects associated with its administration.⁷² Consequently, the Court reasoned, manufacturers bear this responsibility and cannot hide behind the shield of the learned intermediary doctrine.⁷³

This exception was taken even further in *Reyes v. Wyeth Laboratories*.⁷⁴ In this case, the United States Court of Appeals for the Fifth Circuit held that the manufacturer had a duty to warn the consumer directly even when the vaccination occurs under the supervision of a registered nurse and not in a mass immunization setting.⁷⁵ In congruence with *Davis* and *Reyes*, the majority of jurisdictions within the United States recognize this mass immunization exception to the learned intermediary doctrine because physicians do not weigh the risks and benefits of medications in a clinic or mass immunization backdrop.⁷⁶ In cases where a physi-

⁷⁰ *Id.*; see also *supra* notes 53-59 and accompanying text (discussing the rationale behind the learned intermediary doctrine).

⁷¹ *Davis*, 399 F.2d at 131.

⁷² *Id.*

⁷³ *Id.*

⁷⁴ 498 F.2d 1264 (5th Cir. 1974).

⁷⁵ *Id.* at 1277. In this case an eight-month old baby girl received the Sabin polio vaccination, and after two weeks developed paralysis. *Id.* at 1269. Her parents brought the suit against the manufacturer. *Id.* In comparing this case to *Davis v. Wyeth Laboratories* the Court stated that "[w]hether [the] vaccine was received by a nurse or pharmacist, it was, in both these cases, dispensed without the sort of individualized medical balancing of the risks to the vaccinee that is contemplated by the prescription drug exception." *Id.* at 1277.

⁷⁶ See, e.g., *Petty v. United States*, 740 F.2d 1428, 1440 (8th Cir. 1983) (concerning mass immunization for the flu); *Givens v. Lederle Labs.*, 556 F.2d 1341, 1345 (5th Cir. 1977) (recognizing an exception even though the vaccine was dispensed at a small physician's office); *Allison v. Merck & Co.*, 878 P.2d 948, 959 (Nev. 1994) (holding that the learned intermediary rule did not apply when the vaccination took place in a clinic even as a result of a physician's referral); *Kearl v. Lederle Labs.*, 218 Cal. Rptr. 453, 466-67 (finding the warning given from manufacturer to vaccinee adequate); *Samuels v. American Cyanamid Co.*, 495 N.Y.S.2d 1006, 1014 (N.Y. Sup. Ct. 1985) (recognizing an exception for travel vaccines administered in a clinic). Cf. *Mazur v. Merck & Co.*, 964

cian decides to vaccinate, however, most courts apply the learned intermediary doctrine because the physician will properly weigh the benefits and dangers.⁷⁷

2. Contraceptives

Courts have been much more reluctant to recognize exceptions to the learned intermediary doctrine in the case of contraceptives.⁷⁸ Few jurisdictions, however, have allowed exceptions for oral contraceptives.⁷⁹ In *Odgers v. Ortho Pharmaceutical Corpo-*

F.2d 1348, 1361 (3d Cir. 1992) (upholding summary judgment for the defendant manufacturer because the manufacturer had contractually delegated its duty to warn to the Centers for Disease Control).

⁷⁷ See, e.g., *Hurley v. Lederle Labs.*, 863 F.2d 1173, 1178-79 (5th Cir. 1988) (holding no exception to the learned intermediary doctrine when the vaccine was administered in a physician's office by a nurse who fell under a physician's supervision); *Plummer v. Lederle Labs.*, 819 F.2d 349, 356-57 (2d Cir. 1987); *Schindler v. Lederle Labs.*, 725 F.2d 1036, 1039 (6th Cir. 1983); *Stanback v. Parke, Davis, & Co.*, 657 F.2d 642, 644 (4th Cir. 1981); *Rohrbough v. Wyeth Labs.*, 719 F. Supp. 470, 478 (N.D.W. Va. 1989); *Tongate v. Wyeth Labs.*, 580 N.E.2d 1220, 1224-25 (Ill. App. Ct. 1991); *Dunn v. Lederle Labs.*, 328 N.W.2d 576, 579-80 (Mich. Ct. App. 1982).

⁷⁸ See, e.g., *In re Norplant Contraceptive Prod. Litig.*, 165 F.3d 374, 379 (5th Cir. 1999); *Odom v. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992); *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 91-92 (2d Cir. 1980); *MacPherson v. Searle & Co.*, 775 F. Supp. 417, 422 (D.D.C. 1991); *Reaves v. Ortho Pharm. Corp.*, 765 F. Supp. 1287, 1290 (E.D. Mich. 1991); *Zanzuri v. G.D. Searle & Co.*, 748 F. Supp. 1511, 1514-15 (S.D. Fla. 1990); *Allen v. G.D. Searle & Co.*, 748 F. Supp. 1142, 1147-48 (D. Or. 1989); *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024, 1031 (D.N.J. 1988); *Kociemba v. Searle & Co.*, 680 F. Supp. 1293, 1305-06 (D. Minn. 1988); *Goodson v. Searle Labs.*, 471 F. Supp. 546, 548-49 (D. Conn. 1978); *Chambers v. G.D. Searle & Co.*, 441 F. Supp. 377, 381 (D. Md. 1975); *West v. Searle & Co.*, 806 S.W.2d 608, 614 (Ark. 1991); *Lacy v. Searle & Co.*, 567 A.2d 398, 401 (Del. 1989); *Martin v. Ortho Pharm. Corp.*, 661 N.W.2d 352, 356-57 (1996); *Cobb v. Syntex Labs.*, 444 So. 2d 203, 205 (La. Ct. App. 1983); *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 836-37 (Ohio 1981); *McKee v. Moore*, 648 P.2d 21, 24 (Okla. 1982); *Taurino v. Ellen*, 579 A.2d 925, 935 (Pa. Super. Ct. 1990); *Terhune v. A.H. Robins Co.*, 577 P.2d 975, 978-79 (1978).

⁷⁹ See *infra* notes 65-118 and accompanying text (discussing cases that have created an exception to the learned intermediary doctrine for contraceptive medications and devices).

ration⁸⁰ and *Stephens v. G.D. Searle & Company*,⁸¹ the United States District Court for the Eastern District of Michigan imposed a duty on manufacturers of oral contraceptives to warn consumers directly of side effects.⁸² The Supreme Court of Massachusetts in *MacDonald v. Ortho Pharmaceutical Corporation*⁸³ has also allowed the exception for oral contraceptives.⁸⁴ These courts have distinguished oral contraceptives from therapeutic prescription medications and have allowed for an exception to the learned intermediary doctrine for several reasons. First, consumers of oral contraceptives are typically healthy adults who themselves chose a form of contraception from a variety of options.⁸⁵ While

⁸⁰ 609 F. Supp. 867 (E.D. Mich. 1985). The plaintiff in this case alleged that use of oral contraceptives caused a clotting in her leg, which led to partial paralysis. *Id.* at 868. The jury, which was instructed that the manufacturer had a duty to warn the plaintiff directly, found in favor of the plaintiff. *Id.* A new trial was granted on the grounds that the jury instructions were erroneous under Michigan law. *Id.*

⁸¹ 602 F. Supp. 379 (E.D. Mich. 1985). The plaintiff in this case alleged that her use of birth control pills manufactured by the defendant led her to suffer a stroke. *Id.* at 380. The court denied the defendant's motion for summary judgment, holding that it was for a jury to determine whether the manufacturer had adequately warned the plaintiff. *Id.* at 381.

⁸² In these companion cases, the Eastern District of Michigan certified a question to the Supreme Court of Michigan, asking whether the manufacturer of oral contraceptives has a duty to warn consumers directly. *See In re Certified Question*, 358 N.W.2d 873 (Mich. 1984). The majority of the Michigan Supreme Court declined to answer the interrogatory, stating that the determination is one for the legislature. *Id.* at 877-78. However, the district court chose to adopt the rationale of the three dissenting judges, who felt that contraceptive manufacturers should have a duty to warn consumers. *See Odgers*, 609 F. Supp. at 878; *Stephens*, 602 F. Supp. at 830; *see also In re Certified Question*, 358 N.W.2d at 878-887 (dissenting opinion written by Boyle, J., and joined by Williams, C.J., and Brickley, J.).

⁸³ 475 N.E.2d 65 (Mass. 1985).

⁸⁴ *Id.* Plaintiff in this case suffered a stroke after taking Ortho Novum oral contraceptives for three years. *Id.* at 67. A jury determined that the defendant manufacturer was negligent because it failed to give plaintiff adequate warning of the occurrence of blood clotting and stroke associated with its product. *Id.* at 68. The judge, however, granted the defendant's motion for judgment notwithstanding the verdict. *Id.*

⁸⁵ *Odgers*, 609 F. Supp. at 878 ("A woman obviously has a number of

dispersal does require a physician's prescription, consumers do not depend on physicians to the same degree as they do for therapeutic prescriptions.⁸⁶ Contact between consumers and physicians is minimal, typically only through annual examinations; thus, consumers must monitor their own reactions to the product.⁸⁷ Furthermore, consumers are influenced in their choices by the heavy marketing undertaken by the manufacturers.⁸⁸ Finally, consumers receive all the necessary information and warnings from

options open as to methods of birth control. The more information the woman is supplied with directly, the easier it is to ensure that an informed choice is made among the available options.”); *In re Certified Question*, 358 N.W.2d at 884 (Boyle, J., dissenting) (“Patient choice plays a much more prominent role than in the case of drugs prescribed for the treatment of illness or injury. The role of patient choice in this process supports the need for a direct patient warning.”).

⁸⁶ See *In re Certified Question*, 358 N.W.2d at 884 (Boyle, J., dissenting). Justice Boyle stated the following:

The physician makes no assessment of medical need. Rather, the threshold question of need for contraception has already been decided by the patient when she visits the physician These patients have not traditionally received the information from their doctors concerning the risks associated with the use of birth control pills as opposed to other forms of contraception.

Id.; see also *Odgers*, 609 F. Supp. at 878. The *Odgers* court reasoned:

[W]hen a woman takes an oral contraceptive as a means of birth control supervision is minimal [T]he woman generally sees the physician once a year, and even then, a visit is not necessarily required when all that is needed is a refill—such prescriptions may be easily telephoned in. Therefore . . . there is little opportunity for the physician to notice and avert any problems resulting from the use of the oral contraceptive.”

Id.

⁸⁷ *Odgers*, 609 F. Supp. at 878.

⁸⁸ *In re Certified Question*, 358 N.W.2d at 884 (Boyle, J. dissenting).

The marketing and resultant widespread use of oral contraceptives is distinguishable from that of most other prescription drugs in several respects. Consumer demand for the pill can be attributed in part to zealous marketing by manufacturers. Publications extolling the wonders of birth control pills have been addressed to the consumer public as well as the medical profession.

Id.

the FDA mandated inserts within the contraceptive packaging.⁸⁹ As such, these courts have found an exception for oral contraceptives justified and even warranted.

