Old Habits Die Hard: Reforming the Learned Intermediary Doctrine in the Era of Direct-to-Consumer Advertising

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I. INTRODUCTION

Do you want “more normal living?”" or to “stay in the game?”" Would you 
like to “be yourself again?” or become “more like the woman you are?” Do you 
desire “everyday victories?” or “the power to make a difference?” These are just 
a few examples of the slogans that manufacturers utilize in direct-to-consumer 
pharmaceutical advertisements. With promises of “renewed hope” and “more 
possibilities,” these ads are highly effective and largely influence the modern 
medical landscape of prescription drugs."

advertisement for Humira, a prescription drug treatment for rheumatoid arthritis. Id.
2. Id. GlaxoSmithKline employed this slogan in an ad campaign for Levitra, an erectile dysfunction 
medication. Id.
3. Id. Novartis used this slogan in advertisements for Zelnorm, a drug that treats irritable bowel 
syndrome. Id.
4. Id. Eli Lilly and Company ran these words in advertisements for Sarafem, a medication used to treat 
premenstrual dysphoric disorder. Id.
5. Id. Merck used this language in advertisements for Vioxx, an arthritis medication. Id.
6. Id. Alcon Laboratories used this slogan in an advertisement for Travatan, a pharmaceutical used to 
treat glaucoma. Id.
7. See generally id. (listing various prescription drugs and their advertising slogans).
8. Id. Ortho-McNeil-Janssen utilized this slogan in an ad campaign for Regranex, a drug used to treat 
diabetic foot ulcers. Id.
9. Id. Duramed used this tagline for advertising the birth control pill Seasonale. Id.
10. See U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-07-54, PRESCRIPTION DRUGS: IMPROVEMENTS 
NEEDED IN FDA’S OVERSIGHT OF DIRECT-TO-CONSUMER ADVERTISING 14 (2006) (on file with the McGeorge
Direct-to-consumer advertising for pharmaceutical drugs is on the rise. From 1997 through 2005, spending on direct-to-consumer advertising in the United States increased by an average of approximately twenty percent every year, skyrocketing from $1.1 billion in 1997 to $4.2 billion in 2005. Yet, during that same period, spending on drug promotion to physicians and on research and development each increased by about nine percent annually—only half as fast as spending on direct-to-consumer advertising increased. The surge of this form of advertising is further evidenced by the fact that the average television viewer in the United States will be exposed to approximately nine direct-to-consumer advertisements for pharmaceuticals every day.

This increase in direct-to-consumer advertising for prescription drugs has changed the face of medicine. The success of such advertising has created a prosperous market for brand-name drugs. In the process, direct-to-consumer advertising has redefined the doctor–patient relationship.

These changes call into question the continued vitality of the long-standing learned intermediary doctrine. The learned intermediary doctrine shifts the traditional duty to warn consumers of the risks of prescription drug products from the pharmaceutical manufacturer to the physician. This results in a legal

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12. See U.S. GOV'T ACCOUNTABILITY OFFICE, supra note 10, at 12–13 (reporting that the total increase in spending on direct-to-consumer promotion between 1997 and 2005 was 296.4 percent).
13. See id. at 12.
15. See Julie Brienza, N.J. Court Finds Exception to Learned Intermediary Doctrine, 35 TRIAL 94 (1999) (explaining that the New Jersey Supreme Court in Perez was merely “changing with the times”).
16. See U.S. GOV'T ACCOUNTABILITY OFFICE, supra note 10, at 14 (describing the increase in spending on pharmaceuticals as a result of direct-to-consumer advertising).
18. See generally Perez, 734 A.2d at 1255–56 (describing the ways in which the rationale behind the application of the doctrine is weakened by direct-to-consumer advertising).
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principle that, while highly protective of drug manufacturers, greatly “limit[s] an injured [consumer]’s ability to obtain redress.”

While the benefits and drawbacks of direct-to-consumer advertising continue to be debated, the fact that the growth of such advertising has changed society’s relationship with medicine is undeniable. These changes demand shifts in medical–legal jurisprudence. Simply put, the policies that originally justified the learned intermediary doctrine do not apply when a pharmaceutical manufacturer engages in direct-to-consumer advertising.

Therefore, the learned intermediary doctrine should not apply when pharmaceutical manufacturers advertise directly to consumers. This comment proposes that courts should impose liability on pharmaceutical manufacturers who fail to adequately warn consumers when those manufacturers engage in direct-to-consumer advertising. In Part II, this comment discusses the background of the learned intermediary doctrine, its prevalence, the justifications for its use, and exceptions to its application. Part III includes an explanation of direct-to-consumer advertising, the FDA regulations that control its use, and various, differing perspectives concerning the benefits and drawbacks of its widespread use. Part IV focuses on the recent developments in case law that suggest a possible trend toward adopting an exception to the learned intermediary doctrine for manufacturers who utilize direct-to-consumer advertising. Part V explains how the expansive use of direct-to-consumer advertising has undermined the justifications for the continued existence of the learned intermediary doctrine. Finally, Part VI articulates the drawbacks to the current system and the limits of adopting a rebuttable-presumption approach, and calls for the creation of an exception to the learned intermediary doctrine when manufacturers use direct-to-consumer advertising.

21. Id. at 2242.
23. See Calabro, supra note 20, at 2268–69 (explaining that direct-to-consumer advertising has increased patient involvement in treatment decisions and undermined the ability of the physician to act as a learned intermediary).
25. See id. at 1256 (explaining that the premises for the doctrine are now “absent”).
II. THE LEARNED INTERMEDIARY DOCTRINE: AN EXCEPTION TO A MANUFACTURER’S GENERAL DUTY TO WARN

A. The Learned Intermediary Doctrine: The Basics

Generally, a manufacturer of a product is charged with warning consumers directly of the foreseeable risks of harm associated with their product. However, there is an exception to this general duty to warn for manufacturers of prescription drugs and certain medical devices. The learned intermediary doctrine states that pharmaceutical manufacturers have no duty to warn consumers directly. Instead, manufacturers have only the duty to adequately warn the prescribing physician of the risks associated with their products. In turn, the physician acts as a “learned intermediary” between the manufacturers and the patients, and has a duty to warn patients of the risks attendant in the prescription drugs themselves.

In 1948, the New York Supreme Court first introduced the learned intermediary doctrine in Marcus v. Specific Pharmaceuticals. In Marcus, the plaintiff directly sued a suppository manufacturer for the death of a thirteen-month-old infant who overdosed on the drug. The court reasoned that because the pharmaceutical manufacturer made no direct representations to the patient, it

26. Loidolt et al., supra note 19, at 2; see also RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 2 (1998).

A Product (c) 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.

27. See Carole A. Cheney, Not Just for Doctors: Applying the Learned Intermediary Doctrine to the Relationship Between Chemical Manufacturers, Industrial Employers, and Employees, 85 NW. U. L. REV. 562, 581 (1991) (explaining that an exception has been carved out of the general duty to warn for specific categories of products, including prescription drugs).

28. Loidolt et al., supra note 19, at 3; Calabro, supra note 20, at 2242–43.

29. Loidolt et al., supra note 19, at 3; see also RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6(d) (1998).

A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to: (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings . . .

Id.

30. Loidolt et al., supra note 19, at 3; Sterling Drug, Inc., v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966) (coining the phrase); see also Allen Wong, Products Liability: The Fate of the Learned Intermediary Doctrine, 30 J.L. MED. & ETHICS 471, 471 (2002) (the health-care provider as a medical expert “is expected to weigh the risks and benefits of the product” and warn the patient accordingly).


