

2007

“Ask Your Doctor If This Product is Right For You”: Perez v. Wyeth Laboratories, Inc., Direct-to- Consumer Advertising and the Future of the Learned Intermediary Doctrine in the Face of the Flood of Vioxx[®] Claims

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Recommended Citation

Schaecher, Corey (2007) “Ask Your Doctor If This Product is Right For You”: Perez v. Wyeth Laboratories, Inc., Direct-to-Consumer Advertising and the Future of the Learned Intermediary Doctrine in the Face of the Flood of Vioxx[®] Claims,” *Saint Louis University Public Law Review*: Vol. 26 : No. 2 , Article 10.

Available at: <https://scholarship.law.slu.edu/plr/vol26/iss2/10>

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**“ASK YOUR DOCTOR IF THIS PRODUCT IS RIGHT FOR YOU”:
PEREZ v. WYETH LABORATORIES, INC., DIRECT-TO-CONSUMER
ADVERTISING AND THE FUTURE OF THE LEARNED
INTERMEDIARY DOCTRINE IN THE FACE OF THE FLOOD OF
VIOXX® CLAIMS**

I. INTRODUCTION

A television commercial fades into a scene depicting a woman peacefully asleep with a warm smile on her face. The camera pulls back focusing on a cartoon fairy flying around the room while a deep soothing voice recounts the product’s possible risks “product may cause blood clots, heart attack, and in the extremely rare cases, stroke. To find out if this product is right for you, consult your doctor.” The viewer thinks, “Why can’t I sleep like that? I want that magical pill.” However, what consumers need to understand is that there are no magical pills. Every prescription drug is inherently coupled with risks and dangers of which consumers need to consider before swallowing pills by the handful.

Further problematic is the degree to which the average consumer heeds the brief warning at the close of the commercial once they believe the advertised product is their cure-all. Some argue that manufacturers who engage in direct to consumer advertising, the dissemination of product information from drug manufacturers directly to the end consumer, should face direct product liability because of those advertising efforts. Others, however, argue the learned intermediary doctrine, which relieves drug manufacturers of their duty to directly warn the end consumer of product dangers by instead providing warnings to prescribing physicians, should continue to shield manufacturers from liability.¹

Pharmaceutical companies employing mass direct-to-consumer advertising campaigns should remain protected by the learned intermediary doctrine as advertising techniques have not fundamentally changed the physician’s role in prescribing medications to warrant the doctrine’s elimination. A line must be drawn with respect to the degree of warning provided to the American public; manufacturers should not be required to overload consumers with product

1. See discussion *infra* at part III. Also, for a detailed discussion concerning the development of the law of liability for pharmaceutical manufacturers and FDA regulation of prescription drug approval and the learned intermediary doctrine, see Victor E. Schwartz and Phil Goldberg, *A Prescription For Drug Liability and Regulation*, 58 OKLA. L. REV. 135 (2005).

warnings in order to ensure they understand potential hazards. Undeniably, each consumer should retain the ability to read and understand product warnings and appreciate the potential side effects of the product, and corporations should by no means be permitted to misrepresent, leave out, or misconstrue their products' dangers. One commentator noted that "No one disputes that the ultimate user of any product has the right to be apprised of risks associated with that use."²

This comment will discuss whether the learned intermediary doctrine should continue to be applied considering the increase in direct-to-consumer marketing. Specifically, it will address whether an exception to the learned intermediary doctrine should be accepted for product liability claims against pharmaceutical manufacturers for failure of the duty to warn given direct-to-consumer marketing, the court's decision in *Perez v. Wyeth Laboratories, Inc.*,³ and the learned intermediary doctrine, focusing on the influx of litigation concerning the drug Vioxx.

This comment concludes that no exception to the doctrine should be provided due to the increased use of direct-to-consumer advertising because "[l]iability for inadequate warnings will almost certainly increase if courts abandon the learned intermediary rule and require drug manufacturers to warn consumers instead of physicians when they engage in direct to consumer advertising."⁴

To reach this conclusion, this comment will address the current state of the law regarding manufacturers' duty to warn, the advent of direct-to-consumer advertising, the scope of the learned intermediary doctrine, the doctrine's fate following *Perez v. Wyeth Laboratories, Inc.*, FDA regulation of pharmaceutical advertisements, and current mass tort litigation surrounding Vioxx.