Only one jurisdiction has extended this exception beyond oral contraceptives to cover intrauterine devices (“IUDs”).⁹⁰ The United States Court of Appeals for the Eight Circuit in *Hill v. Searle Laboratories* — in adopting the reasoning set forth in *Ogders, Stephens, and MacDonald* — distinguished all forms of contraceptives from therapeutic prescription medications because doctors typically do not make “intervening [or] individualized” birth control decisions.⁹¹ Instead, the court recognized this as a woman’s “private and personal . . . decision that is often dependent on factors to which the physician is not privy.”⁹² These factors include “effectiveness, convenience or cost, rather than medical necessity.”⁹³ In noting that IUDs and other types of birth control are typically dispensed in clinic settings, the court did not consider treating physicians as “intervening” parties.⁹⁴ Thus, the court held strict application of the learned intermediary doctrine unwarranted.⁹⁵ This reasoning, however, has failed to convince the majority to create an exception to the learned intermediary doctrine for any method of contraception.⁹⁶

⁸⁹ See *Ogders*, 609 F. Supp. at 878-79.

⁹⁰ *Hill v. Searle Labs.*, 884 F.2d 1064 (8th Cir. 1989). Plaintiff opted to have a CU-7, a copper IUD, placed in her uterus by her physician. *Id.* at 1065-66. An IUD is a small device placed in a woman’s uterus that contains copper or a hormone that prevents pregnancy for up to ten years. See Planned Parenthood@ Federation of America, *Understanding IUDs*, at <http://www.plannedparenthood.org/bc/IUD.htm> (last visited Mar. 6, 2001). Approximately three years later, a physician had to surgically remove the IUD, which had become implanted into her small bowel. *Id.* The manufacturer conceded that it had not warned plaintiff directly, and the physician could not recall if he had warned her of the dangers associated with the CU-7, although he was aware of the risks. *Id.*

⁹¹ *Hill*, 884 F. Supp. at 1070-71.

⁹² *Id.* at 1071.

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ See *infra* note 78 (listing cases that have refused to create an exception).

3. Direct-to-Consumer Advertising

To date only one jurisdiction has recognized an exception to the learned intermediary doctrine when the pharmaceutical manufacturer has engaged in DTC marketing.⁹⁷ In its 1999 landmark decision in *Perez v. Wyeth Laboratories*, the Supreme Court of New Jersey stepped into *terra incognita* by imposing a duty to directly and adequately warn consumers if they chose to market their products via a public medium.⁹⁸ Several women brought suit against the manufacturer of Norplant⁹⁹ after they suffered pain and permanent scarring from implantation and removal of the devices.¹⁰⁰ Plaintiffs claimed that the manufacturer had engaged in an aggressive advertising campaign since 1991 directed at women as opposed to physicians, which influenced their decisions to choose Norplant as their method of birth control.¹⁰¹ They further alleged that Wyeth Laboratories' advertisements on television and in magazines were manipulative because they did not warn of side effects and only presented the "simplicity and convenience" of Norplant use.¹⁰²

⁹⁷ *Perez v. Wyeth Labs.*, 734 A.2d 1245 (N.J. 1999); see also Julie A. Braun, *Recent Developments in Medicine and Law*, 35 TORT & INS. L.J. 487, 548 (2000) (noting that *Perez* was the first case to recognize an exception to the learned intermediary doctrine for DTC marketing).

⁹⁸ *Perez*, 734 A.2d at 1245.

⁹⁹ Norplant is a reversible contraceptive composed of six, thin capsules, which is surgically implanted in a woman's upper arm. *Id.* at 1247. The capsules release a synthetic hormone continuously into a woman's bloodstream preventing pregnancy for up to five years. *Id.* See also, Planned Parenthood® Federation of America, *Norplant and You*, at <http://www.plannedparenthood.org/bc/Norplant.htm> (last visited Mar. 6, 2001).

¹⁰⁰ *Id.* Plaintiffs assert that Wyeth Laboratories knew that removal of the system was painful and left scarring. *Id.* at 1247. They pointed to several medical studies, which disclosed removal problems with 33% to 52% of women. *Id.* Wyeth, however, failed to provide these warnings in their advertisements to consumers. *Id.*

¹⁰¹ *Id.* Wyeth advertised Norplant directly to women via television commercials and print ads in *Mademoiselle*, *Glamour*, and *Cosmopolitan* magazines. *Id.*

¹⁰² *Id.* at 1247.

The defendant, Wyeth Laboratories,¹⁰³ moved for summary judgment arguing that under the learned intermediary doctrine and the New Jersey Products Liability Act,¹⁰⁴ it had no duty to warn plaintiffs directly through advertisements.¹⁰⁵ The trial court applied the learned intermediary doctrine and granted defendant's motion because the plaintiffs had failed to prove that the manufacturer had failed to provide health care officials with adequate warnings of side effects.¹⁰⁶ The appellate court affirmed.¹⁰⁷

The New Jersey Supreme Court, however, reversed the appellate court's decision.¹⁰⁸ In holding that the manufacturer of Norplant Systems had a direct duty to warn plaintiff, the court

¹⁰³ Wyeth Laboratories is the pharmaceutical manufacturer of Norplant and is based in Philadelphia, Pennsylvania. *Wyeth-Ayerst Pharmaceuticals*, at <http://www.bioanalytical.com/calender/99/10wyeth.htm> (last visited Mar. 6, 2001). It is one of the four major companies that makes up Wyeth-Ayerst Pharmaceuticals, the outfit responsible for innovating the first infant formula patterned after a woman's breast milk, the first orally active estrogen, and the first oral penicillin tablet. *Id.*

¹⁰⁴ N.J. STAT. ANN. § 2A:58C-4 (2000). The New Jersey Products Liability Act provides:

An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, *or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician*. If the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," . . . a rebuttable presumption shall arise that the warning or instruction is adequate.

Id. (emphasis added). The New Jersey Supreme Court ultimately argued that its decision was in compliance with the legislative intent of this statute because "the presumptive effect is in accordance" with the Act. *Perez*, 734 A.2d at 1259.

¹⁰⁵ *Perez*, 734 A.2d at 1249.

¹⁰⁶ *Id.* at 1249.

¹⁰⁷ See *Perez v. Wyeth Labs.*, 713 A.2d 520 (N.J. Super. Ct. App. Div. 1998).

¹⁰⁸ *Perez*, 734 A.2d at 1263-64.

stated that “[d]irect advertising to consumers alters the calculus of the learned intermediary doctrine.”¹⁰⁹ In picking away at the basic assumptions behind the learned intermediary doctrine, the majority found that, (1) in light of managed health care, fewer patients are receiving warnings from their physicians,¹¹⁰ (2) the advertisements themselves buttress the argument that consumers now choose the prescription drugs they take,¹¹¹ (3) the very nature of DTC advertisements intrudes upon the traditional physician-patient relationship because patients, now familiar with prescription products in the market, ask doctors for specific medications,¹¹² (4) DTC advertisements negate the argument that dangers associated with drugs are too complex for patients to comprehend,¹¹³ and (5) manufacturers now have a number of mediums to communicate effectively warnings to consumers.¹¹⁴

Perez, however, is only a limited victory for consumers. The court concluded that a pharmaceutical manufacturer has a duty to warn patients directly and that “any duty to warn . . . is presumptively met by compliance with federal labeling.”¹¹⁵ Under this holding, a plaintiff will only succeed in a suit against advertising

¹⁰⁹ *Id.* at 1254.

¹¹⁰ *Id.* at 1255. “[B]ecause managed care has reduced the time allotted per patient, physicians have considerably less time to inform patients of the risks and benefits of a drug.” *Id.* In fact, according to a 1997 F.D.A. survey only one-third of patients claimed to have received side effect information from their doctors. See *infra* notes 128-144 and accompanying text (discussing managed health care).

¹¹¹ *Perez*, 734 A.2d at 1256 (“[T]he fact that manufacturers are advertising their drugs and devices to consumers suggests that consumers are active participants in their health care decisions, invalidating the concept that it is the doctor, not the patient, who decides whether a drug or device should be used.”).

¹¹² *Id.*

¹¹³ *Id.* (“Because the FDA requires that prescription drug and device advertising carry warnings, the consumer may reasonably presume that the advertiser guarantees the adequacy of its warnings.”).

¹¹⁴ *Id.* These mediums include television, newspapers, magazines, the Internet and others. *Id.*; see also notes 164-174 and accompanying text (describing the regulations behind these mediums).

¹¹⁵ *Perez*, 734 A.2d at 1259 (“[A] rebuttable presumption that the duty to consumers is met by compliance with FDA regulations helps to ensure that manufacturers are not made guarantors against remotely possible, but not scientifically-verifiable, side-effects of prescription drugs.”).

manufacturers if she can demonstrate that the manufacturer deliberately failed to comply with FDA guidelines in its advertisements.¹¹⁶ The FDA regulations serve as the threshold for manufacturers to escape liability and this exception to the learned intermediary doctrine has limited advantages for plaintiffs.¹¹⁷ The Court resolved, however, that this “approach harmonizes the manufacturer's duty to doctors and to the public when it chooses to directly advertise its products, and simultaneously recognizes the public interest in informing patients about new pharmaceuticals.”¹¹⁸ Such a compromise may be suitable in light of the recent changes in the American health care system where DTC advertisements more often than doctors increase consumers' awareness of health issues.

II. THE CHANGING FACE OF HEALTH CARE AND THE BOOM OF PRESCRIPTION DRUG ADVERTISEMENT

While the learned intermediary doctrine is still almost universally accepted, the health care system over the last two decades has seen immense change, bringing into question the underlying rationale behind the doctrine.¹¹⁹ The shift to a system of managed care has permanently changed the dynamics between physicians and patients — for under this system a patient does not have the limitless freedom to choose a physician, and a physician has far less time to spend per patient.¹²⁰ With the recent, massive influx

¹¹⁶ *Id.* at 1259 (“For all practical purposes, absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of such claims.”); *see also* Dreier, *supra* note 21, at 825 (placing such obstacles before a plaintiff's claim presents a practically insurmountable burden).

¹¹⁷ *Perez*, 734 A.2d at 1259.

¹¹⁸ *Id.*

¹¹⁹ *See supra* notes 53-59 and accompanying text (outlining the rationale behind the learned intermediary doctrine); *see also* Plant, *supra* note 14, at 1023 (“Despite the courts' dogged adherence to the Learned Intermediary doctrine, the reality of how patients receive prescription drug therapy in the United States bears increasingly less resemblance to the courts' assumptions.”).

¹²⁰ *See infra* notes 122-44 and accompanying text (discussing the reformation of health care).

of DTC advertisements in magazines and newspapers and on the television, radio, and Internet, patients have begun asking for and receiving specific prescription products.¹²¹

A. *From the 1980s to 2001: The Development of Managed Health Care*

The American health care system has experienced major reform over the last two decades.¹²² In the 1980s and the decades prior, fee-for-service plans¹²³ predominated the health care industry.¹²⁴ Under such plans, individuals or individuals' employers acquired indemnity health insurance;¹²⁵ however, the insurers were indifferent as to the physicians chosen by the individuals they covered.¹²⁶ The physician-patient relationship was thus maximized as patients spent more one-on-one time with their chosen doctors, and doctors were nearly autonomous in treating patients and prescribing medications to them.¹²⁷

¹²¹ See *infra* notes 145-63 and accompanying text (discussing the boom of DTC advertisements).

¹²² See *infra* notes 122-44 and accompanying text (discussing the reformation of health care).