32. Marcus, 77 N.Y.S.2d at 509.
could not be liable for “negligent failure to give adequate information.”\textsuperscript{33} The court explained that there could only be a potentially viable claim if the plaintiffs could show that the manufacturer’s representations to the physician were false or inadequate.\textsuperscript{34} Due to the physician’s position as an intermediary between the patient and the manufacturer for the purposes of providing a required prescription, the court drew a marked distinction in the relationship between manufacturer and consumer.\textsuperscript{35} The learned intermediary doctrine was born.\textsuperscript{36} If the learned intermediary doctrine applies, the plaintiff must show that the warnings given by the manufacturer to the prescribing physician were inadequate and that “those inadequate warnings were a producing cause of and/or proximately caused Plaintiffs’ subsequent injuries.”\textsuperscript{37} If the plaintiff cannot prove the elements necessary to find the manufacturer liable under the learned intermediary doctrine, the plaintiff’s last resort for a remedy is to sue the physician directly for failure to adequately warn of the risks associated with the prescription drug.\textsuperscript{38} The learned intermediary doctrine thus severely impedes the “injured plaintiff’s ability to obtain redress.”\textsuperscript{39}

B. The Learned Intermediary Doctrine: A Fundamental Tenet of Tort Law?

The learned intermediary doctrine has been called one of the “fundamental tenants [sic] of tort law.”\textsuperscript{40} In fact, forty-eight states, the District of Columbia, and Puerto Rico have recognized or accepted the doctrine.\textsuperscript{41} Such widespread use of the doctrine has led to apprehension by many courts that are faced with cases questioning the doctrine’s legitimacy in today’s medical landscape.\textsuperscript{42} The

\textsuperscript{33} See id. (“It may be safely conceded that these allegations would be sufficient if the product were sold to the public generally as a drug for which no physician’s prescription was necessary. The situation alleged is materially different.”).

\textsuperscript{34} Id.

\textsuperscript{35} Id.

\textsuperscript{36} Id. at 509–10.


\textsuperscript{38} See Brooks v. Medtronic, Inc., 750 F.2d 1227, 1232 (4th Cir. 1984) (“Once adequate warnings are given to the physician, the choice of treatment and the duty to disclose properly fall on the doctor.”); see also Calabro, supra note 20, at 2243 (explaining that the “risks normally borne by the manufacturer for injury are largely shifted to the prescribing physician”).

\textsuperscript{39} Calabro, supra note 20, at 2242.


\textsuperscript{41} See In re Norplant, 215 F. Supp. 2d at 806–09 (calculating not only states in which lower state courts have expressly adopted the doctrine but also states in which it was predicted by federal courts applying state law that state high courts would adopt the doctrine); see also Kyle Fogt, Note, The Road Less Traveled: West Virginia’s Rejection of the Learned Intermediary Doctrine in the Age of Direct-to-Consumer Advertising, 34 J. CORP. L. 587, 591 (2009) (referring to the survey that produced these figures as the “most inclusive”); Wong, supra note 30.

\textsuperscript{42} See, e.g., Vitanza v. Upjohn Co., 778 A.2d 829, 847 (Conn. 2001) (“[W]e see no reason to create an
American Tort Reform Foundation (ATRF) evidenced this reluctance when it categorized West Virginia as a “judicial hellhole” for “adopting theories of liability that are out of the mainstream.” In 2009, the ATRF explained that West Virginia holds this title partly due to a decision by its high court in 2007 that made it the first state to completely reject the learned intermediary doctrine.

C. Justifications for the Learned Intermediary Doctrine

There are many justifications for the existence of the learned intermediary doctrine. These rationales can generally be separated into four common arguments. First, the learned intermediary doctrine fosters respect for the doctor–patient relationship. The decision to prescribe a drug uniquely belongs to physicians. In fact, some argue that any duty to warn on behalf of pharmaceutical manufacturers may undermine the revered doctor–patient relationship by interfering with the physician’s ability to make independent judgments regarding their patient’s health and overall well-being.

Second, in deciding to prescribe medications, the theory is that doctor knows best. Proponents of the learned intermediary doctrine believe that physicians are in the best position to know a specific patient’s needs, given the “personal and direct relationship with the patient.” Additionally, proponents find that patients are passive in the treatment process and rely on doctors to make decisions that they accept almost blindly. This paternalistic view of the doctor–patient relationship lends support to the existence of the learned intermediary doctrine.


44. See generally State ex rel. Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899 (W. Va. 2007) (rejecting the application of the learned intermediary doctrine outright); Judicial Hellholes 2009/2010, supra note 40.


46. Wong, supra note 30.

47. See Paul D. Rheingold, Products Liability—The Ethical Drug Manufacturer’s Liability, 18 RUTGERS L. REV. 947, 987 (1964) (arguing that physicians must use “independent judgment, unaffected by the manufacturer’s control” in making the decision to prescribe a patient a drug).

48. See Loidolt et al., supra note 19, at 5 (describing the physician’s role as prescriber).


50. Id.

51. Calabro, supra note 20, at 2252.


53. See Perez, 734 A.2d at 1255 (describing this pre-informed consent conception of the doctor–patient relationship).
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Third, supporters of the doctrine argue that consumers are largely uneducated about medical treatment options. Physicians, on the other hand, have extensive education in the area of medicine and therefore have the ability to communicate complicated information regarding prescription drug treatments to patients. The inability of most patients to comprehend the complexity of warnings would further inhibit a manufacturer from adequately warning lay patients without the assistance of physicians.

Finally, proponents argue that communication between pharmaceutical manufacturers and patients is “virtually impossible.” It would be very difficult for manufacturers to warn all consumers of every risk, except by way of printed labels, which are limited in their effectiveness. Additionally, advertisements could not be trusted as viable warning methods because there would be no guarantee that every patient would see an advertisement and therefore receive the warning.

While each of these justifications have some merit, the learned intermediary doctrine simply fails to adequately protect patients from injury in certain situations. Therefore, courts have adopted several exceptions to the doctrine.

D. Exceptions to the Learned Intermediary Doctrine

Since its introduction in 1948, courts have carved out various exceptions to the application of the learned intermediary doctrine. The most common exceptions that courts recognize include mass immunizations and oral contraceptives. Courts adopted these exceptions because the justifications for applying the learned intermediary doctrine do not apply with such force in these circumstances. Specifically, for both mass immunizations and oral

relationship as a “paternalistic approach”).

54. See Rheingold, supra note 47, at 987 (stating that patients have “limited understanding” on such complex issues as prescription drug treatments and their risks).
55. Calabro, supra note 20, at 2251–53; Rheingold, supra note 47.
56. Perez, 734 A.2d at 1255.
57. See Susan A. Casey, Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine, 19 WM. MITCHELL L. REV. 931, 948 (1993) (explaining that the argument is based on a time when magazines and television had yet to become “disseminators of medical information”).
58. Perez, 734 A.2d at 1255; see also Rheingold, supra note 47, at 987 (explaining that there is “no sure way [for the manufacturer] to reach the patient”).
59. Rheingold, supra note 47, at 987.
60. Casey, supra note 57, at 948.
61. See Loidolt et al., supra note 19, at 7 (asserting that courts have found exceptions should exist for certain pharmaceutical products).
62. Casey, supra note 57, at 948.
63. RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6 cmt. e (1998); Calabro, supra note 20, at 2255.
64. See generally Loidolt et al., supra note 19, at 7–11 (explaining that the premises of the learned intermediary rule have caused some courts to hold that the rule should not apply to certain pharmaceutical drugs).
contraceptives, these circumstances decrease the role of the physician and increase the role of communication between the manufacturer and the patient.\textsuperscript{65} When such an exception applies, a court applying the doctrine shifts the duty to warn patients of risks attendant in the drug directly back to the pharmaceutical manufacturers.\textsuperscript{66}

1. Mass Immunizations

Nearly all jurisdictions recognize an exception to the application of the learned intermediary doctrine for mass immunizations.\textsuperscript{67} In \textit{Davis v. Wyeth Laboratories}, the Ninth Circuit was the first court to develop an exception for mass immunizations.\textsuperscript{68} In \textit{Davis}, the plaintiff contracted polio due to a vaccine received at a mass immunization clinic.\textsuperscript{69} The court declined to apply the learned intermediary doctrine and instead held the drug manufacturer liable for failing to adequately warn the patient of the risks associated with the vaccine.\textsuperscript{70} The \textit{Davis} court reasoned that the circumstances surrounding mass immunizations were similar to the sale of over-the-counter drugs in that the vaccine was given to all patients who requested it without consideration of any individual’s medical history.\textsuperscript{71} In \textit{Reyes v. Wyeth Laboratories}, the Fifth Circuit articulated the rule for the exception, holding that a manufacturer has a duty to warn the patient directly when the product is “dispensed without the sort of individualized medical balancing of the risks [of the vaccine] that is contemplated by the prescription drug exception.”\textsuperscript{72}