II. CURRENT LAW REGARDING THE DUTY TO WARN

A. *General Overview of the Duty to Warn*

Product manufacturers and sellers are generally under a common law duty to provide adequate warning to consumers of possible dangers associated with a product's use.⁵ The duty to warn extends to a product's manufacturer, seller,

2. See discussion *infra* at part IV.

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

4. Richard C. Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?*, 37 WAKE FOREST L. REV. 97, 97 (2002).

5. RESTATEMENT (SECOND) OF TORTS § 402A (1961). It states

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if: (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or

distributor, dealer, wholesaler or supplier.⁶ Thus, non-manufacturers may be subject to liability for a product where predecessors in the distributive chain failed to provide the consumer with an adequate warning.⁷ Under the *Restatement (Second) of Torts*, the duty requires manufacturers to warn of a product's danger if the manufacturer or supplier knows (1) the product is dangerous, (2) that the danger is not obvious or known to or readily discoverable by the user, and (3) not one which arises only because the product is put to some unforeseeable or unexpected use.⁸

The duty to warn serves two specific functions. First, the duty aids in instructing consumers to proper product use in hopes of reducing injuries resulting from misuse. Secondly, by having access to the warnings, the consumer is able to make an informed choice whether to use the product and be exposed to the associated risks.⁹

However, a manufacturer's failure to provide an adequate warning renders the product unreasonably dangerous and thus subjects the manufacturer to liability for damages under strict liability.¹⁰ Though including an adequate

consumer without substantial change in the condition in which it is sold. (2) The rule stated in Subsection (1) applies although: (a) the seller has exercised all possible care in the preparation and sale of his product, and (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Id.

6. RESTATEMENT (SECOND) OF TORTS § 402A cmt. f (1965). It states

The rule stated in this Section applies to any person engaged in the business of selling products for use or consumption. It therefore applies to any manufacturer of such a product, to any wholesale or retail dealer or distributor, and to the operator of a restaurant. It is not necessary that the seller be engaged solely in the business of selling such products. Thus the rule applies to the owner of a motion picture theatre who sells popcorn or ice cream, either for consumption on the premises or in packages to be taken home.

Id.

7. J. Scott Dutcher, Comment, *CAUTION: This Superman Suit Will Not Enable You to Fly—Are Consumer Product Warning Labels Out of Control?*, 38 ARIZ. ST. L.J. 633, 635 (2006).

8. RESTATEMENT (SECOND) OF TORTS § 388 (1965). It states

One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier: (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Id.

9. JAMES A. HENDERSON & AARON D. TWERSKI, *PRODUCTS LIABILITY AND PROCESS* 337 (4th ed. 2000); Caroline L. Nadal, *The Societal Value of Prescription Drug Advertisements in the New Millennium: Targeted Consumers Become the Learned*, 9 J.L. & POL'Y 451, 457-58 (2001).

10. RESTATEMENT (SECOND) OF TORTS § 402A (1965).

warning provides protection from strict liability, warnings will not necessarily protect manufacturers from claims for product defects.¹¹ In constructing these adequate warnings, manufacturers are not required to foresee all possible uses or misuses of their products, but are only required to provide warnings to each consumer according to reasonably foreseeable uses and misuses.¹²

B. Foundational Elements of a Failure to Warn Cause of Action

Plaintiffs injured from allegedly defective products may bring failure to warn claims against the product's manufacturer, seller or distributor.¹³ To succeed, plaintiffs must establish (1) that the manufacturer, supplier, or seller knew or should have known of the dangers related to the product's intended use; (2) the product's user was reasonably unaware of these dangers; (3) the manufacturer, supplier or seller failed to exercise reasonable care to notify the consumer of the product's unsafe condition or of facts which make the product prone to be dangerous, and (4) that the risk and degree of harm was large enough to justify that a warning should have been provided.¹⁴

Under the *Restatement (Third) of Torts*, three primary methods exist for plaintiffs to establish that a product is defective.¹⁵ First, a consumer can establish a manufacturing defect in the product by proving that the product deviates from the manufacturer's design or performance standards of identical units.¹⁶ Secondly, a product may be defective by design where the injured

11. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1998); see also Dutcher, *supra* note 8, at 635.

12. Dix W. Noel, *Products Defective Because of Inadequate Directions or Warnings*, 23 SW. L.J. 256, 264 (1969) (citing *Glittenberg v. Doughboy Recreational Indus.*, 491 N.W.2d 208, 212 (Mich. 1992)).

13. RESTATEMENT (SECOND) OF TORTS § 402A (1961).

14. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) (1998).

15. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(a)-(c) (1998) It states A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product: (a) contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product; (b) is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe; (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.; see also Kenneth Ross, *Legal and Practical Considerations for the Creation of Warning Labels and Instruction Books*, 379 P.L.I. LITIG. 103, 105 (1989).

16. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(b) (1998).

party can establish that a design defect exposed the user to a reasonably preventable risk.¹⁷ Finally, the product may be deemed unreasonably dangerous due to market defects.¹⁸ Market defects include (1) the failure to provide warning of the risks or hazards of using the product, (2) *failure to provide an adequate warning of those risks or hazards*,¹⁹ or (3) failure to provide appropriate and adequate instructions and directions for safe use of the product.²⁰

C. Liability and Prescription Drug Manufacturers

Restatement (Second) of Torts places pharmaceutical drugs into a category of products designated as "unavoidably unsafe."²¹ The "unavoidably unsafe" product category of comment k is governed by a separate standard which stands as "an exception to the Restatement's general rule that one who markets goods must warn foreseeable ultimate users of dangers inherent in the product."²² Distribution of unavoidably unsafe products is rationalized on the ground that "[a]ll prescription drugs pose hazards, whether minute or great, to consumers. However, the same drugs cure life-threatening diseases, remedy crippling illnesses, alleviate physical aches, pains, and provide numerous other benefits."²³ More specifically, section 6 of the *Restatement (Third) of Torts*

17. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(c) (1998).

18. See *id.*

19. For the purposes of this note, what constitutes an inadequate warning for general consumer goods is immaterial and will not be discussed. See *infra* text accompanying notes 106-07 for a discussion of adequate warnings for pharmaceuticals.

20. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(c) (1998) (emphasis added).

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

Unavoidably unsafe products. 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 warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Id.

22. Woodside, III & Maggio, *supra* note 3, at 2; see also RESTATEMENT (SECOND) OF TORTS § 402(A) cmt. k (1969).

23. Nadal, *supra* note 10, at 459.

addresses product liability for prescription drug manufacturers²⁴ and applies only to those products sold or distributed through a health care provider prescription.²⁵

Restatement (Third) of Torts §6(d), addressing liability for defective or inadequate warnings for pharmaceuticals, provides:

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

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

(2) The patient when the manufacturer knew or had reason to know that no health care provider would be in a position to reduce the risks of harm in accordance with instructions or warnings.²⁶

An adequate warning is one that presents information about all significant risks accompanying a product's use and discloses "the actual likelihood and gravity of such risks when they are known by the manufacturer."²⁷ A warning may be deemed inadequate if the print is too small, not in a prominent position, phrased with insufficient intensity to be proportional to the danger, is ambiguous or not easily understood, not geared toward its intended audience (i.e. technical language to warn lay persons), or not communicated through appropriate channel.²⁸

Both the *Restatement (Second) of Torts* and *Restatement (Third) of Torts* suggest that drug manufacturers should not be held strictly liable for failure of

24. Michael J. Wagner & Laura L. Peterson, *The New Restatement (Third) of Torts—Shelter From the Product Liability Storm for Pharmaceutical Companies and Medical Device Manufacturers*, 53 FOOD & DRUG L.J. 225, 229 (1998).

25. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(a) (1998), stating, A manufacturer of a prescription drug or medical device who sells or otherwise distributes a defective drug or medical device is subject to liability for harm to persons caused by the defect. A prescription drug or medical device is one that may be legally sold or otherwise distributed only pursuant to a health-care provider's prescription.

Id.

26. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) (1998).

27. Ausness, *supra* note 5, at 104-05 (citing *Martinkovic v. Wyeth Labs., Inc.*, 669 F. Supp. 212, 216 (N.D. Ill. 1987)).

28. See *id.* at 105-06 (citing *Gardner v. Q.H.S., Inc.*, 448 F.2d 238, 243 (4th Cir. 1971); *D'Arienzo v. Clairrol, Inc.*, 310 A.2d 106, 111 (N.J. Super. Ct. Law Div. 1973); *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1363 (4th Cir. 1975); *Mahr v. G.D. Searle & Co.*, 390 N.E.2d 1214, 1230 (Ill. App. Ct. 1979); *Bryant v. Technical Research Co.*, 654 F.2d 1337, 1345-46 (9th Cir. 1981); *MacDonald v. Ortho Pharm. Corp.*, 475 N.E. 2d 65, 71-72 (Mass. 1985); *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978, 991-92 (4th Cir. 1975)).

the duty to warn of unknown potential dangers.²⁹ Recognizing the potential negative impacts product liability could have on a manufacturer's future research and development, courts adopted a negligence standard for imposing liability on drug manufacturers when they act unreasonably by failing to warn of dangers of which they knew or should have known.³⁰ "The test turns on whether the defendant acted as a reasonably prudent manufacturer would have acted in similar circumstances. . . .the test plainly provides that no liability results for unknown and unknowable risks."³¹