¹²³ Fee-for-service plans are "per case basis" plans. See Neelam K. Sekhri, *Managed Care: The U.S. Experience*, BULL. WORLD HEALTH ORG., June 1, 2000, at 830. Under such a plan "[p]atients select health care providers [who then] bill the private insurer or public payer" per patient visit. *Id.*

¹²⁴ *Id.*; see also Rashi Fein, *The Mechanics of Backlash: Changing Perceptions, Changing Reality*, J. HEALTH, POL., POL'Y & L., Oct. 1999, at 985-986 (noting that under a fee-for-service system, "in large measure insurers behaved in a generally permissive manner, bowing to the behavior of physicians whose judgements, presumably, were based solely on their views of what was and what was not good medical practice").

¹²⁵ See Sekhri, *supra* note 123, at 830 ("Under the traditional indemnity insurance, the money follows the patient . . . Most indemnity plans attempt to limit demand through financial barriers to the patient, such as deductibles and co-insurance rather than constraints on the provider.").

¹²⁶ See Sekhri, *supra* note 123, at 830 ("This system of employer based, indemnity insurance and fee-for-service health care conditioned both providers' and patients' expectations of unlimited resources and unrestrained choice."); see also Fein, *supra* note 124.

¹²⁷ See David A. Balto, *A Whole New World?: Pharmaceutical Responses*

Due to rising concerns in “care, cost, and coverage,” reformation of America's health care system began in the late 1980s and is still taking place today.¹²⁸ The emergence of managed care organizations (“MCO”),¹²⁹ which act as third-party payors,¹³⁰ brought with it the inclusion of monetary incentive arrangements for providers to reduce costs¹³¹ and has permanently altered the

to the Managed Care Revolution, 52 FOOD & DRUG L.J. 83 (1997) (recognizing that under fee-for-service care, doctors paid little attention to the costs of drugs and infrequently offered generic substitutes); Plant, *supra* note 14, at 1023 (noting that under this traditional system of health care, physicians and patients more often established extended relationships).

¹²⁸ Mark A. Peterson, *Introduction: Healthcare into the Next Century*, J. HEALTH, POL., POL'Y & L., Apr. 1997 at 291, 301.

¹²⁹ John K. Inglehart, *Physicians and the Growth of Managed Care (Health Policy Report)*, 331 NEW ENG. J. MED. 1167, 1167 (1994) (“Managed care refers to a variety of methods of financing and organizing the delivery of comprehensive health care in which an attempt is made to control costs by controlling the provision of services.”). MCOs include privately run health maintenance organizations (HMOs) and preferred provider organizations (PPOs). See Peterson, *supra* note 128, at 297. The government, through Medicare and Medicaid, also provides managed care to the elderly, poor, and disabled. See Plant, *supra* note 14, at 1078 n.81. From 1992 to 1997, a third of all individuals receiving care through private insurers moved over to MCOs. Kenneth E. Thorpe, *Managed Care as Victim or Villain?*, J. HEALTH, POL., POL'Y & L., Oct. 1999 at 949, 953. By the year 2000, 86% of those receiving health benefits through employment had a managed-care plan. Susan Brink, *To Get Top Care, Get Pushy: If Your Health Plan Won't Send You to a Leading Hospital, Seek Allies*, U.S. NEWS & WORLD REPORT, Jul. 17, 2000, at 62.

¹³⁰ Third party payors are managed care organizations that physicians join in return for payment. See Sekhri, *supra* note 123, at 830. “[P]roviders are paid in a variety of ways. The physicians, as a group, may receive a capitated payment, while individual physicians receive either a salary or a combination of salary and incentive payment.” See Sekhri, *supra* note 123, at 830.

¹³¹ Andrew B. Bindman, *Primary Care Physicians' Experience of Financial Incentives in Managed-Care Systems*, 339 NEW ENG. J. MED. 1516 (1998).

Managed-care organizations use a variety of strategies to influence the practice styles of primary care physicians. One of the most controversial of these methods is the use of financial incentives, particularly incentives designed to encourage physicians to limit services, such as referrals to specialists. Such incentives usually take the form of bonuses paid over and above the physician's base income.

Id.

dynamics between physicians and patients.¹³² The key differences between fee-for-service plans and MCOs are patient choice and physician control.¹³³ Under managed care, patients receiving health insurance through employers or government programs must choose a primary care physician from a limited list.¹³⁴ Physicians, reacting to the pressures of the managed care system, crowd more patients into their schedules.¹³⁵ As a result, they have less time to develop a rapport with and gain the trust of their patients.¹³⁶ Further, they have diminished opportunities to properly diagnose a patient, choose the most appropriate medication, and then adequately warn patients of the medication's dangers.¹³⁷ Moreover, under managed health care, doctors have lost control over the medications that they can prescribe.¹³⁸ In an effort to control the high costs of prescription medication, third-party payors often restrict a doctor's choices through the use of formularies,¹³⁹ require a

¹³² See Thorpe, *supra* note 129, at 949 ("Surveys of physicians clearly report their concern over the loss of clinical autonomy, a reduction in time spent with patients, and slower growth in their income."); see also Fein, *supra* note 124, at 985 ("We are troubled by the fact that our physician, now an employee of an HMO and subject to its rules and regulations, seems busier and more rushed.")

¹³³ Catherine McLaughlin, *The Who, What, and How of Managed Care*, J. HEALTH, POL., POL'Y & L., Oct. 1999, at 1047 ("[T]he management of physician practice is at the heart of managed care plans In some studies of managed care, the focus is not on the management of physicians and their practices, but rather on the control of consumers and their utilization of physician services."); see also Fein, *supra* note 124, at 987 (feeling that public has become mad over its inability to freely choose physicians).

¹³⁴ See McLaughlin, *supra* note 133, at 1047.

¹³⁵ See Bindman, *supra* note 131, at 1516. Of 776 primary care physicians working in managed health care surveyed, 75% felt pressure to see more patients per day. Bindman, *supra* note 131.

¹³⁶ See Sana Loue, *An Epidemiological Framework for the Formulation of Health Insurance Policy*, 14 J. LEGAL MED. 523, 530 (1993) (noting that patients, stripped of direct physician contact, feel less able to develop long-term relationships with particular doctors).

¹³⁷ *Id.*

¹³⁸ See Balto, *supra* note 127, at 83 (explaining how physicians have less control over their prescriptions due to the impact of managed care on the pharmaceutical industry).

¹³⁹ See Plant, *supra* note 14, at 1078 n.89. A formulary is a catalogue of prescription drugs that doctors can choose from. See Plant, *supra* note 14.

doctor to prescribe generic drugs,¹⁴⁰ and/or offer monetary bonuses for doctors who choose less expensive drugs.¹⁴¹ Managed care organizations, private insurers, and government programs are more frequently hiring pharmacy benefit managers (“PBM”) to procure bulk, discounted supplies of prescription drugs from pharmaceutical manufacturers.¹⁴² Many pharmaceutical manufacturers, in turn, buy out PBMs or contract with them in order to secure their products' place in the market.¹⁴³ Consequently, under a

Usually, physicians will have to make a special request to prescribe a drug not on the formulary, and the MCO will discourage the physician from so doing. *See* Plant, *supra* note 14.

¹⁴⁰ *See* Balto, *supra* note 127, at 83 (“[G]eneric substitution has increased from approximately 20% to 40% of new prescriptions, and generics have become a far more significant force in the market, leading to lower prices for consumers.”); Henry Grabowski, *Health Reform: A Pharmaceutical Innovation*, 24 SETON HALL L. REV. 1221, 1224 (1994) (noting the increase of generic drugs on formularies and describing the incentive programs offered to doctors to prescribe them over the more expensive brand names).

¹⁴¹ Plant, *supra* note 14, at 1026 n.93.

[P]hysicians are promised a monetary bonus if they prescribe drugs in such a way as to save money. Doctors are encouraged to use drug classes intrinsically less expensive than others, to maximize the use of generic products, and perhaps delay or even avoid the use of medications for certain conditions.

Plant, *supra* note 14, at 1026 n.93.

¹⁴² *See* Balto, *supra* note 127, at 83-84.

PBMs typically select participating pharmacists and drug manufacturers and suppliers, create and administer a point-of-scale claims processing system, negotiate quantity discounts with pharmaceutical manufacturers, administer the record keeping and payment systems of the plans, and maintain quality control. A PBM typically acts as the agent for the plan sponsor to influence product selection—encourage generic and therapeutic substitution based on negotiated prices with manufacturers.

Balto, *supra* note 127, at 84.

¹⁴³ *See* Balto, *supra* note 127, at 84. The Federal Trade Commission monitors these acquisitions between pharmaceutical manufacturers and PBMs very closely due to potential antitrust abuses. Balto, *supra* note 127, at 85. The Commission typically requires PBMs to use open formularies that include a number of drugs from various manufacturers so that the acquiring manufacturer will not monopolize the formulary with its own products. Balto, *supra* note 127, at 85.

managed care system, the manufacturers have arguably gained a good portion of the control physicians have lost in putting prescription drugs in the hands of consumers.¹⁴⁴ This system may provide, in part, an explanation for the boom in direct-to-consumer prescription drug advertisements.

B. The Boom of Direct-to-Consumer Prescription Drug Advertisements

In light of such widespread health care changes, the pharmaceutical industry has expanded its marketing to consumers.¹⁴⁵ With patients now playing a larger role in their health care decisions, manufacturers have found that familiarizing consumers to prescription pharmaceuticals has led to profound increases in their profit margins.¹⁴⁶ Consumers exposed to print, television, and radio advertisements and Internet web sites are more likely to ask their doctors for specific brands of prescription drugs.¹⁴⁷ Doctors, out of fear of losing patients and/or due to less time spent per patient, are more inclined to grant patients' requests.¹⁴⁸ Hence, manufac-

¹⁴⁴ Balto, *supra* note 127, at 85.

¹⁴⁵ See *infra* notes 122-44 and accompanying text (providing information about the recent changes in health care).

¹⁴⁶ Nancy Chockley, *Selling Doctors on What to Prescribe*, USA TODAY, Dec. 22, 1999, at 19A ("It's more than a coincidence that 22% of the \$43-billion increase in prescription-drug sales came from the 10 drugs most heavily advertised to consumers."); Robert A. Rosenblatt, *Drug Firms' TV Ads Fuel Rise in Costs and Demand*, L.A. TIMES, Nov. 26, 1999, at A1 ("Americans spent \$100 billion for prescription drugs in 1998, an 84% increase in five years.").

¹⁴⁷ Michael Kirsch, *Even if They're Too Slick and Manipulative, Drug Ads Are Useful*, PLAIN DEALER, Sept. 8, 2000, at 11B. Mr. Kirsch, an advocate of DTC advertising, analogizes the marketing of prescription drugs to patients to the marketing of toys and cereals to children. *Id.* Children cannot go out and purchase these products alone as patients cannot purchase drugs without a prescription. *Id.* Children, however, can certainly influence their parents' purchases by pleading for the marketed product. *Id.* Likewise, patients can influence the prescriptions they receive by pushing a brand on the prescribing physician. *Id.*

¹⁴⁸ See Rosenblatt, *supra* note 146, at A1. Mr. Rosenblatt quotes a Salt Lake City physician, Dr. John C. Nelson, who states, "When the patient says 'Give me something, give me something,' physicians often acquiesce because they are

turers have begun inundating consumers with more advertisements.¹⁴⁹

Before the 1990s, DTC prescription drug advertisements were relatively rare.¹⁵⁰ In 1982, after physicians working for the FDA deemed the first two DTC advertisements inappropriate out of fear that consumers would be misled and confused,¹⁵¹ the FDA requested that all pharmaceutical manufacturers abstain from advertising in order to allow for a proper assessment of the societal implications of DTC marketing.¹⁵² In 1989, after the FDA lifted the voluntary moratorium, money spent on DTC print advertisements rose from nearly zero to almost \$12 million per annum.¹⁵³ The FDA spent the early 1990s trying to figure out how best to regulate DTC advertisements,¹⁵⁴ and the amount of prescription drug marketing increased steadily.¹⁵⁵ For example, in 1991 manufacturers spent over \$55 million in prescription drug marketing.¹⁵⁶ By 1996, this amount increased to \$600 million.¹⁵⁷ In

afraid they may end up losing the patient." Rosenblatt, *supra* note 146, at A1.