The exception for mass immunizations is premised on the fact that modern physicians play a very limited role in a patient’s decision to be immunized.\textsuperscript{73} Mass immunization clinics do not provide individually tailored medical advice regarding risks and benefits of vaccinations to patients.\textsuperscript{74} In fact, a doctor–patient

\textsuperscript{65} Calabro, supra note 20, at 2255.
\textsuperscript{66} Fogt, supra note 41, at 592.
\textsuperscript{67} See Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir. 1974) (explaining that a drug meets the mass immunization exception when “no individualized medical judgment intervenes between the manufacturer of a prescription drug and the ultimate consumer . . . .”); see also Loidolt et al., supra note 19, at 8 (explaining that it was the first major exception to be adopted). Victor E. Schwartz et al., \textit{Marketing Pharmaceutical Products in the Twenty-First Century: An Analysis of the Continued Viability of Traditional Principles of Law in the Age of Direct-to-Consumer Advertising}, 32 HARV. J.L. & PUB. POL’Y 333, 357–58 (2009).
\textsuperscript{68} Casey, supra note 57, at 939.
\textsuperscript{69} Davis v. Wyeth Labs., Inc., 399 F.2d 121, 122 (9th Cir. 1968).
\textsuperscript{70} See \textit{id.} at 131 (“it is the responsibility of the manufacturer to see that warnings reach the consumer”).
\textsuperscript{71} See \textit{id.} (articulating that although the vaccine was technically considered a prescription drug, “it was not [being] dispensed as such”). The protection of the learned intermediary doctrine does not extend to over-the-counter medicines. Stephen R. Kaufmann & Jason D. Johnson, \textit{The Learned Intermediary Doctrine and Pharmaceutical Company Liability}, 95 ILL. B.J. 202, 206 (2007).
\textsuperscript{72} Reyes, 498 F.2d at 1276–77.
\textsuperscript{73} Casey, supra note 57, at 949.
\textsuperscript{74} \textit{Id.}
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relationship is never established in most immunization clinics due to the expedited process and limited interaction between health providers and patients. As such, physicians do not act as learned intermediaries in these situations and therefore the learned intermediary doctrine does not apply.

2. Oral Contraceptives

Some jurisdictions also recognize an exception to the learned intermediary doctrine for oral contraceptives. In MacDonald v. Ortho Pharmaceutical Corporation, the Massachusetts Supreme Court declined to apply the learned intermediary doctrine in a failure-to-warn suit where a patient suffered a stroke in response to taking an oral contraceptive. The court reasoned that because patients play an active role in determining which birth control pill they prefer, the prescribing physician is “relegated to a relatively passive role.” The court therefore held that because of the “peculiar characteristics” of oral contraceptives, the drug manufacturer bore the duty to directly warn patients of the risks associated with the medication.

Similar to mass immunizations, the physician does not play a large role in determining what kind of contraceptive a patient will use. Additionally, unlike most prescription drugs, oral contraceptives are entirely elective. Therefore, prescriptions for such drugs are less based on a physician’s independent assessment of the best option to treat a patient’s illness and more derived from a patient’s personal request for a specific product. Furthermore, jurisdictions that recognize an exception to the learned intermediary doctrine do so in part because there is limited physician involvement during the course of the contraceptive’s use, unlike most therapeutic drug treatments.

75. See Schwartz et al., supra note 67, at 359 (explaining that the mass immunization method resembles an “assembly-line”); see also Loidolt et al., supra note 19, at 8 (stating that often in mass immunization situations, such as in Reyes, physicians do not even administer the vaccines).
76. See Casey, supra note 57, at 949 (explaining that the rationale for manufacturers being required to directly warn patients is that patients must have the information to properly balance the benefits and risks of immunization for themselves).
77. Id. at 944.
79. Id. at 69.
80. Id.
82. See Casey, supra note 57, at 942 (referring to oral contraceptive prescriptions as “product[s] of patient demand”). Schwartz et al., supra note 67, at 360.
83. See Casey, supra note 57, at 949 (explaining that this limited involvement may not provide patients with the opportunity to discuss the medication with the prescribing physician); Cheney, supra note 27, at 586.
III. DIRECT-TO-CONSUMER ADVERTISING OF PHARMACEUTICALS

“Direct-to-consumer advertising” refers to promotional materials directed at consumers, rather than physicians, and includes such methods as broadcast, print, and Internet advertising. This form of advertising is only legal in two countries: the United States and New Zealand. In 1985, the United States legalized direct-to-consumer advertising for pharmaceuticals. While that method of advertising gradually began to grow in popularity from that time, such advertising did not truly begin to flourish until 1997, when the Food and Drug Administration (FDA) issued its guidance that relaxed certain criteria required to meet regulatory standards.

Since that guidance was finalized in 1999, direct-to-consumer advertising of prescription drugs has grown rapidly. In the United States, the average television viewer will view up to sixteen hours of direct-to-consumer advertisements for prescription drugs each year. This influx of advertisements has increased the utilization of pharmaceuticals in the U.S. generally. Despite the prevalence of direct-to-consumer advertisements for pharmaceuticals, the FDA has been slow to adopt enforceable regulations that adequately ensure those advertisements do not mislead consumers.

84. See U.S. GOV’T ACCOUNTABILITY OFFICE, supra note 10, at 8 (differentiating between direct-to-consumer and “consumer-directed advertising,” which is designed be provided to patients by physicians).
85. Id.
87. U.S. GOV’T ACCOUNTABILITY OFFICE, supra note 10, at 10 n.17 (2006). Specifically the guidance, finalized in 1999, provided that pharmaceutical manufacturers could meet the “adequate provision” requirement by providing complete information in a drug’s labeling through alternatives such as the manufacturer’s web site or a toll-free number. Id.
88. See Palumbo & Mullins, supra note 86, at 423.
89. See Dominick L. Frosch et al., Creating Demand for Prescription Drugs: A Content Analysis of Television Direct-to-Consumer Advertising, 5 ANNALS OF FAMILY MED. 6, 6 (2007) (commenting that this is far more time than the average American spends with their physician every year).
91. Id. at 27. This is in part due to the fact that the FDA only reviews a small segment of the direct-to-consumer materials it receives because the review group is composed of only seven staff members. Additionally, the influx of direct-to-consumer advertising coupled with limited resources allocated to review means that the process of drafting and issuing regulatory letters takes longer and the FDA issues fewer letters per year. In fact, the nineteen regulatory letters issued between 2004 through 2005 were sent out an average of eight months after the materials were first disseminated to consumers. Id. at 5–6.
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A. Current FDA Regulation of Direct-to-Consumer Advertising

The FDA, through the Division of Marketing, Advertising, and Communications (DDMAC),\(^{92}\) is responsible for implementing the rules regulating prescription drug advertising.\(^{93}\) Specifically, the DTC Review Group of the DDMAC monitors direct-to-consumer advertising.\(^{94}\) The FDA delineates three separate forms of direct-to-consumer advertising: reminder advertisements, help-seeking advertisements, and product-claim advertisements.\(^{95}\) Reminder advertisements simply alert consumers to the name of the product, without giving further information, while help-seeking advertisements inform consumers of a medical condition without naming any specific product.\(^{96}\) Product-claim advertisements\(^{97}\) market the product's name, its efficacy, and its risks.\(^{98}\)

Product-claim advertisements must provide “a true statement of information in brief summary,” presenting the effectiveness, side effects, and contraindications of the advertised drug.\(^{99}\) Additionally, that brief summary must be “fairly balanced,” meaning that the entire advertisement must provide consumers with an accurate and balanced statement of the risks and benefits of the drug.\(^{100}\) There is, however, an exception for broadcast advertisements, which do not have to meet the brief summary requirement. Instead, broadcast advertisements must only include the major side effects and contraindications of the drug if the advertisement makes “adequate provision” to provide consumers with access to the information in the drug labeling.\(^{101}\)

While the FDA does not require drug manufacturers to submit ads before public release, some companies voluntarily submit the ads to obtain advisory commentary from the FDA.\(^{102}\) The DDMAC regulates direct-to-consumer advertising primarily by monitoring drug advertisements as they are released.\(^{103}\) If the DDMAC finds that an advertisement is in violation of an FDA regulation, the

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\(^{92}\) The DDMAC is a division of the Center for Drug Evaluation and Research (CDER). Palumbo, supra note 86, at 429.