The *Restatement (Third) of Torts*, therefore, has adopted what is known as the learned intermediary doctrine, which relieves drug manufacturers of their duty to warn end consumers when adequate warnings were instead provided to prescribing physicians.³² The physicians then have the duty to warn individual patients of the drug's dangers before issuing a prescription.³³

III. DIRECT-TO-CONSUMER ADVERTISING

In 2003 alone, American pharmaceutical companies spent \$3.2 billion marketing prescription drugs directly to consumers.³⁴ Direct-to-Consumer (DTC) advertising is the dissemination of product information by pharmaceutical manufacturers directly to end consumers, subject to the control of the Food & Drug Administration (FDA).³⁵ DTC advertising employs an array of mediums, including magazines, newspapers, television, radio, and other outdoor advertising.³⁶ Marjorie Powell, General Counsel for the Pharmaceutical Research and Manufacturers of America, stated that "DTC

29. See Nadal, *supra* note 10, at 459; see also RESTATEMENT (SECOND) OF TORTS § 402(A) cmt. k (1965); RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. m (1998).

30. See Nadal, *supra* note 10, at 451.

31. Wagner & Peterson, *supra* note 25, at 234-235.

32. The learned intermediary doctrine (LID), the focus of this note, is the subject of greater discussion starting in Part IV. Also adopted by the *Restatement (Third) of Torts*, however, are several generally accepted exceptions to the LID, and one hotly contested proposed exception. The debated exception, holding manufacturers liable for failure of their duty to warn when engaging in Direct-to-Consumer (DTC) advertising, is also the subject of discussion beginning in Part IV.C.

33. See *infra* Part IV: The Learned Intermediary Doctrine.

34. See KAISER FAMILY FOUNDATION, *Prescription Drug Trends*, Oct. 2004, available at <http://www.kff.org/rxdrugs/upload/Prescription-Drug-Trends-October-2004-UPDATE.pdf> (last visited May 16, 2007).

35. See *Direct-to-Consumer Advertising of Prescription Drugs: What are the Consequences?: Hearing Before the Special Comm. on Aging*, 108th Cong. 61 (2003) (statement of Marjorie E. Powell, Senior Assistant General Counsel, Pharmaceutical Research and Manufacturers of America) [hereinafter Powell].

36. KAISER FAMILY FOUNDATION, *Impact of Direct-to-Consumer Advertising on Prescription Drug Spending*, Jun. 2003, at 4, available at <http://www.kff.org/rxdrugs/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14378> (last visited May 16, 2007) [hereinafter *Impact*].

advertising's purpose is to inform and educate consumers about treatable conditions, the symptoms that may help them identify the diseases, and available therapies."³⁷

Though hard to imagine, pharmaceuticals, unlike most products, were not always advertised directly to potential consumers.³⁸ Instead, drugs were only marketed directly to physicians who would then choose which drugs they would prescribe.³⁹ Undoubtedly, pharmaceutical advertising changed drastically with the advent of DTC advertising. "The modern era of DTC advertising really began in 1985 when [the] FDA announced that the regulations for overseeing promotion to doctors provided sufficient safeguards to protect consumers, as well. After this, increasing numbers of DTC print advertisements appeared."⁴⁰

DTC advertising further evolved in the 1980s with the infamous product Rogaine®, manufactured by the Upjohn Company, the first prescription drug to be advertised on television.⁴¹ Following Upjohn's marketing breakthrough, "almost all pharmaceutical companies have engaged in this direct marketing practice."⁴² In 1997, further changes in FDA regulations, which removed the requirement that broadcast advertisements must state all product information, also had a significant impact on the use of DTC advertising.⁴³ The new regulations regarding broadcast advertisements provided manufacturers the ability to promote specific products on television and radio with less information regarding side effects than what was required of print ads.⁴⁴ By eliminating the full disclosure requirement, the FDA provided the industry

37. Powell, *supra* note 36, at 61.

38. See *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245, 1246-47 (N.J. 1999) ("Our medical-legal jurisprudence is based on images of health care that no longer exist. At an earlier time, medical advice was received in the doctor's office from a physician who most likely made house calls if needed. The patient usually paid a small sum of money to the doctor. Neighborhood pharmacists compounded prescribed medicines. Without being pejorative, it is safe to say that the prevailing attitude of law and medicine was that the 'doctor knows best.'" (citing *Logan v. Greenwich Hosp. Ass'n* 465 A.2d 294, 299 (Conn. 1983))).

39. See Ausness, *supra* note 5, at 98 ("At one time, prescription drug manufacturers directed their promotional efforts solely at physicians and other health care providers. They provided information about their products in the *Physician's Desk Reference* and sometimes placed discreet advertisements in medical journals and other professional publications.").