¹⁴⁹ See *infra* notes 150-63 and accompanying text (providing overview of the exponential growth of DTC marketing).

¹⁵⁰ Rosenblatt, *supra* note 146, at A1 (noting that advertisements prior to the 1990s boom were focused towards the medical community and could be found almost entirely in medical journals or other specialized publications).

¹⁵¹ Wayne L. Pines, *A History and Perspective on Direct-to-Consumer Promotion*, 54 FOOD & DRUG L.J. 489, 491 (1999). One of the products advertised was Rufen®, an ibuprofen manufactured by Boots Pharmaceuticals, a British company, and the other was Pneumovax®, a pneumonia vaccination manufactured by Merck, Sharpe & Dohme. *Id.* The existing FDA guidelines were geared primarily towards advertisements for doctors, and the FDA was unsure of how to regulate marketing directly to consumers. *Id.*

¹⁵² *Id.*

¹⁵³ *Id.* at 493.

¹⁵⁴ *Id.* Most of the advertising was in print although some ads were broadcast on cable channels. *Id.* The FDA guidelines during these years limited the advertisements from being product-specific, but required interested consumers to consult their physicians. *Id.* at 494. For example, Upjohn released commercials promoting hair growth in men without specifically mentioning their product, Rogaine®. *Id.*

¹⁵⁵ *Id.* at 496.

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

August of 1997 the FDA relaxed its guidelines for product-specific television and radio ads.¹⁵⁸ Consequently, DTC marketing has grown exponentially with pharmaceutical manufacturers spending almost \$1.9 billion on DTC advertisements in 1999, more than triple what they spent in 1996.¹⁵⁹ Furthermore, a comparison between the first four months of 2000 and the first four months of 1999 shows a 58% increase in spending by pharmaceutical manufacturers on DTC advertisements.¹⁶⁰ Today, one can hardly turn on the television or radio or open a magazine or newspaper without confronting advertisements for prescription medications offering to clear seasonal allergies,¹⁶¹ promote hair growth,¹⁶² ease cancer symptoms, alleviate sexual dysfunction, reduce high

¹⁵⁸ 21 C.F.R. § 202.1 (2000); *see also infra* notes 164-74 (providing overview of the FDA regulations).

¹⁵⁹ Carol M. Ostrom, *Lower Drug Prices in Canada a Prescription for Outrage in the U.S.: Are We Being Soaked Because U.S. Lacks Price Control, or Are the Charges Necessary to Keep Research Robust?*, THE SEATTLE TIMES, Sept. 5, 2000, at A1. The money spent by pharmaceutical manufacturers now rivals and has surpassed that spent by Coca-Cola and other large companies. *Id.*; *see also* Susan Okie, *With TV Spots, Drug Firms Aim at Patients' Role; Strategy for Prescriptions Shifts Away From Doctors*, THE WASH. POST, May 22, 2000, at A01 (noting that nearly 60% of money spent on DTC ads went towards television commercials, "the fastest-growing medium for advertising prescription medications").

¹⁶⁰ *DTC Drug Ads Up 58 Percent, But Recall Doesn't Match Spend Level*, MED., MARKETING & MEDIA, Sept. 1, 2000, at 6.

¹⁶¹ *See* Francesca Lunzer Kritz, *Ask Your Doctor About . . . ; Which of the Many Advertised Allergy Drugs Are Right for You?*, WASH. POST, June 6, 1000, at Z09. The advertising for antihistamines, or allergy medications, comprised three-fourths of all prescription drug advertisements in 1999. *Id.* Claritin® has become the top-selling allergy medicine and the eighth overall best selling medicine through advertisements, with 1999 sales surpassing \$1.5 billion. *Id.*

¹⁶² *See* Jon D. Hanson & Douglas A. Kysar, *Taking Behaviorism Seriously: Some Efforts of Market Manipulation*, 112 HARV. L. REV. 1420, 1456 (1999). Rogaine®, manufactured by Upjohn and now available over-the-counter, was the first prescription drug advertised through television commercials. *Id.* The advertisements were geared to convince balding men that Rogaine could prevent hair loss and promote hair growth, which would boost job performance and enhance their sexual appeal. *Id.*

blood pressure and cholesterol, prevent heart attacks, or relieve insomnia.¹⁶³

C. FDA Regulations: TV, Radio, and Print Ads

The FDA guidelines, under the Food, Drug, and Cosmetic Act (FDCA),¹⁶⁴ require all prescription drug advertisements to include the “side effects, contraindications, and effectiveness” of promoted products.¹⁶⁵ The regulations for presenting such information, however, are different for print ads in magazines and newspapers and broadcast ads on radio and television.¹⁶⁶ Print advertisements require the insertion of a “brief summary” that includes all the side effects and contraindications associated with the prescription medication.¹⁶⁷ This term “brief summary,” however, is a “misnomer considering that the summary is anything but brief.”¹⁶⁸ An abundance of data is often squeezed in fine print on the back page of the advertisement.¹⁶⁹

¹⁶³ See Darryl E. Owens, *RX-Rated Diagnosis; From Allergies to Love Life, Are TV Drug Ads Creating a Nation of Savvy Patients or a Bunch of Worrywarts?*, ORLANDO SENTINEL, Apr. 18, 2000, at E1.

¹⁶⁴ See 21 U.S.C. §§ 301-392 (2000).

¹⁶⁵ *Id.* § 352(n)(3); see also 21 C.F.R. § 202(c)(3)(i) (2000).

¹⁶⁶ 21 C.F.R. § 202.1 (e) (2000).

¹⁶⁷ *Id.*

¹⁶⁸ *Perez*, 734 A.2d at 1258.

¹⁶⁹ *Id.* While the front page or two-page spread of an advertisement often presents colorful pictures of smiling people, the back page is crowded with information presented in small, difficult to read print. See Advertisement for Claritin®, REDBOOK, Oct. 2000, at 54-56 (offering to alleviate seasonal allergies); Advertisement for Flonase®, REDBOOK, Oct. 2000, at 131-32 (offering to help clear up nasal allergies); Advertisement for Paxil®, REDBOOK, Oct. 2000, at 59-60 (offering to mitigate the symptoms of social anxiety disorder); Advertisement for Singulair®, REDBOOK, Oct. 2000, at 145-46 (offering to help control asthma); Advertisement for Zithromax®, REDBOOK, Oct. 2000, at 216-218 (offering to cure children's ear infections); Advertisement for Prevnar®, GOOD HOUSEKEEPING, Sept. 2000, at 55-57 (offering a child's immunization that helps reduce the risk of bacterial meningitis); Advertisement for Renova®, GOOD HOUSEKEEPING, Sept. 2000, at 39-41 (offering to reduce wrinkles); Advertisement for Viagra®, GOOD HOUSEKEEPING, Sept. 2000, at 77-78 (offering to cure erectile dysfunction); Advertisement for Visudyne®, GOOD HOUSEKEEPING, Sept.

Broadcast advertisements, on the other hand, do not include brief summaries, as their format does not permit such extensive disclosure.¹⁷⁰ Rather, prescription drug manufacturers must include a “major statement” of risks that is balanced with its promotion of the drug's benefits.¹⁷¹ Because a brief summary is not included, the manufacturer must make an “adequate provision for the dissemination of the approved package labeling in connection with the broadcast presentation.”¹⁷² This includes directing consumers to such information by presenting a toll-free telephone number, an Internet web site, a printed advertisement, and by

2000, at 99-100 (offering to reduce symptoms of age-related muscular degeneration, the leading cause of blindness in people over the age of fifty). The details on the back page of these advertisements include information about usage, dosage and administration, contraindications, warnings, precautions, and adverse reactions. See Advertisement for Claritin®, REDBOOK, Oct. 2000, at 54-56. The print is extremely difficult to read on several of the advertisements, not only because the font used is tiny but because the spaces between lines of text have been reduced to crowd in more information. See Advertisement for Zithromax®, REDBOOK, Oct. 2000, at 216-18 (providing barely legible script in the brief summary). Some of these brief summaries also contain medical terminology that the average lay person would not ordinarily understand. For example, Pfizer used words like “angioedema,” “nephritis,” “cholestatic jaundice,” “dyspepsia,” and “monolia” in its advertisement for Zithromax in the Oct. 2000 edition of *Redbook*. Some advertisements, on the other hand, include understandable descriptions of side effects, warnings, and precautions. For example Merck's advertisements for Singulair® in the Oct. 2000 edition of *Redbook* used terms and phrases like “bad/vivid dreams,” “a flu-like illness,” “a feeling of pins and needles or numbness of arms and legs,” and “abdominal (stomach) pain.” Advertisement for Singulair®, REDBOOK, Oct. 2000, at 145-46.

¹⁷⁰ 21 C.F.R. § 202.1(e)(1) (2000).

Advertisements broadcast through media such as radio, television, or telephone communications systems shall include information relating to the major side effects and contraindications of the advertised drugs in the audio or audio and visual parts of the presentation and unless adequate provision is made for dissemination of the approved or permitted package labeling in connection with the broadcast presentation shall contain a brief summary of all necessary information related to the side effects and contraindications.

Id.

¹⁷¹ *Id.*

¹⁷² *Id.*

requesting that consumers see their physician.¹⁷³ The FDA, however, has not yet determined how best to regulate the wealth of information pharmaceutical manufacturers are providing consumers over the Internet.¹⁷⁴

D. The Internet

Currently, approximately 48% of consumers receive information from the over two million Internet web sites offering health care information.¹⁷⁵ The Internet has been touted “the most economical and powerful means of mass promotion yet created”¹⁷⁶ because it has enabled the pharmaceutical industry to reach consumers across the globe with product promotions and information.¹⁷⁷

Despite the limitless amount of health care information the Internet can provide,¹⁷⁸ the FDA has not yet established guide-

¹⁷³ See Guidance for Industry: Consumer-Directed Broadcasting Advertisements, at <http://www.fda.gov/cder/guidance/index.htm> (last visited Feb. 6, 2001).

¹⁷⁴ See *infra* note 178-84 and accompanying text (discussing the FDA's confusion over how best to regulate the prescription drug information provided over the Internet).

¹⁷⁵ *The Doctor is in . . . the Internet*, GROCERY HEADQUARTERS, Aug. 1, 2000, at 62 [hereinafter *The Doctor*].

¹⁷⁶ See Emile L. Loza, Note, *FDA Regulations of Internet Pharmaceutical Communications: Strategies for Improvement*, 55 FOOD & DRUG L.J. 269, 270 (2000).

The Internet is the most economical and powerful means of mass promotion yet created. Around the clock, the Internet reaches markets virtually around the world. Internet investment is miniscule when compared with the likely returns on such a worldwide marketing presence. These economies of scale are attractive to manufacturers as they seek to maximize returns on their enormous outlays in bringing a new drug into the market.