\(^{93}\) See id. (explaining that the regulations do not differentiate between direct-to-consumer advertising and general drug advertising).

\(^{94}\) U.S. GOV’T ACCOUNTABILITY OFFICE, supra note 10, at 10.


\(^{96}\) Id.

\(^{97}\) This Comment is largely focused on this form of direct-to-consumer advertising.


\(^{101}\) This is due in part to the fact that the average length of broadcast product-claim ads (fifty-one seconds) makes it difficult to provide consumers with every side effect or contraindication. See Frosch, supra note 89 (discussing average ad lengths); 21 C.F.R. §202.1(e)(1) (2008); U.S. GOV’T ACCOUNTABILITY OFFICE, supra note 10, at 9–10.

\(^{102}\) Palumbo & Mullins, supra note 86, at 429.

\(^{103}\) See id. ("Concerned citizens, healthcare practitioners, and competitor pharmaceutical companies are invited to alert the agency to questionable advertisements.").
FDA may choose to issue a letter to the drug manufacturer disseminating the advertisement. There are two forms of letters that the DDMAC may issue to alert drug companies of a violation. A notice-of-violation letter is sent to pharmaceutical manufacturers when an advertisement contains only minor violations. However, when a violation is more serious, the DDMAC will issue a letter warning that the FDA will seek recourse if the manufacturer does not correct the ad or pull it entirely.

B. Benefits and Drawbacks of Direct-to-Consumer Advertising: Differing Perspectives

Direct-to-consumer advertising is a controversial method of advertising. The benefits it affords to some groups create risks to others. While it is unclear whether the benefits of this model of advertising outweigh the drawbacks, direct-to-consumer advertising of pharmaceutical medications is clearly an ever-present part of modern society.

The pharmaceutical industry, on the whole, is supportive of the use of direct-to-consumer advertising for pharmaceuticals. First, direct-to-consumer advertising “is highly cost effective,” which provides pharmaceutical manufacturers with an obvious financial incentive to support its continued use. In fact, every $1.00 spent on television advertisements yields $1.69 in drug sales, while magazine advertising yields $2.51 in drug sales for every $1.00 spent. Additionally, the pharmaceutical industry urges that direct-to-consumer advertising is beneficial for patients and the public in that it “start[s] a dialogue between patients and physicians.”

When consumers are better educated about...
treatment options, they are likely to be more comfortable visiting doctors, which leads to early detection of disease and higher levels of compliance with physician orders.116 The pharmaceutical industry argues that direct-to-consumer advertising promotes competition amongst different products.117 This in turn provides consumers with a wide variety of options in medical treatment. A competitive market also encourages innovation and improvement in treatment options leading to higher quality medications for consumers.118 The industry explains that this will ultimately result in lower overall healthcare costs for consumers.119

Consumers, on the other hand, are less supportive of direct-to-consumer advertising, expressing mixed emotions over the use of such a method to promote prescription drugs.120 Consumer groups express support for the advertising because it promotes patient communication with physicians and encourages individuals to seek medical treatment.121 However, concerns that direct-to-consumer advertising is not objective, providing patients with only selective information about treatment options and thus limiting the consumer’s ability to make an informed decision regarding his or her healthcare, limits this support. An additional concern for consumers is the inherent conflict of interest that exists in relying on the advertiser to provide objective information to the consumer, when ultimately the purpose of advertising is to increase profits.122

Insurance and managed care groups have voiced the most apprehension over the use of direct-to-consumer advertising for pharmaceutical medications.123 Direct-to-consumer advertising encourages the use of the newest, brand-name drugs—often the most expensive drugs on the market.124 This expense not only

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118. Id. at 436–37.
119. Id. at 436.
120. Id. at 436–37.
121. Id. at 440.
123. See Palumbo & Mullins, supra note 86, at 438 (“[T]hese ads are primarily calculated to encourage increased consumption of the advertised products.”); see also Barbara Mintzes, Direct to Consumer Advertising is Medicalising Normal Human Experience, 324 BMJ 908, 908 (2002) (“[T]here is] an inherent conflict of interest between the legitimate business goals of manufacturers and the social, medical and economic needs of providers and the public to select and use drugs in the most rational way.”).
124. See Palumbo & Mullins, supra note 86, at 437 (describing their apprehensive view of the advertising).
125. Michael D. Dalzell, Direct-to-Consumer Advertising: Can Everyone’s Interests Be Balanced?,
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increases the price consumers will pay for their medications, but more importantly, it drives up the cost of health insurance for everyone. The Health Insurance Association of America has indicated that direct-to-consumer advertising places a “burden” on physicians to prescribe drugs that are requested regardless of the efficacy or cost. In the U.S., the third-party-payer system provides physicians with “no financial incentives to limit prescription drug costs,” which impacts the way physicians prescribe. Furthermore, insurance companies and managed care organizations often feel pressured by patients to add the highly advertised, expensive drugs to their formularies. Ultimately, those most directly affected by direct-to-consumer advertising of prescription drugs are physicians.

Studies have shown that the advertisements have “limited educational value and may oversell the benefits of drugs in ways that might conflict with promoting population health.” This leads to unreasonable patient expectations and increased pressure on physicians to prescribe certain advertised drugs when requested. Specifically, a 2007 study in the Annals of Family Medicine analyzing the methodology and impact of direct-to-consumer advertising for pharmaceuticals found that, on the whole, the ads provided limited information about the disease itself, including the causes and who may be at risk. Additionally, many ads portrayed characters who “lost control” of their lives without the medication. Finally, the study concluded that overall, the ads tended to minimize the value of lifestyle changes as a method of improving health.

Furthermore, direct-to-consumer advertising of pharmaceuticals has led to the medicalization of the human experience. Medicalization is defined as the “process by which non-medical problems become defined and treated as medical


126. See id. at 31–32 (arguing that flat fees increase demand for expensive drugs, thereby increasing costs for providers of managed care plans).
128. See Jun Yan, DTC Advertising Going Global, but Not Without Controversy, PSYCHIATRIC NEWS, May 16, 2008 (on file with the McGeorge Law Review) (explaining that “physicians behave differently in these systems”).
130. See Yan, supra note 128 (discussing the fact that physicians must “negotiate” with patients since the advent of direct-to-consumer advertising).
131. Frosch, supra note 89.
132. Terzian, supra note 129, at 158.
133. Frosch, supra note 93.
134. Id.
135. Id.
136. Mintzes, supra note 123.
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problems, usually in terms of illnesses and disorders."\textsuperscript{137} The influx of direct-to-consumer advertising increases the use of prescription medications for symptoms that were traditionally treated by over-the-counter methods or other alternative remedies.\textsuperscript{138} Many physicians are concerned that such advertising creates an overreliance on prescription drugs by otherwise-healthy patients.\textsuperscript{139}

IV. A TREND TOWARD A NEW EXCEPTION TO THE LEARNED INTERMEDIARY DOCTRINE FOR DIRECT-TO-CONSUMER ADVERTISING: THE DEVELOPMENT OF CASE LAW

While the learned intermediary doctrine remains a fundamental tenet of legal jurisprudence, in the past decade and a half, two courts have been willing to weaken the doctrine: the first by creating yet another exception to the doctrine in cases where pharmaceutical manufacturers use direct-to-consumer advertising, and the second by rejecting the doctrine completely.\textsuperscript{140}

A. Perez v. Wyeth Laboratories: “The Beginning of the Break in the Dam?”\textsuperscript{141}

In 1999, the Supreme Court of New Jersey, in Perez v. Wyeth Laboratories Inc., became the first high court in the U.S. to create an exception to the learned intermediary doctrine for manufacturers utilizing direct-to-consumer advertising of prescription drugs, when it barred the defendant pharmaceutical manufacturer from invoking the doctrine in a failure-to-warn case.\textsuperscript{142} In Perez, the plaintiffs sued the manufacturer of Norplant contraceptive for failing to adequately warn consumers about the side effects of the medication.\textsuperscript{143} Crucial to the court’s decision was the fact that Wyeth had undertaken a massive advertising campaign directed at consumers, not physicians.\textsuperscript{144}

The court held that in situations where a manufacturer utilizes advertising methods aimed at the consumer instead of the physician, the manufacturer cannot

\textsuperscript{137} Id. An example of medicalization is exemplified by a seventy-nine percent increase in visits to U.S. doctors for baldness between 1997 and 1998 following a direct-to-consumer advertising campaign for Propecia. Id. This increase displays the effect of such advertisements in encouraging “healthy” people to believe they need medical attention. Id.