40. See *Direct-to-Consumer Advertising of Prescription Drugs: What are the Consequences?: Hearing Before the Special Comm. on Aging*, 108th Cong. 29 (2003) (statement of Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration) [hereinafter Woodcock].

41. See *Perez*, 734 A.2d at 1251.

42. *Id.* The court also stated "These campaigns 'bring to bear all the slick pressure of which Madison Avenue is capable.'" *Id.* (citation omitted).

43. See *infra* Part VI.A-B.

44. See *Impact*, *supra* note 37, at 1.

with a more cost-effective method of advertising warning compliance.⁴⁵ After the 1997 changes, "the FDA provided the impetus for drug manufacturers to launch full-scale advertising programs (in broadcast media) directed at consumers," and manufacturers dramatically increased the use of television ads to tout their latest products.⁴⁶ The number of DTC broadcast advertisements submitted to the FDA following the changes has been 293 in 1999, 443 in 2000, 376 in 2001, 486 in 2002, 474 in 2003, and 586 in 2004.⁴⁷

Although pharmaceutical promotion spending has increased, doubling from \$9.2 billion in 1996 to \$19.1 billion in 2000, most promotional spending (approximately 86%) remains directed towards physicians.⁴⁸ Thus, only 14% of pharmaceutical advertising dollars are spent on DTC advertisements. Though only a small portion is spent on DTC advertising, it "seems to be the fastest growing part of the marketing budget."⁴⁹ Expenditures on DTC advertising rose from \$800 million in 1996 to \$2.7 billion in 2001, and reached \$3.2 billion in 2003.⁵⁰ Further, 84% of those surveyed in a 2002 Kaiser Family Foundation study reported they had seen or heard an ad for prescription medication.⁵¹

To pharmaceutical companies, these advertising campaigns serve a vital function. DTC advertising focuses the consumer's attention on the product and encourages those patients to consult their physicians regarding the

45. Jaclyn Carole Hill, *The Learned Intermediary Doctrine and Beyond: Exploring Direct-to-Consumer Drug Advertising Liability In the New Millennium*, 72 DEF. COUNS. J. 362, 362 (2005).

46. *Id.* at 364-65 (parentheses added); Christopher Q. Pham, *The Learned Intermediary Doctrine and DTC Advertising*, L.A. LAW. Feb. 26, 2004, at 16; see also MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT 123-24 (2004); see also *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245, 1251 (N.J. 1999) ("Pressure on consumers is an integral part of drug manufacturer's marketing strategy. From 1995 to 1996, drug companies increased advertising directed to consumers by ninety percent.").

47. *The Impact of Direct-to-Consumer Drug Advertising on Seniors' Health and Health Care Costs: Hearing Before the Special Comm. on Aging*, 109th Cong. 20 (2005) (statement of Rachel E. Behrman, M.D., M.P.H., Deputy Director, Office of Medical Policy Center for Drug Evaluation and Research, U.S. Food and Drug Administration) [hereinafter Behrman].

48. See *Impact*, *supra* note 37, at 3 (further breaks down the spending and shows 29% of the spending is through sales representative directed at physicians and hospitals, 55% of the spending is accounted for by free drug samples that pharmaceutical representatives provide to physicians, 14% on DTC advertising, and 2% on advertising in medical journals).

49. ANGELL, *supra* note 47, at 123.

50. Press Release, Kaiser Family Foundation, *Direct-to-Consumer Prescription Drug Advertising Adds Significantly to Prescription Drug Spending Growth*, New Study Finds (Jun. 11, 2003), available at <http://www.kff.org/rxdrugs/upload/impact-of-direct-to-consumer-advertising-on-prescription-drug-spending-new-release.pdf>; U.S. GEN. ACCOUNTING OFFICE, REPORT TO CONGRESSIONAL REQUESTORS 03-177, PRESCRIPTION DRUGS: FDA OVERSIGHT OF DIRECT-TO-CONSUMER-ADVERTISING HAS LIMITATIONS 3 (2002).