Id. at 272.

¹⁷⁷ Marilyn A. Moberg, et al., *Surfing the Net in Shallow Waters: Product Liability Concerns and Advertising on the Internet*, 53 FOOD & DRUG L.J. 213, 217 (1998) (“The Internet . . . provides access to an almost unlimited amount of information.”).

¹⁷⁸ See Alan N. Sutin & Ellen Goldberg, *Is the Internet Safe for Consumers?*, N.Y.L.J., Mar. 27, 2000, at S9 (“[T]he Internet is by its very nature inherently borderless. For the first time in history, there is an efficient channel

lines or restrictions tailored for this medium.¹⁷⁹ The Internet poses unique challenges to FDA regulators.¹⁸⁰ First, the FDA has not decided the central issue of whether Internet sites constitute labeling or advertising.¹⁸¹ Both methods of disseminating product information — labeling and advertising — fall under different FDA regulations.¹⁸² The FDA has allowed the manufacturers to deter-

of distribution that permits even the smallest of businesses to reach the global market.”).

¹⁷⁹ See P. Terrance Gaffney, *N.J. High Court Scuttles Learned Intermediary Rule*, NAT'L L.J., May 22, 2000, at B11 (observing that “the FDA has not issued any specific guidance on DTC advertising and the Internet”); Loza, *supra*, note 176, at 269 (criticizing the FDA for failing to establish regulations over the Internet); Moberg, *supra*, note 177, at 213.

¹⁸⁰ See Gaffney, *supra* note 179, at B11.

In fairness to the FDA, regulating the Internet is not a simple task, and the Internet raises a plethora of regulatory nightmares. For example, what types of links can a company provide, and does that company have a duty to monitor those links to ensure that off-label (promoting of a drug for purposes other than it was originally approved) is not occurring? If a U.S. resident contacts the site for information about a company product not approved for sale in the United States, what information may the company provide?

In an instance in which a visitor to a Web site informs the drug company via e-mail that he or she is using that company's product for a nonapproved indication and is seeking additional testing information, does that company have a duty to warn the consumer about a nonapproved use? If so, what information should be provided? What about chat rooms and news groups? Where would these ubiquitous forums fall in the FDA's regulatory scheme? These questions are not easily answered, but nonetheless need to be addressed.

Gaffney, *supra* note 179, at B11.

¹⁸¹ See Loza, *supra* note 176, at 274 (“[The] FDA states that the requirements are essentially the same regardless of the classification, but does not indicate which regulations control Internet communication.”).

¹⁸² The FDA's labeling and advertising requirements are set forth in 21 C.F.R. §§ 201, 202 (2000). The term “labeling” refers to “written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” 21 U.S.C. § 321(m) (2000). The manufacturer must fully disclose all side effects and contraindications associated with the prescription medication. See Moberg, *supra* note 177, at 216. The FDA considers

mine which regulation to follow,¹⁸³ and the manufacturers have more often observed the FDA guidelines for labeling as those guidelines require full disclosure of side effects and contraindications, affording manufacturers the most legal protection.¹⁸⁴ Regardless, the pharmaceutical companies do not have any control over much of the on-line information as other individuals and organizations are free to put out information on their product through web sites and chat rooms.¹⁸⁵ As a result, the health care industry has expressed growing concern that misinformation will fall into the hands of consumers.¹⁸⁶ This concern is justifiable, especially now that consumers spend less time with their doctors¹⁸⁷ and are even able to obtain drugs without prescriptions

labeling to include any written or oral data that explains the drug even if it does not accompany the product. 21 C.F.R. § 201.1 (2000). Labeling statements must meet approval by the FDA or else the product will be “misbranded.” *Id.* The FDA requires under its advertising guidelines only that the manufacturer provide a balanced statement disclosing major side effects and contraindications. 21 C.F.R. § 202.1(l)(1) (2000); *see also supra* notes 164-74 and accompanying text (discussing FDA guidelines for DTC advertising).

¹⁸³ *See Gaffney, supra* note 179, at B11.

If the lack of formal guidance were not troublesome enough, the FDA has given off a number of conflicting signals, leaving promoters to guess where it will come down on Web site content. An FDA official in the Division of Drug Marketing, Advertising and Communications commented “For now, we’re letting drug companies choose whatever category of current regulations they think best fits their presence on the Internet.”

Gaffney, *supra* note 179, at B11.

¹⁸⁴ Manufacturers likely choose to follow the labeling guidelines versus the advertisement guidelines because labeling guidelines are far more comprehensive in requiring detailed information on all side effects and contraindications. *See supra* note 182 (describing the distinctions between labeling and advertising); *see also* Loza, *supra* note 176, at 274 (“Manufacturers, however, likely regard a labeling classification as key to their learned intermediary defense.”).

¹⁸⁵ *See Healthcare Grows Consumer Appeal*, *MARKETING*, May 25, 2000 (“Ludicrously, anyone can launch a web site describing what a pharmaceutical product does.”).

¹⁸⁶ *See The Doctor, supra* note 175, at 62.

¹⁸⁷ *See supra* notes 131-32 and accompanying text (discussing the changes in physician-patient relationships due to the evolving health care system).

through on-line pharmacies.¹⁸⁸ The FDA has issued a number of warnings to consumers to beware of false information and web sites offering prescription medications;¹⁸⁹ however, they should do more to ensure consumer safety.¹⁹⁰

¹⁸⁸ See Amy J. Oliver, *Internet Pharmacies: Regulation of a Growing Industry*, 28 J.L. MED. & ETHICS 98 (2000) (noting that pharmaceutical companies, most of which are non-U.S. based, dispensing prescription medications without requiring a prescription are of questionable reputation and often do not provide any warnings of side effects). A number of on-line pharmacies doling out prescription drugs will require the on-line patient to fill out a health form that will be evaluated by an on-line "doctor" before the prescription approval. See, e.g., 4 Health Drugs, *Buy Viagra, Meridia, Paxil, Xenical, Propencia, Zyban Online!*, at <http://www.4-health-drugs.com/> (last visited Feb. 17, 2001) (requiring on-line consumers to disclaim any legal rights in authorizing "4 Health Drugs, LLC and any physicians, associates or assistants of its choice to perform and undertake an on-line medical consultation and evaluation of [the consumer] as a potential patient and to treat [the consumer]."). There is, however, much room for abuse. Other on-line pharmacies offering drugs from foreign countries require no health information from the on-line patient. See, e.g., Drugquest, at <http://www.drugquest.com/> (last visited Feb. 17, 2001) (advertising that anyone can "purchase any prescription drug legally without a prescription" from countries like Mexico, Spain, Thailand, India, etc. for a membership fee of \$64.95, and 75% off U.S. costs).

¹⁸⁹ See United States Dep't of Health and Human Services: Food and Drug Administration, at <http://www.fda.gov/> (last visited Sept. 6, 2000). The FDA's web site provides consumers with warnings on how to safeguard against "rogue [pharmaceutical] sites." *Id.* at <http://www.fda.gov/fdac/features/2000/100-online.html>. The Clinton-Gore administration placed \$10 million into the fiscal year 2001 budget to help the FDA respond to such Internet sites that threaten the health of consumers that allow them to obtain prescription medications without the prescription. See White House Office of the Press Secretary, *Clinton Administration Unveils New Initiative to Protect Consumers Buying Prescription Drug Products Over the Internet*, at <http://www.fda.gov/oc/buyonline/online-salespr.html> (last visited Sept. 6, 2000).

¹⁹⁰ See Loza, *supra* note 176, at 269.

III. THE SOCIETAL VALUE OF PRESCRIPTION DRUG ADVERTISEMENTS: THE CHOICES COURTS FACE IN A SOCIETY IN WHICH THE CONSUMER IS BECOMING THE LEARNED

Such an influx of DTC prescription drug information through advertisements and the Internet has both beneficial and harmful effects on society. A court considering whether to create an exception to the learned intermediary doctrine for DTC advertisements should first consider these benefits and risks and should weigh the societal ramifications of its decision on consumers and on the health and pharmaceutical industries. Even if a court finds an exception warranted, as the New Jersey Supreme Court did,¹⁹¹ it may still use the FDA guidelines as a measure of protection against a pharmaceutical manufacturer's liability exposure.

The four options outlined below take into account the societal value a court chooses to place on DTC advertisements.¹⁹² In doing so, this Note concludes that the third option presents the optimal solution for courts. Under this option, courts recognize an exception to the learned intermediary doctrine, but require plaintiffs to rebut a presumption that the defendant manufacturer has complied with the FDA regulations.¹⁹³ With the FDA guidelines as a shield, pharmaceutical manufacturers will not be discouraged from advertising, moreover, they will also have incentive to comply with existing regulations.¹⁹⁴ As a result, the harmful effects of DTC marketing will be reduced, while the consumers will remain informed.

¹⁹¹ *Perez*, 734 A.2d 1245 (N.J. 1999); *see also supra* notes 97-117 (discussing *Perez*).

¹⁹² *See infra* notes 230-68 and accompanying text (outlining the four options).

¹⁹³ *See infra* notes 250-57 and accompanying text (detailing this option).

¹⁹⁴ *See infra* notes 269-71 and accompanying text (discussing the implications of courts choosing the third option).

A. *The Societal Benefits and Harms of DTC Advertising*

Advocates of DTC prescription drug advertisements argue that these advertisements produce better-educated and informed patients and encourage treatment of physical and mental ailments.¹⁹⁵ Undoubtedly the pharmaceutical manufacturers argue that their advertisements raise consumer awareness by educating them on various health problems and corresponding drug treatments.¹⁹⁶ A spokesman from Schering-Plough, the maker of top-selling Claritin®,¹⁹⁷ stated that “[w]e believe advertising can play a key role in informing the public of drug advances.”¹⁹⁸ As a result of better education, the manufacturers intend for patients to become more involved in personal health care decisions.¹⁹⁹ The evidence

¹⁹⁵ See, e.g., Ostrom, *supra* note 159, at A1 (noting the pharmaceutical manufacturers' arguments in favor of DTC marketing); *Media Drives Public Drug Awareness*, CHEMIST & DRUGGIST, June 24, 2000, at 6 (“Television is best at creating awareness of new drugs.”); Laura Newman, *Avalanche of Direct-to-Consumer Drug Marketing Brings New Questions*, 92 J. NAT'L CANCER INST. 964 (2000) (quoting the director of the FDA's Drug Marketing, Advertising, and Communications division, who stated that the “advertising can serve an educational function, educa[ting] the public about diseases that they were not aware of”); Okie, *supra* note 159, at A1 (“Advocates say [that] the ads alert people to new treatments and open up discussion of the once-forbidden topics such as impotence or depression.”); Owens, *supra* note 163, at E1 (“Drug-makers say the ads educate consumers about disease and treatment, empower patients to become more involved in their health and encourage better compliance with prescriptions.”); Rosenblatt, *supra* note 146, at A1 (quoting advocates of DTC ads who feel that the ads raise awareness and reduce stigmas of certain diseases).

¹⁹⁶ Pamela L. Moore, *An Overdose of Drug Advertising?*, BUSINESS WEEK, May 22, 2000, at 52 (noting that “[p]harmaceutical companies say their ads prompt people to seek life-saving treatment”). A lobbyist for the pharmaceutical companies, Meredith Art, claims that the advertisements “empowers patients” who want information. See Ostrom, *supra* note 159, at A1.