\textsuperscript{138} Id. at 909.

\textsuperscript{139} See id. at 908 (explaining that the most dangerous aspect of direct-to-consumer advertising is that it “encourage[s] healthy people to believe they need medical attention.”).

\textsuperscript{140} See generally Perez v. Wyeth Labs. Inc., 734 A.2d 1245 (N.J. 1999) (articulating an exception for direct-to-consumer advertising); see also State ex rel. Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899 (W. Va. 2007) (rejecting the learned intermediary doctrine entirely).

\textsuperscript{141} Brienza, supra note 15.

\textsuperscript{142} Id. See generally Perez, 734 A.2d at 1263 (holding that direct marketing of prescription drugs to patients “generates a corresponding duty requiring manufacturers to warn.”).

\textsuperscript{143} Perez, 734 A.2d at 1248.

\textsuperscript{144} Id.
shield itself behind the learned intermediary doctrine if it fails to provide adequate warnings and information about the side effects of the product.\textsuperscript{145} Articulating its reasoning, the court stated that the current “medical-legal jurisprudence is based on images of health care that no longer exist.”\textsuperscript{146} The court reasoned that changes brought on by direct-to-consumer advertising included the redefinition of the traditional doctor–patient relationship and increased channels of direct communication between manufacturers and consumers.\textsuperscript{147} While \textit{Perez} created another exception to the learned intermediary doctrine, it held that a rebuttable presumption of adequate warning would apply when a manufacturer complied with FDA advertising, labeling, and warning requirements.\textsuperscript{148} Finding that such a standard was “fair and balanced,” the court held that a rebuttable presumption would protect pharmaceutical manufacturers from being “guarantors” against side effects that manufacturers are unable to anticipate.\textsuperscript{149} While some at the time viewed this holding as a victory for plaintiffs, in reality it has had a limited impact.\textsuperscript{150} By establishing a rebuttable presumption that a warning is adequate, the rule makes it very difficult for plaintiffs to even survive summary judgment.\textsuperscript{151} Nonetheless, the narrow exception fashioned by the \textit{Perez} court would not be the last time a court would find an exception for direct-to-consumer advertising.\textsuperscript{152}


In 2007, the West Virginia Supreme Court of Appeals was the next court to undermine the strength of the learned intermediary doctrine.\textsuperscript{153} In \textit{State ex rel. Johnson & Johnson Corp. v. Karl}, the high court went further than the \textit{Perez} court and declined to adopt the learned intermediary doctrine altogether.\textsuperscript{154} Faced with a product liability suit for failure to warn filed by the estate of a woman who

\begin{itemize}
  \item \textsuperscript{145} See \textit{id.} at 1253–58 (discussing the reasons for creating such an exception including changes in modern medical care).
  \item \textsuperscript{146} \textit{id.} at 1246.
  \item \textsuperscript{147} See \textit{id.} at 1247, 1255 (“The question in this case . . . is whether our law should follow these changes in the marketplace or reflect images of the past.”).
  \item \textsuperscript{148} \textit{id.} at 1259.
  \item \textsuperscript{149} \textit{id.} By establishing this rebuttable presumption to avoid imposing liability for unknown risks, the court went further than needed to address the issue.
  \item \textsuperscript{151} See \textit{id.} at 816 (explaining that compliance with FDA standards is “virtually dispositive” of the claims).
  \item \textsuperscript{152} See generally \textit{State ex rel. Johnson & Johnson Corp. v. Karl}, 647 S.E.2d 899 (W. Va. 2007) (eliminating the application of the learned intermediary doctrine outright).
  \item \textsuperscript{153} \textit{id.} at 914.
  \item \textsuperscript{154} \textit{id.}
\end{itemize}
died while using the heartburn medication Propulsid,\textsuperscript{155} the court agreed with \emph{Perez} and found that the justifications for the doctrine were “outdated and unpersuasive.”\textsuperscript{156}

The court reasoned that the open channels of communication created by the advent of direct-to-consumer advertising established that there was no “substantial impediment” to manufacturers themselves providing adequate warnings to consumers.\textsuperscript{157} The opinion asserted that imposing the general duty to warn consumers directly upon pharmaceutical manufacturers was “in the best interest[s] of the public.”\textsuperscript{158} The court found that given the financial benefits afforded to pharmaceutical manufacturers through direct-to-consumer advertising, manufacturers—rather than patients or physicians—should bear the ultimate burden of adequately warning consumers of the risks of their products.\textsuperscript{159} This decision was “revolutionary” in many ways, making West Virginia the first state whose high court refused to adopt the doctrine altogether.\textsuperscript{160} It has laid the foundation for the twenty-eight other states whose high courts or legislatures have not expressly adopted the doctrine to consider an outright rejection in the future.\textsuperscript{161}

\subsection*{C. The Impact of the “Trend” on the Continued Vitality of the Learned Intermediary Doctrine}

At the time of the \emph{Perez} decision in 1999, and then again after \emph{Karl} in 2007, lawyers and legal scholars anticipated that each decision would have a “tremendous effect nationwide.”\textsuperscript{162} However, neither opinion has brought about the enormous change in jurisprudence that was once predicted.\textsuperscript{163} In fact, since

\begin{itemize}
  \item \textsuperscript{155} \textit{Id.} at 901.
  \item \textsuperscript{156} \textit{Id.} at 906.
  \item \textsuperscript{157} \textit{See id.} at 913 (describing the effective methods that manufacturers have developed to communicate directly with consumers).
  \item \textsuperscript{158} \textit{See id.} at 913–14 (describing such advertising as a “very profitable venture” for manufacturers, but as creating increased exposure to harm for consumers).
  \item \textsuperscript{159} \textit{See id.} at 913.
  \item Finally, because it is the prescription drug manufacturers who benefit financially from the sales of prescription drugs and possess the knowledge regarding the potential harms, and the ultimate consumers who bear the significant health risks of using those drugs, it is not unreasonable that prescription drug manufacturers should provide appropriate warnings to the ultimate users of their products. \textit{Id.}
  \item \textsuperscript{160} Fogt, \textit{supra} note 41, at 601; \textit{see also} Schwartz et al., \textit{supra} note 67, at 364 (describing how the ruling expanded the analysis of \textit{Perez}).
  \item \textsuperscript{161} Johnson & Johnson, 647 S.E.2d at 903–04.
  \item \textsuperscript{162} Brienza, \textit{supra} note 15.
  \item \textsuperscript{163} \textit{See} Fogt, \textit{supra} note 41, at 599 (explaining that some jurists viewed \textit{Karl} as the “harbinger[] of things to come”); \textit{see also} Aaron D. Twerski, \textit{Liability for Direct Advertising of Drugs to Consumers: An Idea Whose Time Has Not Come}, 33 Hofstra L. Rev. 1149, 1150–51 (2005) (describing \textit{Perez} effect on the learned
\end{itemize}
Perez, there have been no reported New Jersey opinions in which a court has applied the direct-to-consumer advertising exception to find a pharmaceutical manufacturer liable. Additionally, outside of New Jersey and West Virginia, no other state has adopted a categorical carve-out to the learned intermediary doctrine for direct-to-consumer advertising. However, several courts, in dicta, have applauded the reasoning applied in Perez and Karl, suggesting growing support for fashioning an exception to the doctrine for direct-to-consumer advertising.