51. See *Impact*, *supra* note 37, at 4.

advertised drug.⁵² “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.”⁵³ In 2001, AstraZeneca spent \$500 million persuading consumers to switch from Prilosec to Nexium.⁵⁴ Of specific importance to this comment, as will later be discussed, Merck & Co., Inc. spent \$160 million in 2000 advertising its osteoarthritis drug Vioxx.⁵⁵

Overwhelming evidence establishes the effectiveness of such campaigns as “[t]hese efforts are not just an essential part of manufacturer’s marketing plans; they are an extremely successful one.”⁵⁶ Prior to 1980, drug sales remained relatively level.⁵⁷ However, from 1980 to 2002 drug sales in the United States tripled, reaching more than \$200 billion a year.⁵⁸ Further, a 2001 Kaiser Family Foundation study showed 30% of consumers discussed a drug they had seen advertised with their physician,⁵⁹ half of which received prescriptions.⁶⁰ Further, a result of male celebrity testimonials in print and broadcast, sales of male impotency products increased to \$788 million in 1998, with approximately 7.5 million prescriptions being written.⁶¹ A National Institute for Health Care Management (NIHCM) study also showed that between 1999 and 2000, prescriptions for the fifty most heavily advertised drugs rose six times greater than all other drugs.⁶² Specifically, Merck’s \$160 million advertising investment in 2000 netted the company a 360% increase in sales of

52. See Tamar V. Terzian, *Direct-to-Consumer Prescription Drug Advertising*, 25 AM. J.L. & MED. 149, 157 (1999) (noting physicians feel more pressure from patients to prescribe drugs patients have seen advertised); see also ANGELL, *supra* note 47, at 116 (“You also pay for a nearly infinite variety of promotions directed at you. Here the expectation is that you will ask your doctor to prescribe the drugs for you.”).

53. Nadal, *supra* note 10, at 453.

54. ANGELL, *supra* note 47, at 118.

55. KATHARINE GREIDER, *THE BIG FIX: HOW THE PHARMACEUTICAL INDUSTRY RIPS OFF AMERICAN CONSUMERS* 89 (Public Affairs 2003) (stating that Merck spent more advertising Vioxx than did Pepsi Cola, Budweiser, Nike, or Campbell’s soups).

56. *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245, 1252 (N.J. 1999).

57. See ANGELL, *supra* note 47, at 3; see also Powell, *supra* note 36, at 62 (Attributing the rise in pharmaceutical spending instead to “changing standards of medical care that emphasize greater use of medicines, and treatment of previously untreated or undertreated patients”).

58. See ANGELL *supra* note 47, at 3.

59. See *Impact*, *supra* note 37, pg 5.

60. See GREIDER, *supra* note 56, at 89; see also Powell, *supra* note 36, at 62 (“Despite claims by some critics, there is no evidence that DTC advertising encourages inappropriate prescribing of prescription medicines.”).

61. See *Perez*, 734 A.2d at 1252.

62. See GREIDER, *supra* note 56, at 89.

Vioxx.⁶³ Thus, "the return generated by increasing spending on DTC advertising appears to be significant."⁶⁴

Manufacturers argue DTC ads are beneficial because they serve an educational function of raising viewers' awareness of personal health.⁶⁵ DTC proponents suggest a variety of benefits flowing from DTC advertising, including the fact that the advertising informs consumers of an existing treatment for a certain condition, may cause the consumer to realize he suffers from a certain condition by identifying like symptoms, alerts those with ailments that a treatment has become available where one previously did not exist, and alerts those under treatment that a new more convenient remedy with reduced side effects is available.⁶⁶ Janet Woodcock, Director of the FDA's Center for Drug Evaluation and Research, reported in 2003 that "[r]esearch by FDA and other entities has documented that accurate [DTC] prescription drug promotion can lead to significant increases in the detection of under-treated conditions like high blood pressure, diabetes, and depression with consequent health benefits for Americans."⁶⁷

Opponents of DTC advertising, however, respond "that the advertisements undermine 'the protection that is a result of requiring a physician to certify a patient's need for a prescription drug.'"⁶⁸ Further, there is the danger that information supplied by manufacturers to consumers is self-interested and biased.⁶⁹ Others believe DTC marketing manipulates consumers because "[e]verything is being presented as a wonderdrug."⁷⁰ Another opposing argument is that DTC ads are contributing to the drastic increases in health care costs and spending⁷¹ because "[d]octors don't want to alienate their

63. See *id.*; see also Rosenthal et al., *Demand Effects of Recent Changes in Prescription Drug Promotion*, May 29, 2003, available at <http://www.kff.org> ("every additional \$1 the industry spent on DTC advertising yielded an additional \$4.20 in sales").

64. See *Impact*, *supra* note 37, at 8.

65. See Alan V. Holmer, *Direct-to-Consumer Advertising—Strengthening Our Health Care System*, 346 NEW ENG. J. MED. 526, 526-27 (2002).

66. See Paul H. Rubin, *Ignorance is Death: The FDA's Advertising Restrictions*, in AMERICAN HEALTH CARE: GOVERNMENT, MARKET PROCESS, AND THE PUBLIC INTEREST 285, 285-311, 304-05 (Roger D. Feldman ed., 2000).