¹⁹⁷ Claritin® is one of the most heavily advertised prescription drug advertisements. See Kritz, *supra* note 161, at Z09. As a result, it has been the top selling prescription medication for seasonal allergies and the eighth best selling drug in the United States. See Kritz, *supra* note 161, at Z09.

¹⁹⁸ See Moore, *supra* note 196, at A1.

¹⁹⁹ See Owens, *supra* note 163, at E1.

indicates that the advertisements in fact help achieve that goal.²⁰⁰ In a recent magazine survey, 76% of respondents believed that DTC advertisements helped them to become more involved in their own health care.²⁰¹ As more people are requesting specific drugs from their physicians, these advertisements are turning passive patients into engaged consumers.²⁰² Engaged consumers who take an active role in their health care are more likely to actively seek out additional information and make informed decisions regarding drug choices.²⁰³

Moreover, the advertisements increase awareness of physical and mental diseases and ailments and eliminate stigmas often associated with certain conditions.²⁰⁴ For example, a person

²⁰⁰ See Owens, *supra* note 163, at E1. This article reported that, of the over 175 million people exposed to DTC advertisements, 55 million spoke directly to their physicians about the advertisements and 15 million actually requested an advertised drug. See Owens, *supra* note 163, at E1.

²⁰¹ See *Rx Video PR Soars; Sparks Concern Among Physicians*, O'DWYER'S PR SERVICES REPORT, Apr., 2000, at 1 [hereinafter *Rx Video*] (discussing results of survey).

²⁰² See *Id.* Some studies may suggest, however, that the advertising pharmaceutical companies do not do an adequate job of conveying side effect risks; thus, consumers are not properly being informed. Charlotte E. Sibley, *Can't We Get Better DTC Advertising Research?*, MED., MARKETING & MEDIA, Feb. 1, 2000, at 96. The author of this article conducted a survey finding that 81% of respondents reported seeing DTC advertisements, but only roughly 20% found the advertisements to be clear and understandable, while a mere 10% felt the pharmaceutical companies were doing an adequate job of presenting side effect information. *Id.* One further survey found that roughly half of consumers surveyed believed that DTC advertisements play a useful role in society. Michael F. Conlan, *Consumers Speak Out*, DRUG TOPICS, Mar. 20, 2000, at 71 [hereinafter Conlan, *Consumers*].

²⁰³ See Michael F. Conlan, *In-Your-Face Pharmacy: Will the Boom in Rx Ads Aimed at Consumers Continue?*, DRUG TOPICS, July 8, 1996, at 92 ("A properly educated, properly motivated patient-partner is the best bet the physician has for getting a good outcome for the patient overall . . . and [a]nd direct-to-consumer ads play a part in that.").

²⁰⁴ See Michael C. Allen, *Medicine Goes Madison Avenue: An Evaluation of the Effect of Direct-to-Consumer Advertising on the Learned Intermediary Doctrine*, 20 CAMPBELL L. REV. 113, 128 (1997).

An analysis of the potential benefits of the direct-to-consumer pharmaceutical advertising indicates that such advertising can often be

affected by mental depression might recognize personal symptoms in an advertisement for Prozac®²⁰⁵ and might finally muster the courage to see a doctor.²⁰⁶ Furthermore, many impotent men likely suffered in shame and silence before former Senator Bob Dole encouraged treatment through Pfizer's Viagra®.²⁰⁷ A number of health care officials and consumers alike have voiced opinions that these advertisements serve a valuable purpose by giving recognition to genuine, treatable health problems — health

the first source of information on newly available treatments. Consumer advertising may also increase awareness of established treatments and procedures. An example of the educational benefits of consumer advertising is the ability to trigger consumer recognition of symptoms of various illnesses and diseases. Specific examples might include information on symptoms such as excessive thirst as a potential warning sign of diabetes and unexplained weight loss and insomnia as potential indicators of depression.

Direct-to-consumer advertisements may also encourage consumers who may have previously discontinued treatment due to side effects to consult the appropriate health professional concerning new treatment alternatives. For example, many commonly prescribed anti-hypertensive medications may cause impotence in male patients often resulting in patient self-termination of treatment. Information on the availability of potential alternative medications with a lower incidence of side effects may encourage such patients to seek additional treatment.

Id.

²⁰⁵ Advertisement for Prozac®, LADIES HOME JOURNAL, Oct. 2000, at 65-67 (offering to help ease symptoms of depression).

²⁰⁶ See Rosenblatt, *supra* note 146, at A1.

[An] under-treated group motivated by advertizing is the population suffering from depression. Many are embarrassed or afraid to seek help. "There has been a stigma about depression," said Mary Graham, vice president of the National Mental Health Assn., an advocacy group. "Advertising gets consumers talking to physicians and seeking help."

Rosenblatt, *supra* note 146, at A1.

²⁰⁷ Advertisement for Viagra®, GOOD HOUSEKEEPING, Sept. 2000, at 77-78 (offering to cure erectile dysfunction); see also Rosenblatt, *supra* note 146, at A1.

problems that sufferers should not be ashamed to admit they have.²⁰⁸

Opponents, including consumer groups and health care officials, feel that DTC prescription drug advertisements serve little use to consumers and health care officials.²⁰⁹ Their arguments against DTC advertisements are threefold. First, some believe that such ads are merely manipulative marketing schemes that increase pharmaceutical manufacturers' profit margins and mislead consumers with false promises.²¹⁰ Second, some feel that patients are not capable of fully understanding the highly technical information provided in a brief summary and, as a result, sometimes receive the wrong medications.²¹¹ Finally, a number of opponents believe that such extensive advertising drives up the costs of already pricey prescription drugs.²¹²

By not providing an equal and accurate balance of benefits and risks, a number of DTC advertising critics feel that prescription drug marketing creates "misdirected expectations and desires."²¹³ The pharmaceutical industry is driven by profit, and not public education; thus, manufacturers will overplay benefits and create an

²⁰⁸ See Rosenblatt, *supra* note 146, at A1; see also Conlan, *Consumers*, *supra* note 202, at 71 (reporting that over half of consumers surveyed found the DTC ads to be useful and easy to understand).

²⁰⁹ See, e.g., Owens, *supra* note 163, at E1 (noting that consumer groups and health care officials have voiced opposition to DTC advertising). Cf. Michael F. Conlan, *Who Will Land Your Vote? R.Ph. Panel Casts Its Vote for President and Some of the Controversial Issues Facing the Country*, DRUG TOPICS, Oct. 16, 2000, at 50.

Two-thirds of the R.Ph.s [pharmacists] do not think direct-to-consumer advertising of prescription drugs is good for consumers, mostly because they believe patients pressure doctors to prescribe. "I like that it's educating consumers," said an Illinois chain R.Ph. "But, since we are a nation of sheep, I am uncomfortable with the concept of a patient demanding a med from his M.D. simply because it was on TV. It's sort of like children and the latest toy." A Pennsylvania chain R.Ph. said DTC ads were "bad for hypochondriacs."

Id.

²¹⁰ See *infra* notes 213-18 and accompanying text (detailing criticisms).

²¹¹ See *infra* notes 219-23 and accompanying text (detailing criticisms).

²¹² See *infra* notes 224-27 and accompanying text (detailing criticisms).

²¹³ See Owens, *supra* note 163, at E1.

unrealistic, "cure-all" mentality in consumers' minds.²¹⁴ In a study analyzing over 320 DTC advertisements, researchers found that "DTC ads tended to play up positive features of a drug and downplay the negative and unknown aspects."²¹⁵ Consumers, however, view these advertisements as credible and reliable.²¹⁶ In a 1999 telephone survey of over 2000 consumers, 62% classified the ads as "trustworthy."²¹⁷ Yet the FDA has had to reprimand pharmaceutical companies a number of times for deceiving or misleading consumers because the companies have not provided a fair and balanced picture of the advertised drug.²¹⁸

Compounding the misleading effects of the majority of DTC ads, opponents argue consumers will have difficulty accurately weighing the side effects in a condensed television or radio ad and comprehending the highly technical nature of the information provided in printed brief summaries.²¹⁹ However, the nature of

²¹⁴ See Nancy Chockley, *supra* note 146, at 19A.

²¹⁵ Amy Slugg Moore, *DTC Pharmaceutical Ads May Confuse Readers*, RN, June 1, 2000, at 16; David W. Glasscoff, *The Internet and Pharmaceuticals*, MARKETING HEALTH SERV., Spring 2000, at 37 ("The impact of DTC advertising on the medical community is that it seems to increase . . . the 'pill-for-everything' mentality that might not constitute 'good medicine.'"). Moreover, consumer-patients are often inclined not even to see and read the fine print containing all the risks of pharmaceuticals. See Michael F. Conlan, *Many Consumers Ill-Informed About Rx's, Says AARP*, DRUG TOPICS, June 5, 2000, at 20 ("While 65% of all consumers said they had seen a printed DTC ad, one in three of them reported not noticing the 'small-print' information about risks and potential side effects. Only 34% of those who noticed the small print reported reading it.").

²¹⁶ *Study Shows Positive Action, Attitude, from TV Drug Ads*, 35 MED., MARKETING & MEDIA 26 (2000) (reporting that 62% of consumers responding to a survey found DTC ads to be "trustworthy").

²¹⁷ *Id.*

²¹⁸ Janice Turner, *A New RX for Drugs*, TORONTO STAR, Dec. 10, 1999 (noting that in 1998, the FDA had to reprimand pharmaceutical companies repeatedly for making false claims).

²¹⁹ See Newman, *supra* note 195, at 92. Dr. Brian Strom, a professor at the University of Pennsylvania School of Medicine says the following:

Drugs are too difficult for patients to understand, dosing is hard to understand, and assessment of disease is best done by a doctor Patients are not the ones qualified to make an assessment of what they need. The whole thing ads up to no benefits and lots of harm.

pharmaceuticals requires a careful balance of a patient's history and the specific drug's risks to ensure maximum safety.²²⁰ Under a managed care system, where doctors have less time with patients, doctors are spending more time explaining the information from advertisements than diagnosing patients.²²¹ Often doctors just prescribe the requested drug instead of taking time to discourage the patient and inform her that there is a better, cheaper alternative.²²² The patient may receive the wrong medication as a result.²²³

Newman, *supra* note 195, at 92.

²²⁰ Grace L. Johnson & Arkalgud Ramaprasad, *Patient-Physician Relationships in the Information Age*, MARKETING HEALTH SERV., Spring 2000, at 21.

Critics claim that [health information is] virtually impossible for the vast majority of non-professionally educated patients to adequately understand, assimilate, and mentally process . . . The following example involving promotion of drugs in the antihypertensive market illustrates this point. One alpha-blocker manufacturer promotes its brand using the "alpha advantage"; another company emphasizes the beta difference; a third company promotes its brand by emphasizing once-a-day dosing; while a fourth explains that a major factor in hypertension is fluid retention and that its product is the "most potent diuretic (fluid reducer) on the market." Can a patient be expected to comprehend or sort the many issues put forward by these messages? A physician presumably chooses a particular treatment based on a tradeoff between costs and benefits and the appropriate treatment-patient match on an individual basis. Information that the patient obtains and brings could upset this careful "therapeutic marketing equilibrium."

Id.