V. DIRECT-TO-CONSUMER ADVERTISING: UNDERMINING THE JUSTIFICATIONS FOR THE LEARNED INTERMEDIARY DOCTRINE

The proliferation of direct-to-consumer advertisements for prescription drugs has undermined the justifications for the learned intermediary doctrine. In fact, “when all of its premises are absent . . . the learned intermediary doctrine . . . simply drops out of the calculus.”

A. Direct-to-Consumer Advertising Has Fundamentally Altered the Doctor–Patient Relationship

As the Perez court so aptly stated, the “Norman Rockwell image of the family doctor no longer exists.” With the advent of informed consent, patients are playing a larger role in their medical decisions such that in today’s society, the decision to take a prescription drug is not simply an issue of a trained intermediary doctrine as “the case that broke the dam”).

164. Fogt, supra note 41, at 596.
165. See Beale v. Biomet, 492 F. Supp. 2d 1360, 1376 (S.D. Fla. 2007) (rejecting the argument to follow Perez because “no other state has followed suit”; see also In re Meridia Prods. Liab. Litig., 328 F. Supp. 2d 791, 812 n.19 (N.D. Ohio 2004) (finding that the court “could not apply Perez’s logic” because no other state had done so).
166. See, e.g., In re Meridia Prods. Liab. Litig., 328 F. Supp. 2d at 812 n.19 (describing Perez as “well-reasoned”); Rimbert v. Eli Lilly & Co., 577 F. Supp. 2d 1174, 1214–15 (D. N.M. 2008) (predicting that the New Mexico Supreme court would reject the learned intermediary doctrine like West Virginia had done in Karl); Centocor, Inc. v. Hamilton, 310 S.W.3d 476, 508 (Tex. Ct. App. 2010) (agreeing that the justifications for the doctrine are “unpersuasive when considered in light of direct marketing to patients”).
168. Id.
169. Id. at 1255 (quoting Paul D. Rheingold, The Expanding Liability of the Drug Manufacturer to the Consumer, 40 FOOD DRUG COSM. L.J. 135, 136 (1985)).
170. See Canterbury v. Spence, 464 F.2d 772, 782 (D.C. Cir. 1972) (“We now find, as a part of the physician’s overall obligation to the patient, a similar duty of reasonable disclosure of the choices with respect to proposed therapy and the dangers inherently and potentially involved.”).
physician’s medical judgment. The expansion of direct-to-consumer advertising has further transformed the doctor–patient relationship.

Direct-to-consumer advertising of pharmaceutical drugs “appears to affect prescribing volume as well as product choice.” In fact, an FDA survey found that forty-seven percent of U.S. physicians surveyed admitted to feeling pressured by patients to prescribe requested advertised drugs, and ninety-two percent could recall at least one patient who wanted to discuss an advertised drug during an appointment.

A consumer’s increased exposure to these advertisements is closely correlated to an increase in requests for specific name-brand drugs. Studies have found that such a request often results in a prescription for the requested drug. These conversations between physicians and patients, fueled by increased direct-to-consumer advertising, are not always amicable, with sixty-two percent of U.S. physicians claiming that direct-to-consumer advertising has caused tension between the surveyed doctor and a patient. Furthermore, the practice of pharmaceutical manufacturers “gifting” physicians in an attempt to increase prescription drug sales provides additional evidence that the doctor–patient relationship has been substantially altered.


172. See Terzian, supra note 129, at 158 (describing the pressures felt by physicians to prescribe certain types of requested drugs over others).


175. DTCA, supra note 173.

176. Id. at 412. See U.S. GOV’T ACCOUNTABILITY OFFICE, supra note 10, at 15–16. The GAO reviewed surveys of physicians and patients and found that “[ninetynine percent] of consumers report[ed] having seen a DTC advertisement. . . . [About thirty percent] reported discussing with their physician either the condition seen in an advertisement or an advertised drug. Of [these consumers], about one quarter . . . reported requesting a prescription for the advertised drug.” And of these requests, more than half were granted. Id.

177. Metzl, supra note 177.

178. Calabro, supra note 20, at 2258–59. Gifting is the practice of pharmaceutical companies indirectly giving physicians incentives to prescribe specific drugs by providing them with gifts, ranging anywhere from pens and notepads branded with logos to expensive dinners and exotic vacations. Such practices have been found to impact prescribing patterns. When gifting is coupled with direct-to-consumer advertising, physicians are often unable to make completely independent determinations when prescribing. Id. The Office of Inspector General for the U.S. Department of Health and Human Services developed a voluntary compliance program guidance document for pharmaceutical manufacturers. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23737 (May 5, 2003). The document articulates the risks of gifting and suggests that “any time a pharmaceutical manufacturer provides anything of value to a physician who might prescribe the manufacturer’s product, the manufacturer should examine whether it is providing a valuable tangible benefit to the physician with the intent to induce or reward referrals.” Id.
Combined, all of these changes in the doctor–patient relationship clearly undermine a physician’s ability to function as a learned intermediary. The paternalistic relationship that once existed between physicians and their patients has disappeared. These changes demand a reconsideration of the continued vitality of the long-standing learned intermediary doctrine because our jurisprudence must not “reflect . . . images of the past.”

B. Changes in the Healthcare System and Rise of Managed Care Organizations Have Reduced the Ability of the Physician to Act as a “Learned Intermediary”

The structure of managed care organizations acts to limit the time available for doctors to spend with their patients in an attempt to make healthcare more cost-effective. More specifically, managed care systems encourage physicians to spend less time per patient visit and to limit the type of care regularly provided. Shorter visits mean that physicians are left with less time to consider the treatment options available to a patient based on that patient’s personal medical history. Without time to adequately weigh alternatives, a physician cannot be said to be in the best position to act as a learned intermediary.

Furthermore, these organizations utilize preferred drug programs that have the effect of constraining physicians’ independence in prescribing medications. In fact, oftentimes, physicians will need authorization to prescribe non-preferred drugs. The pressures created by a managed care health system further undermine the foundation for the learned intermediary doctrine, as physicians are less able to provide the personalized and independent medical opinions regarding prescription drug treatments that the doctrine had originally envisioned.

179. Id. at 2259.
181. Id. at 1247.
182. See id. at 1255 (explaining that a 1997 survey by the FDA found that only one-third of 1000 patients received information from their doctors about side effects of the drugs they were prescribed); Nancy S. Jecker & Clarence H. Braddock III, Managed Care, U. WASH. ETHICS IN MED., http://depts.washington.edu/bioethx/topics/manag.html (last modified Apr. 11, 2008) (on file with the McGeorge Law Review).
185. See Calabro, supra note 20, at 2266 (“[Managed care organizations] impose[e] third party payor constraints on a physician’s independent, professional judgment. Specifically, capitation, which involves HMO payment of a predetermined fee to the physician for each patient under the physician’s care, is a particularly troublesome practice.”).
186. Paytash, supra note 183, at 1358.
187. Id.
188. See generally Perez v. Wyeth Labs. Inc., 734 A.2d 1245, 1255 (N.J. 1999) (explaining that the premises underlying the learned intermediary doctrine are absent in direct-to-consumer advertising situations).
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C. Direct-to-Consumer Advertising Has Created a Direct Channel of Communication Between Manufacturer and Patient

Spending on direct-to-consumer advertising has grown exponentially over the last decade. The influx in advertising directly increases drug utilization and spending. This increase in direct-to-consumer advertising challenges the argument that it is impossible for manufacturers to warn consumers directly of a product’s risks.

When put in perspective, the learned intermediary doctrine is “itself an exception to the manufacturer’s traditional duty to warn consumers directly of the risk associated with any product . . . .” Manufacturers who communicate directly with consumers by way of advertisements cannot be said to be any less able than other product manufacturers to provide adequate warnings to consumers directly. In products liability law generally, consumer-directed advertising has played a significant role in determining the duties of all manufacturers. In Henningsen v. Bloomfield Motors, Inc., the New Jersey Supreme Court held that a manufacturer’s duty runs directly to consumers when it advertises its products directly to its consumers. The court reasoned that such marketing provided a means of communication sufficient for the manufacturer to convey adequate warnings to the consumers. The reasons for applying such a rule to automobile manufacturers applies with equal force to pharmaceutical manufacturers who engage in the lucrative practice of direct-to-consumer advertising.