67. Woodcock, *supra* note 41, at 32.

68. Mitchell S. Berger, *A Tale of Six Implants: The Perez v. Wyeth Laboratories Norplant Case and the Applicability of the Learned Intermediary Doctrine to Direct to Consumer Promotion*, 55 FOOD & DRUG L.J. 525, 566 (2000) (citing Matthew F. Hollon, *Direct-to-Consumer Marketing of Prescription Drugs*, 281 JAMA 382, 383-84 (Jan. 27, 1999)).

69. See *id.*

70. *Id.* (citation omitted).

71. See *The Impact of Direct-to-Consumer Drug Advertising on Seniors' Health and Health Care Costs*, 109th Cong. 92 (2005) (statement of Peter Lurie, M.D., M.P.H., Deputy Director, Public Citizen's Health Research Group) ("Predictably, the cost of health care is being driven up, as patients are induced to request newer, more expensive medications instead of equally effective, older, generic alternatives.").

patients, and too many of them find it faster and easier to write a prescription than to explain why it isn't necessary."⁷²

Consequently, DTC advertising "has generated a direct tort action assault on pharmaceutical companies."⁷³ Litigation centers on the warnings included in DTC advertisements and packaging inserts accompanying prescribed drugs.⁷⁴ The issue of manufacturer liability for the failure of the duty to warn has specifically focused on the learned intermediary doctrine.

IV. THE LEARNED INTERMEDIARY DOCTRINE

A. *Introduction to the Learned Intermediary Doctrine*

Generally, the learned intermediary doctrine (LID) establishes that manufacturers fulfill their duty to warn consumers of product hazards by providing accurate warning information to the prescribing physician.⁷⁵ The physician is then charged with providing those warnings to individual patients.⁷⁶ Simply stated, the manufacturer is excused from its duty to warn each patient receiving the product when adequate warnings are provided to prescribing physicians.⁷⁷

Prescribing physicians, therefore, act as "learned intermediaries"⁷⁸ between the manufacturer and consumer in relieving the manufacturer of its duty to purvey product warnings to the ultimate consumer.⁷⁹ Such practice seems paradoxical to the duty to warn discussed at the start of this comment. Instead, the LID is a deviation from the general rule that manufacturers owe a

72. ANGELL, *supra* note 47, at 125.

73. Jack E. Karns, *Direct Advertising of Prescription Drugs: The Duty to Warn and the Learned Intermediary Rule*, 3 DEPAUL J. HEALTH CARE L. 273, 274 (2000) (citing *In re Norplant Contraceptive Prod. Liab. Lit.*, 165 F.3d 374, 377, 379 (5th Cir. 1999)).

74. *See id.* at 274 (citing *In re Norplant*, 165 F.3d at 377, 379).

75. *See In re Norplant*, 165 F.3d 364; *see also* BLACK'S LAW DICTIONARY 898 (7th ed. 1999) ("[A] prescription drug manufacturer fulfills its duty to warn of a drug's potentially harmful effects by informing a prescribing physician, rather than the end user, of those effects.").

76. *See In re Norplant*, 165 F.3d 364.

77. *See* Mark P. Robinson, Jr. & Kevin F. Calcagnie, *Vioxx and the Learned Intermediary Doctrine*, 8 ANDREWS DRUG RECALL LITIG. REP. 7, 1 (2005).

78. *See id.* at 1 ("The term 'learned intermediary' is said to have been first articulated in *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966). [I]n this case we are dealing with a prescription drug rather than a normal consumer item. In such a case the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer. If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided.").

79. *See* Jeffrey E. Grell, *Restatement (Third) of Torts, Section 8(D): Back to the Future of the Learned Intermediary Doctrine*, 19 HAMLINE L. REV. 349, 349 (1996).

duty to reasonably warn consumers of a product's dangers.⁸⁰ Though a manufacturer is relieved of its duty to directly warn consumers, it may be held liable for failure to provide adequate warnings to prescribing physicians.⁸¹ If the manufacturer fails to provide an 'adequate'⁸² warning to the learned intermediary, it then faces liability directly to the injured patient.⁸³

These learned intermediary physicians provide information compiled by the manufacturer to the patient regarding side effects and other information discovered through product research.⁸⁴ Manufacturers provide product information to physicians in two primary methods, through the *Physician's Desk Reference* or via packaging inserts accompanying the drug, or both.⁸⁵

According to *Perez v. Wyeth Laboratories, Inc.*, the underlying theory behind the LID is that:

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 danger. The choice he makes is an informed one, an individualized medical judgment on knowledge of both patient and palliative.⁸⁶

The physician plays such an integral role in a patient's health care and has a relationship with the patient placing him in the best position to warn individual patients of potential adverse effects.⁸⁷ Thus, the LID ensures patients receive an independent party's opinion in determining whether the product's dangers outweigh its benefits⁸⁸ as "[t]he physician's role is intended to provoke a meaningful discussion between patient and physician prior to making any decision to prescribe the drug."⁸⁹

80. See Nadal, *supra* note 10, at 456-57.

81. See *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245, 1255 (N.J. 1999); *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 764 (Ky. 2004).