²²¹ See David W. Glascoff, *The Internet and Pharmaceuticals*, MARKETING HEALTH SERVICES, Spring 2000, at 37 (suggesting "that the role of the physician might seem (to the physician) as changing from skilled diagnostician to that of a waiter in a restaurant serving what the patient 'orders'"); *Rx Video*, *supra*, note 201, at 1.

²²² See Dana James, *Prescription for Sale*, MARKETING NEWS TM, Oct. 23, 2000 ("Drug companies' mass media advertising may be luring patients to newer, more expensive drugs when less expensive alternatives would work just as well."); Johnson, *supra* note 220, at 21 ("Physicians also fear the demands of time on already tight schedules made by aggressive patients who insist on discussing their discoveries.").

²²³ See Johnson, *supra* note 220, at 21 (noting that critics of DTC advertising

Finally, DTC advertisements have been heavily criticized because they drive up the cost of prescription medications, which are already costly commodities.²²⁴ Many argue that consumers are the ones who ultimately pay for the information they receive from these advertisements and that these dollars are better put towards research and development of new pharmaceuticals.²²⁵ For these reasons, critics feel society would be better off without DTC advertisements.²²⁶ While it appears DTC advertisements are here to stay,²²⁷ the question remains, however, as to how the courts will handle future failure to warn claims against advertising pharmaceutical companies. Courts should heed and weigh these benefits and risks of DTC advertising, as well as the interplay of the FDA regulations, in deciding whether to create an exception to the learned intermediary doctrine.

warn that “chances for problems . . . such as overmedication and drug abuse, increase with greater patient awareness”).

²²⁴ Milt Freudenheim, *New Focus Put on Old Debate of Controlling Drug Costs*, N.Y. TIMES, May 7, 2000, at 12A (“[D]rug spending is growing three times as fast as overall health spending, which rose about 6% in 1999.”); Chockley, *supra* note 146, at 19A (“[T]here is equal evidence that, thanks to advertising's success in getting the doctors to prescribe new high-priced drugs—whether they're needed or not—we are all paying a multi-billion dollar price.”). *But cf.* James G. Dickinson, *DTC Spending Booms; DTC Doesn't Lift Rx Prices*, MED., MARKETING & MEDIA, May 1, 2000, at 34 (“New research sponsored indirectly by pharmaceutical manufacturers says that increased prescription drug spending is primarily due to the increased use of medicines rather than higher prices or the impact of DTC advertising.”).

²²⁵ *See, e.g., Media Drives Public Awareness*, CHEMIST & DRUGGIST, June 24, 2000, at 6; Linda Marsa, *Out of Reach? The Rise in Drug Prices Is Causing the Public to Ask Why*, L.A. TIMES, May 29, 2000, at S1.

²²⁶ *See* Chockley, *supra* note 146, at 19A (“[T]he marketing success of drug firms carries a significant downside for health care consumers [W]ildly escalating drug costs are crippling the ability of health plans to provide us with affordable health care coverage.”).

²²⁷ *See, e.g., Glascoff, supra* note 221, at 37 (“DTC advertising exists and will continue to exist in some form.”).

B. *The Four Options for Courts*

As long as manufacturers of a prescription drugs communicate directly to consumers through advertisements, courts will continue to face the complex question of whether an exception to the learned intermediary doctrine should be adopted. In so deciding, courts should perform a social risk-utility test for DTC marketing by examining whether the social benefits outweigh the harms and by how much. They should also consider the societal and judicial effects of either embracing or abandoning a well-grounded doctrine,²²⁸ as well as the effects on DTC advertising itself. If the court decides an exception to the learned intermediary doctrine is warranted, it should then decide what deference to afford governing FDA regulations.²²⁹ This decision, in large part, should be based on balancing the regulations' effectiveness in deterring misinformation with the benefits the existing advertisements provide.

1. *No Exception to the Learned Intermediary Doctrine*

If the deciding court weighs the benefits of the DTC advertising significantly over the risks, it should not create an exception to the learned intermediary doctrine. Holding otherwise would discourage the advertisements, conceivably denying consumers valuable health information.²³⁰ The learned intermediary doctrine protects pharmaceutical manufacturers from exposure to numerous lawsuits, thus giving them the freedom to advertise directly to consumers without becoming social insurers of their marketed products.²³¹ If an

²²⁸ See *supra* note 1 (listing a sample of cases where courts have adhered to the learned intermediary doctrine).

²²⁹ See *supra* notes 164-74 and accompanying text (discussing the FDA regulations for DTC marketing).

²³⁰ See Jack B. Harrison & Mina J. Jerrerson, "Some Accurate Information Is Better than No Information at All": Arguments Against Exceptions to the Learned Intermediary Doctrine Based on Direct-to-Consumer Advertising, 78 OR. L. REV. 605 (1999); Allen, *supra* note 204, at 130; Noah, *supra* note 54, at 141.

²³¹ Allen, *supra* note 204, at 130.

exception to the learned intermediary doctrine were created, many pharmaceutical companies, particularly those manufacturing newer, cutting-edge drugs, would not advertise for fear of opening themselves up to endless litigation.²³² In our evolving health care system, a reduction in such health information could force consumer-patients to rely completely on busy physicians with whom they have developed little rapport.²³³ Advocates of the learned intermediary doctrine believe that arming a consumer with some information is far superior than depriving her of all information.²³⁴

Moreover, with the learned intermediary doctrine intact, pharmaceutical companies avoid wading into the nebulous waters of determining what warnings are adequate, leaving such determi-

Imposing of legal liability for failure to warn the consumer of risks would have a 'chilling effect' on the use of direct-to-consumer advertisements. Pharmaceutical manufacturers provide many needed products which have immensely improved the quality and duration of life The potential liability associated with abandoning the learned intermediary doctrine in advertising cases would most assuredly minimize the use of this potentially beneficial activity.

Allen, *supra* note 204, at 130.

²³² Allen, *supra* note 204, at 130 (illustrating past examples of how exposing pharmaceutical manufacturers of new vaccinations to liability cut down on the availability of those drugs and hypothesizing that the same result would occur if an exception to the learned intermediary doctrine is created for DTC advertising); *see also* Harrison & Jerrerson, *supra* note 230, at 623.

In an attempt to avoid future litigation manufacturers may stop advertising if they believe litigation costs will outweigh the sales expected from marketing their products. Courts, however, disfavor keeping consumers in the dark because informed consumers are reflective of an informed citizenry.

Harrison & Jerrerson, *supra* note 230, at 623.

²³³ Furthermore, physicians may be inclined to give patients who have seen DTC ads less medical information because the duty has been shifted to the manufacturer. *See* Noah, *supra* note 54, at 178.

²³⁴ *See* Noah, *supra* note 54, at 178 ("Direct advertising encourages active participation by consumers in prescribing decisions, a favorable development that courts should not 'reward' by expanding tort duties of drug manufacturers and, thereby, discouraging such advertising in the future."); *see also* Harrison & Jerrerson, *supra* note 230, at 605.

nations entirely to the legislative process and prescribing physicians.²³⁵ If a pharmaceutical company chooses to advertise without the protection the doctrine affords, it is placed in the awkward position of determining which warnings are necessary for a consumer-patient to make an informed choice.²³⁶ The company will hence end up spreading the costs of litigation to the consumers themselves, or it will deplete funding for drug research and development.²³⁷ Preservation of the learned intermediary doctrine prevents such mayhem and safeguards the free flow of information from manufacturer to consumer about various health options.²³⁸

2. *An Exception to the Learned Intermediary Doctrine with a Strong Rebuttable Presumption*

Most of the advocates for adhering to the learned intermediary doctrine in light of DTC advertising have not addressed the benefits of using the FDA guidelines as determinative of liability as the New Jersey Supreme Court did in *Perez v. Wyeth Laborato-*

²³⁵ See Noah, *supra* note 54, at 174-175.

²³⁶ Allen, *supra* note 204, at 129.

[A]ttempts in a direct-to-consumer ad to adequately convey sufficient information to enable a consumer to make a reasonably informed and educated decision would be prohibitively lengthy and difficult to convey. As an example, the Food and Drug Administration's mandated physician information required for a popular oral contraceptive contains over eight hundred lines of text. Additionally, serious difficulties are present in attempting to translate the complexities and subtleties of medical terminology and consumer usable information.

Allen, *supra* note 204, at 129; see also Noah, *supra* note 54, at 176 n.131. The author notes that "adequate consumer labeling cannot be designed for prescription drugs" and cites *Dunkin v. Syntex Lab, Inc.*, 443 F. Supp. 121, 123 (W.D. Tenn. 1977), which states that "prescription drugs are sold on a prescription basis and not over-the-counter because of the special expertise of a trained physician necessary for their safe use." Noah, *supra* note 54, at 176 n.131. As a result, an effective warning could only go to "the medical profession, and not to an untrained patient." Noah, *supra* note 54, at 176 n.131.

²³⁷ Harrison & Jerrerson, *supra* note 230, at 623-24 (noting that consumers pay the ultimate price of creating an exception to the learned intermediary doctrine).

²³⁸ See Allen, *supra* note 204, at 129.

ries.²³⁹ If a court should decide the underlying assumptions behind the learned intermediary doctrine no longer apply in our evolving health care system, an exception can be created without all of the negative repercussions.²⁴⁰ By creating a rebuttable presumption against the plaintiff that the defendant manufacturer has met its duty in complying with FDA regulations, the risks presented by creating the exception — for example, depriving consumers of valuable health information — are minimized.²⁴¹ The manufacturer, having the FDA guidelines as a powerful shield, will not face the open-ended lawsuits that will deter it from advertising or that will divert massive funding away from valuable research and development of new drugs.²⁴² In deciding whether to create a strong or weak rebuttable presumption — in other words, whether the plaintiff must prove deliberate FDA violations — courts should consider which option will deter manufacturers from misleading the public without infringing upon the benefits the advertisements provide.

The New Jersey Supreme Court struck a balance between the utility and harms of DTC advertising by recognizing an exception to the learned intermediary doctrine but requiring plaintiff consumers to rebut a strong presumption that defendant has satisfied its duty to warn by complying with FDA mandates.²⁴³ The court set forth a strong rebuttable presumption by stating that “absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of such claims.”²⁴⁴ The court’s decision rested, in part, on an implicit notion that DTC advertisements benefit more than harm society.²⁴⁵ It noted that, while these ads

²³⁹ See *supra* notes 115-18 and accompanying text (discussing the threshold FDA guideline presumption established in *Perez*).

²⁴⁰ See generally *Perez*, 734 A.2d at 1259.

²⁴¹ *Id.* (noting that this approach prevents manufacturers from being made insurers of their products).

²⁴² See Dreier, *supra* note 21, at 825 (noting that plaintiffs claims will likely not survive summary judgment when the manufacturer can hide behind its FDA compliance).

²⁴³ *Perez*, 734 A.2d at 1259.

²⁴⁴ *Id.*

²⁴⁵ *Id.*

do help educate the public, over-deterrence could have a “significant anti-utilitarian effect.”²⁴⁶

By allowing defendant manufacturers to use FDA regulations as shields against liability and by creating a strong rebuttable presumption for plaintiffs to surmount, the decision will not likely alter the existing format of DTC advertisements.²⁴⁷ However, it will force manufacturers to at least avoid deliberate FDA violations.²⁴⁸ This could protect consumers from some of the blatantly misleading information pharmaceutical manufacturers may otherwise put in their advertisements. The threat of litigation will likely deter manufacturers from blatant violations more so than the current slap on the wrist the FDA imparts.²⁴⁹

3. *An Exception to the Learned Intermediary Doctrine with a Weak Rebuttable Presumption*

If a court believes that a strong rebuttable presumption places an insurmountable burden before the plaintiff and that the harmful effects of existing DTC advertisements are at least equivalent to the

²⁴⁶ *Id.* Over-deterrence could discourage manufacturers from advertising at all, thus depriving consumers of valuable health information. See Allen, *supra* note 204, at 130 (“The potential liability associated with abandoning the learned intermediary doctrine in advertising cases would most assuredly minimize the use of this potentially beneficial activity.”).