However, many proponents of the learned intermediary doctrine argue that, regardless of all of these changes, the physician is still in the best position to

189. See U.S. GOV’T ACCOUNTABILITY OFFICE, supra note 10, at 13 (finding that between 1997 and 2005, spending on direct-to-consumer advertising has increased 296.4%).
190. Id. at 14.
191. See Perez, 734 A.2d at 1255–56 (questioning the validity of the argument that manufacturers are unable to communicate the risks of their products directly to consumers).
192. Id. at 1256 (quoting Edwards v. Basel Pharm., 116 F.3d 1341, 1343 (10th Cir. 1997)).
193. See RESTATEMENT (SECOND) OF TORTS § 388 (1965) (explaining the general rule for when warnings must be given directly to consumers by manufacturers); see also Moran Schwartz, supra note 171, at 840 (articulating that, because promotion has changed, the doctrine does not “reflect the reality of new marketing practices”).
194. Perez, 734 A.2d at 1257.
196. Id. at 84.
As has been observed above, a number of jurisdictions, conscious of modern marketing practices, have declared that when a manufacturer engages in advertising in order to bring his goods and their quality to the attention of the public and thus to create consumer demand, the representations made constitute an express warranty running directly to a buyer who purchases in reliance thereon.
197. Moran Schwartz, supra note 171, at 841.
know an individual patient’s needs. While this is true, absolving manufacturers of any responsibility for communicating warnings directly to patients eliminates the burden that manufacturers of all other products bear when they market dangerous yet profitable items to consumers. Furthermore, even without the doctrine in place to shield manufacturers from liability, the principle of informed consent imposes an independent duty on physicians to utilize their unique position to inform patients of the risks associated with treatment options, including prescription drug treatments.

Changes in the traditional doctor–patient relationship, coupled with the rise of managed care and increased communication between manufacturers and consumers, suggest that the time has come for pharmaceutical manufacturers to provide warnings in the same way that they market their products: directly to consumers.

VI. REALIGNING OUR LEGAL JURISPRUDENCE FOR THE MODERN MEDICAL LANDSCAPE: A CALL FOR CHANGE

Some have called into question the learned intermediary doctrine’s continued effectiveness at adequately warning patients of the risks of pharmaceuticals. There have been dramatic changes in healthcare and the doctor–patient relationship, particularly in a world of billion dollar-marketing campaigns funded by pharmaceutical manufacturers and aimed directly at consumers. Further complicating this fact, the FDA, the only agency charged with regulating direct-to-consumer advertising, has been ineffective at stopping the publication of violative advertisements. With the roles of patients, doctors, and manufacturers shifting, courts must reconsider the allocation of risk under the doctrine to ensure that responsible parties bear the consequences of their actions.

198. Calabro, supra note 20, at 2252.
199. Id. at 2241–42.
201. Calabro, supra note 20, at 2250–51 (explaining that the learned intermediary doctrine is unlike traditional product liability norms and has created a unique “safe haven” for manufacturers of pharmaceuticals).
203. See supra Part V (discussing the changes brought on by direct-to-consumer advertising).
204. See Bulletin, supra note 10(examining the $260 million ad campaign Pfizer funded to promote the cholesterol drug Lipitor).
206. See Calabro, supra note 20, at 2299 (describing how risk allocation is an important factor in determining where liability should fall).
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A. The Limits of Adopting Perez’s Rebuttable Presumption

The New Jersey Supreme Court in Perez created an exception to the learned intermediary doctrine in cases where pharmaceutical manufacturers engage in direct-to-consumer advertising of their products. However, the court also articulated that a warning would be presumed adequate when a manufacturer complied with FDA advertising, labeling, and warning requirements. This method is problematic for two reasons.

First, the current regulatory scheme under the FDA is unable to effectively ensure that inadequate or misleading warnings do not reach consumers. The FDA only reviews a small number of the direct-to-consumer advertisements actually submitted to the agency. Furthermore, the FDA’s method for ensuring that the highest-priority advertisements are reviewed is inadequate. The agency takes an average of four months to issue regulatory letters for violative advertisements. Furthermore, the FDA has been issuing fewer regulatory letters per year, decreasing from ninety-eight letters between 1997 and 2001 to thirty-seven letters between 2002 and 2005. Both the increasing time to issue letters and the decreasing volume of letters produced have created an inefficient regulatory scheme. By the time that the FDA issues regulatory letters, many of the violative advertisements have been available to consumers for several months. Additionally, a drug company generally does not comply with an FDA request to issue corrective advertisements until at least five months after the agency issues such a request. Finally, studies show that FDA regulatory letters are ineffective at deterring subsequent publishing of violative direct-to-consumer advertisements for the same drug. Overall, the current FDA regulatory scheme is limited in its effectiveness at reducing “consumers’ exposure to false or misleading [direct-to-consumer] advertising.” As such, creating a presumption

207. See Perez, 734 A.2d at 1253–58 (discussing the reasons for creating such an exception).
208. See id. at 1259 (explaining that the presumption is rebuttable).
209. U.S. GOV’T ACCOUNTABILITY OFFICE, supra note 10 at 27.
210. See id. at 19 (“[T]he agency receives substantially more final and draft materials than the DTC Review Group can review.”).
211. See id. at 20 (explaining that instead they rely on the few reviewers on the DTC review staff to track which advertisements have been reviewed and to be sure that they are handling the highest priority ads first).
212. See id. at 21–22 (explaining that this is due to the 2002 policy change that requires legal review of all regulatory letters before they can be issued to drug companies).
213. Id. at 25.
214. Id. at 28.
215. Id.
216. Id. at 30.
217. Id. at 31.
218. See id. at 34 (recommendling that the FDA “document criteria for prioritizing materials that it receives for review, systematically apply its documented criteria to all of the materials it receives, and track which materials have been reviewed”).
that warnings are adequate for failure-to-warn suits if pharmaceutical manufacturers comply with FDA advertising requirements does little to protect consumers from harm.\(^{219}\) Courts should hardly deem such warnings adequate solely because they comply with a clearly inadequate regulatory scheme.\(^{220}\)

Second, a rebuttable presumption of adequacy makes it difficult, if not nearly impossible, for plaintiffs to survive summary judgment.\(^{221}\) Indeed, compliance with FDA requirements is “virtually dispositive” of failure-to-warn claims brought against pharmaceutical manufacturers under the Perez standard.\(^{222}\) Further, it would be a “rare case[]” for a plaintiff to successfully rebut this presumption once found.\(^{223}\) In cases where the FDA has provided a positive comment on an advertisement, courts will presume that the advertisement is adequate for liability purposes.\(^{224}\) However, in cases where no such comment has been given, courts will apply FDA regulations themselves to determine whether an advertisement is adequate.\(^{225}\)

The Perez court believed the rebuttable presumption it formulated was “fair and balanced” because it ensured that manufacturers would not be liable for every remote side effect that may or may not be warned against.\(^{226}\) In doing so, the court ensured that research and development would not be hindered and that beneficial drugs would remain available to consumers.\(^{227}\) Additionally, the court stated that such a system reserves compensatory damages for the limited cases where the presumption is overcome.\(^{228}\)

However, the limits of such a method for plaintiffs are clear.\(^{229}\) Faced with a “superpresumption of adequacy,” plaintiffs in failure-to-warn cases will rarely be able to survive the summary judgment stage, leaving them to seek compensation for their harm elsewhere.\(^{230}\) While the idea of creating an exception to the learned

\(^{219}\) See id. (expressing concern for consumers who are exposed to violative advertisements).

\(^{220}\) See generally id. at 6–7 (describing the FDA’s ineffectiveness at ensuring that direct-to-consumer advertisements are proper).

\(^{221}\) Dreier, supra note 150, at 825.

\(^{222}\) Perez v. Wyeth Labs. Inc., 734 A.2d 1245, 1259 (N.J. 1999) (“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.”).

\(^{223}\) Id. at 1259.

\(^{224}\) See Dreier, supra note 150, at 825 (describing a favorable FDA comment as a “de facto clearance”).

\(^{225}\) Id.

\(^{226}\) See Perez, 734 A.2d at 1259 (explaining that such as system would “have a ‘significant anti-utilitarian effect’”) (quoting Feldman v. Lederle Labs., 592 A.2d 1176, 1200 (N.J. 1991) (Garibaldi, J., dissenting)).


\(^{228}\) Perez, 734 A.2d at 1259.

\(^{229}\) See Dreier, supra note 150, at 825 (“Read properly, the Perez opinion is a victory for the defense.”).

\(^{230}\) Id.
intermediary doctrine for direct-to-consumer advertising seemed revolutionary at
the time, the method fashioned by the Perez decision has proven minimally
beneficial to patients, if at all.

B. Proposal for an Exception to the Learned Intermediary Doctrine for Direct-
to-Consumer Advertising

The drafters of the Restatement (Third) of Torts left resolving the issue of
whether to adopt an exception to the learned intermediary doctrine for direct-to-
consumer advertising to “developing case law.” Therefore, the adoption of such
an exception is not a revolutionary idea, nor entirely unfounded. Other
exceptions to the doctrine, recent case law, and changes in modern medicine support
this assertion.

Adopting an exception to the learned intermediary doctrine for direct-to-
consumer advertising by pharmaceutical manufacturers would allow the market
to regulate the use of such advertising. If manufacturers perform a cost–benefit
analysis and find the risks of liability for inadequate warnings are worth the
benefits from advertising directly to consumers, then they should bear the
consequences of their choices. Such a method would utilize a theory of risk
allocation, generally applicable to products liability cases, which shifts liability to
the party who is in the best position both to bear the risk of loss and to act to
reduce that risk in the future.

In applying this approach, a pharmaceutical manufacturer is in the best
position to bear the costs of the risks it creates—and profits from. First, the
manufacturer alone makes the profit-motivated decision to promote drugs
directly to consumers.

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231. See Fogt, supra note 41, at 596–97 (explaining that the Perez opinion was viewed by some as the
opening of “Pandora’s Box”).
232. See generally Dreier, supra note 150 (characterizing the exception as an “empty gift to plaintiffs”).
234. See discussion supra Parts II.D, IV, & V.
235. See supra Part II.D (discussing exceptions to the doctrine).
236. See supra Part IV (describing the case law that has chipped away at the doctrine).
237. See supra Part V (explaining that the use of direct-to-consumer advertising undermines the
justifications for the doctrine).
238. See Guido Calabresi, Product Liability: Curse or Bulwark of Free Enterprise, 27 CLEV. ST. L. REV.
313, 315–16 (1978) (describing risk allocation in products liability cases as a “free enterprise” method).
239. See id. at 317 (explaining that the system “lets those on whom it has placed the risk make the
decision between risk avoidance and risk bearing”).
240. Id. at 316.
241. See Mae Joanne Rosok, Comment, Direct-to-Consumer Advertising of Prescription Drugs: After A
Decade of Speculation, Courts Consider Another Exception to the Learned Intermediary Rule, 24 SEATTLE U.
L. REV. 629, 642–43 (2000) (discussing how various cases have applied this risk allocation method).
companies have engaged in this direct marketing practice.”).
many drug companies, while potentially misleading advertisements expose consumers to an increased risk of harm.\(^{243}\) Second, pharmaceutical manufacturers have the ability to shoulder the cost of increased exposure to liability by increasing their drug prices to customers.\(^{244}\) Unlike the injured consumers, manufacturers have the ability to insure themselves against potential failure-to-warn claims by treating liability as a “cost of doing business,” if they choose to do so, or refrain from advertising directly to consumers altogether.\(^{245}\) Therefore, shifting liability onto manufacturers is the proper balance between “the need for adequate recovery and viable enterprises.”\(^{246}\)

Proponents of the learned intermediary doctrine argue that such a threat of liability will drive pharmaceutical manufacturers to raise their prices to unaffordable levels or, even worse, to stop manufacturing beneficial prescription drugs completely.\(^{247}\) However, the allocation of liability should not be determined by whether a business can afford it, but on a business’s decision to bear the risks in the first place.\(^{248}\) After all, every manufacturer has the opportunity to choose between avoiding and bearing risks.\(^{249}\) In the lucrative market of pharmaceuticals, the proper allocation of risk is even more important.\(^{250}\)

Furthermore, under the doctrine of informed consent, the quality of the warnings that patients would receive from their physicians regarding the risks of any treatment, including pharmaceuticals, would be unaffected by an exception to the learned intermediary doctrine.\(^{251}\) In fact, by warning consumers directly, manufacturers would supplement the information that informed consent already requires physicians to provide,\(^{252}\) thus helping to satisfy the learned intermediary doctrine’s goal of “preventing avoidable patient injury.”\(^{253}\) In fact, enforcing such a duty to warn upon manufacturers would simply require them to accept the same

\(^{243}\) See State ex rel. Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899, 913–14 (W. Va. 2007) (explaining that consumers need more protection because of an increase in direct-to-consumer advertising).

\(^{244}\) Reyes v. Wyeth Labs., 498 F.2d 1264, 1294 (5th Cir. 1974).

\(^{245}\) Rosok, supra note 241, at 643.

\(^{246}\) Reyes, 498 F.2d at 1294.

\(^{247}\) See Fogt, supra note 41, at 606–07 (describing such a scenario as a “tragedy for society as a whole”).

\(^{248}\) See Calabresi, supra note 238, at 319–21 (describing the factors that are considered in risk allocation generally and explaining that the decision to bear a risk plays a large role in that allocation).

\(^{249}\) Id. at 317.

\(^{250}\) See Rosok, supra note 241, at 643 (describing the importance of proper risk allocation in the healthcare field).

\(^{251}\) See Canterbury v. Spence, 464 F.2d 772, 782 (D.C. Cir. 1972) (discussing the physician’s duty to disclose information to patients before beginning treatment of any kind); see also Moran Schwartz, supra note 171, at 831 (“[I]t is not sound to leave the job of informing consumers exclusively to the physician intermediary.”).

\(^{252}\) Moran Schwartz, supra note 171, at 831.

\(^{253}\) Casey, supra note 57, at 959.
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types of responsibilities we already impose upon the physicians who write the prescriptions.\(^{254}\)

VII. CONCLUSION

After a thorough examination of the background of the learned intermediary doctrine, the impacts of the influx of direct-to-consumer advertising of pharmaceutical drugs, and recent developments in case law, it is apparent that the premises for the continued application of the doctrine have been severely undermined.\(^{255}\) The upheaval of the traditional doctor–patient relationship, the rise of managed care organizations, and the increased channels of communication between manufacturers and patients each suggest that the bases for adhering to the doctrine are eroding.\(^ {256}\)

Given the changing landscape of health care, our medical–legal jurisprudence must no longer “reflect the images of the past.”\(^ {257}\) Instead, we ought to lay to rest the learned intermediary doctrine—a once-fundamental tenet of tort law\(^ {258}\)—and replace it with a more appropriate standard.\(^ {259}\) This comment calls for states to adopt an exception to the application of the learned intermediary doctrine where pharmaceutical manufacturers engage in direct-to-consumer advertising. This proposal is not as drastic or revolutionary as it may seem.\(^ {260}\) Indeed, it simply suggests that courts should subject pharmaceutical manufacturers to the same duty to warn consumers as all other manufacturers.\(^ {261}\)

\(^{254}\) State \textit{ex rel.} Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899, 914 (W. Va. 2007).
\(^{255}\) See discussion supra Parts II, III, & IV.
\(^{256}\) See supra Part V (explaining how the justifications have been undermined).
\(^{259}\) Casey, supra note 57, at 931.
\(^{260}\) See discussion supra Parts II.D, IV, & V.
\(^{261}\) See Loidolt et al., supra note 19, at 1–2 (explaining the general duty to warn for manufacturers).