²⁴⁷ See Fushman, *supra* note 14, at 1181 (noting that the *Perez* decision will not likely impact current DTC advertising).

²⁴⁸ *Id.* (surmising that manufacturers will likely submit their ads to the FDA for pre-approval before airing or printing, a process which could delay ads reaching the public for a number of weeks).

²⁴⁹ See Terzian, *supra* note 10, at 153. The FDA does not require pre-approval of advertisements from pharmaceutical manufacturers before they are printed or aired. Terzian, *supra* note 10, at 153. If the FDA finds a violation, the administration issues a letter of reprimand to the company telling them to change the ad so that it complies with regulations. Terzian, *supra* note 10, at 153. If the manufacturer does not react appropriately to this warning, the FDA will then require the advertisement be pulled off the air or out of print. Terzian, *supra* note 10, at 153. The FDA has the power to bring criminal sanctions, but this rarely occurs. Terzian, *supra* note 10, at 153.

utilitarian effects,²⁵⁰ it may take the *Perez* decision one step further and impose only a weak rebuttable presumption against the plaintiff. Under a weak rebuttable presumption, the plaintiff must only prove that the pharmaceutical manufacturer did not comply with current FDA guidelines regardless of their intentional or deliberate acts. This is the optimal approach, as manufacturers will likely give great attention and deference to the FDA guidelines if they face potentially numerous lawsuits for non-compliance.²⁵¹ They will strive to present a more accurate balance of risks and benefits as the guidelines dictate, thus maximizing the educational benefits of DTC advertisements while idealistically minimizing the risks of false or deceptive marketing schemes.²⁵² As a result, the advertisements will better serve the public.²⁵³

While some manufacturers may choose not to advertise at all under such a scheme, the likelihood of deterrence from advertising is not overwhelming.²⁵⁴ Manufacturers have the FDA regulations as a shield, although courts and juries will likely spend much more time scrutinizing the regulations to determine compliance or non-compliance.²⁵⁵ The most significant potential downfall, however, is that manufacturers will divert research and development funds to litigate against claims that they failed to meet FDA guide-

²⁵⁰ See Dreier, *supra* note 21, at 806 (arguing that the rebuttable presumption placed before a plaintiff as a result of *Perez* “stifles any claim” because “absent such fraud or concealment . . . it would be highly unusual if any plaintiff’s case is able to survive a motion for summary judgment”).

²⁵¹ See generally Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 329-35 (1985) (opining that FDA guidelines should be used as the standard for liability).

²⁵² *Id.*

²⁵³ See Fushman, *supra* note 14, at 1181 (suggesting that, in gaining pre-approval from the FDA before airing or printing ads, the public will receive more balanced, less misleading information).

²⁵⁴ See Fushman, *supra* note 14, at 1181 (opining that the increased revenues resulting from DTC advertisements will outweigh any deterrence to cease DTC marketing as a result of *Perez*).

²⁵⁵ See Fushman, *supra* note 14, at 1181 (noting that manufacturers can avoid some of this by seeking pre-approval from the FDA).

lines.²⁵⁶ Consumers will also bear these costs through increased drug prices.²⁵⁷

4. *An Exception to the Learned Intermediary Doctrine with No Rebuttable Presumption*

Courts determining that the harmful effects of DTC marketing significantly outweigh the benefits should adopt an exception to the learned intermediary doctrine without imposing a rebuttable presumption upon the plaintiff. While manufacturers will certainly emphasize compliance with FDA regulations as evidence of adequate warnings, such compliance will not shield them against liability.²⁵⁸ The nebulous question of what constitutes an adequate warning will thus be before a court and jury, and the manufacturer will face imposing burdens of justifying why a specific warning was not presented thoroughly in a thirty-second advertisement.²⁵⁹

Facing such open-ended lawsuits and liabilities, many manufacturers who decide the benefits do not outweigh the costs will cease advertising altogether.²⁶⁰ As a result, consumers may be spared some of the deceptive marketing schemes and the added costs of advertising.²⁶¹ Physicians will gain more autonomy in selecting prescriptions without being bombarded by patients' requests.²⁶² Those manufacturers who do choose to advertise will have to

²⁵⁶ See Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 467-468 (1997) (describing how the litigation itself costs manufacturers billions of dollars).

²⁵⁷ See generally *supra* notes and accompanying text 194-95 (noting the already exorbitant costs of prescription drugs).

²⁵⁸ See generally Green, *supra* note 256, at 508.

²⁵⁹ See generally Huber, *supra* note 251, at 329-35 (questioning whether the courts are appropriate vehicles for determining the limits of societal risks and opining that government agencies, such as the FDA, are better suited for dealing with these issues).

²⁶⁰ See Allen, *supra* note 204, at 130 (describing the "chilling effect" that the pharmaceutical industry would have in the face of unfettered lawsuits).

²⁶¹ See Allen, *supra* note 204, at 130.

²⁶² See generally *supra* notes 221-23 and accompanying text (explaining the negative effects of DTC advertisements on the limited amount of time physicians and patients spend together).

examine carefully their presentations of risks to consumers, thus increasing the educational benefits of the remaining advertisements.²⁶³

Advocates of such an exception argue that patients are entitled to all the benefits and risks in order to make an informed choice in taking a prescription medication, and that courts should impose reasonableness standards to ensure this.²⁶⁴ Moreover, pharmaceutical manufacturers who choose to advertise directly to consumers incur a responsibility to warn them adequately and reasonably.²⁶⁵ While this viewpoint has merit in theory, critics note the immense, impractical uncertainties of placing the question of what constitutes reasonableness before a jury.²⁶⁶ As mentioned, “[p]rescription drugs are likely to be complex medicines, esoteric in formula and varied in effect.”²⁶⁷ The variety of different standards of reasonableness could overwhelm manufacturers and serve as an effective deterrent.²⁶⁸ The FDA with its expertise is better suited to deal with these uncertainties if DTC advertisements are found to have more than minimal social value.

C. *The Optimal Choice: Option 3*

While the ultimate decision of how best to handle future challenges to the learned intermediary doctrine in light of pharmaceutical companies' massive DTC marketing campaigns rests with the courts, Option 3 presents the best balance for courts to follow. The New Jersey Supreme Court recognized valid arguments for creating an exception to the learned intermediary doctrine.²⁶⁹ When the underlying reasons behind the doctrine are diminished, as in the case of DTC advertising, an exception is warranted with

²⁶³ See generally *supra* notes 195-203 and accompanying text (comparing the educational benefits of DTC advertising on the public).

²⁶⁴ See, e.g., Plant, *supra* note 14, at 1007 (advocating an informed consent doctrine).

²⁶⁵ Plant, *supra* note 14, at 1007.

²⁶⁶ See *supra* note 236.

²⁶⁷ See *supra* note 53.

²⁶⁸ See *supra* note 236.

²⁶⁹ Perez, 734 A.2d at 1259.

limitations.²⁷⁰ A judge or jury, however, is not best suited to determine the arbitrary and complex question of what constitutes an adequate warning in DTC advertising. Therefore, adopting the FDA guidelines as the standard of reasonableness strikes a rational and fair balance to both plaintiffs and manufacturers.

The New Jersey Supreme Court, on the other hand, went too far in requiring plaintiffs to prove deliberate concealment.²⁷¹ A plaintiff's burden is virtually insurmountable under such a mandate. Under Option 3 a plaintiff will have a claim that survives summary judgment if she can prove that the manufacturer failed to comply with the FDA guidelines. She need not prove deliberate concealment, as under *Perez*, thus her burden is lessened. For those plaintiffs who have truly been misled by overtly deceptive advertising, a remedy exists. Moreover, manufacturers will be forced to take a close look at their advertisements to ensure FDA compliance.

This option will have the salutary effect of preserving the benefits of DTC advertising while diminishing some of its harms. The justified concern over the misleading nature of DTC ads will be lessened as manufacturers who wish to advertise will seek pre-approval from the FDA. At the same time, the advertisements will continue to provide valuable health information to the public by increasing awareness and reducing stigmas. In this new and changing age of health care, where targeted consumers have stepped at least partially into the shoes of learned intermediaries, such an exception with boundaries is warranted.

CONCLUSION

The learned intermediary doctrine, relieving prescription drug manufacturers from the duty of warning consumers directly, remains a sound rule in products liability as prescription drugs are

²⁷⁰ See generally RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 cmt. b (1998) ("In certain limited therapeutic relationships the physician or care-giver has a much diminished role as an evaluator or decision-maker. In these instances it may be appropriate to impose on the manufacturer a duty to warn the patient directly.").

²⁷¹ *Id.*; see also Dreier, *supra* note 15.

complex in nature and warnings are difficult to convey. Limited exceptions, however, are warranted when the assumption that the prescribing physician will adequately convey warnings is not present. For these reasons, courts have recognized the validity of exceptions for a mass immunizations and contraceptives. Further embracing this rationale, the New Jersey Supreme Court in *Perez v. Wyeth Laboratories* was the first to extend an exception to the learned intermediary doctrine to situations where the manufacturer has engaged in DTC marketing.

As a result of the movement in health care towards a system of managed care, the dynamics between physicians and patients have changed. Now, patients do not have the limitless freedom to choose their physicians and physicians are not able to devote the same amount of time to individual patients. Pharmaceutical manufacturers, on the other hand, have begun reaching patients directly and inundating them with product information through print and media advertisements and informational Internet web sites. As a result, patients often tell their physicians which prescription medication they wish to take, sometimes reducing physicians into mere purveyors of prescription slips. To an extent, consumers have stepped into the roles that intermediaries once filled.

In addressing the learned intermediary doctrine when the manufacturer has engaged in DTC advertising, courts should consider the societal value of the ads themselves. On one hand, these advertisements notify consumers of valuable health information that their physicians may not provide and enable patients to make informed choices concerning individual health care. On the other hand, these advertisements often are deceptive and manipulative, minimizing complex side effects and contraindications of the product. In reaching a solution, courts should consider what option would maximize the positive effects of DTC advertising, while minimizing the negative consequences. The solution, presented in Option 3, allows for a limited exception to the learned intermediary doctrine. While, under this solution, the manufacturer bears the duty to warn the consumer directly, it can use the FDA regulations as a shield against liability. Any plaintiff bringing a failure to warn claim against a pharmaceutical manufacturer will have to rebut a presumption that the manufacturer complied with FDA regulations. Absent proof of a violation of the FDA guidelines, a plaintiff's

claim will not survive summary judgment. Manufacturers will have incentive to follow strictly the regulations set forth by the FDA, and the consumers will have legitimate claims against manufacturers for non-compliance. Moreover, the nebulous question of what constitutes a reasonable warning will rest in the hands of the able FDA experts. As a result, manufacturers will continue to advertise and inform consumers in a more balanced approach, and consumers will continue to take charge of their own health care decisions.