82. For a discussion on when warnings are deemed adequate, see *infra* text accompanying notes 106-07.

83. See Robinson, Jr. & Calcagnie, *supra* note 78, at 5 (citing *McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522, 529 (Or. 1974)) ("Although the duty of the ethical drug manufacturer is to warn the doctor, rather than the patient, the manufacturer is directly liable to the patient for a breach of such duty.").

84. See Karns, *supra* note 74, at 276.

85. *Wolfgruber v. Upjohn Co.*, 423 N.Y.S.2d 95, 97 (N.Y. App. Div. 1979) ("[W]here the warning given to the prescribing physician by the manufacturer through the Physician's Desk Reference (PDR), packaging inserts and other literature gives specific detailed information on the risks of the drug, the manufacturer has been absolved from liability as a matter of law.").

86. *Perez*, 734 A.2d at 1255.

87. See Nadal, *supra* note 10, at 562 n.56.

88. See *Martin v. Hacker*, 628 N.E.2d 1308, 1311 (N.Y. 1933).

89. See Karns, *supra* note 74, at 277.

Courts have adopted the LID for four distinct reasons. First, the complexities of medication, the ailments medications treat, and the intricacy of the human body preclude average consumers from understanding manufacturers' warnings.⁹⁰ Second, physicians have specialized training to understand the warnings and caution patients accordingly.⁹¹ Therefore, "information about prescription drugs can best be utilized more effectively by physicians than by patients."⁹² Third, the LID aids to preserve the traditional physician-patient relationship where patients give greater deference to their physicians.⁹³ The physician is largely responsible for deciding which drugs to prescribe, and the patient must rely on the physician's choice of medication.⁹⁴ As such, "warnings are best directed at the physician rather than at the patient."⁹⁵ Finally, manufacturers cannot reach all potential consumers and therefore cannot effectively convey the necessary warnings while physicians have the requisite individualized contact with patients to adequately convey product hazards.⁹⁶ Thus, "[t]his special standard for prescription drugs is an understandable exception to the *Restatement's* general rule that one who markets goods must warn foreseeable ultimate users of dangers inherent in [the] products."⁹⁷ Guided by these principles, forty-eight states, the District of Columbia and Puerto Rico have recognized the LID as an exception to the manufacturer's general duty to warn⁹⁸ Consequently, product liability actions in these jurisdictions will often be confronted with the manufacturer's LID defense.

90. See Nadal, *supra* note 10, at 461-62 (citing Hill v. Searle Labs, 884 F.2d 1064, 1070 (8th Cir. 1989)).

91. See *id.*

92. Ausness, *supra* note 5, at 109.

93. Nadal, *supra* note 10, at 461-62.

94. Ausness, *supra* note 5, at 108 (citing West v. Searle & Co., 806 S.W.2d 608, 613 (Ark. 1991) (stating that "the patient relies upon the physician's judgment in selecting the drug, and the patient relies upon the physician's advice in using the drug.")).

95. *Id.* at 108-09.

96. See Nadal, *supra* note 10, at 461-62 (citing Hill v. Searle Labs., 884 F.2d 1064, 1070 (8th Cir. 1989); Martin v. Ortho Pharm Corp., 661 N.E.2d 352, 357 (Ill. 1996); Brooks v. Medtronic, Inc., 750 F.2d 1227, 1232 (4th Cir. 1984); Terhune v. A.H. Robins Co., 577 P.2d 975, 978 (Wash. 1978); Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 156-59 (1997); Swayze v. McNeil Labs, 807 F.2d 464, 471 (9th Cir. 1988); Dunkin v. Syntax Labs., 443 F. Supp. 121, 123 (W.D. Tenn. 1977); Davis v. Wyeth Labs., Inc., 399 F.2d 121, 130 (9th Cir. 1968)).

97. Perez v. Wyeth Labs., Inc., 734 A.2d 1245, 1254 (N.J. 1999) (quoting Reyes v. Wyeth Labs., Inc., 498 F.2d 1264, 1276 (5th Cir. 1974)).

98. See Robinson, Jr. & Calcagnie, *supra* note 78, at 3 (citing *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 806 (E.D. Tex. 2002)).

B. The Learned Intermediary Doctrine and Consumer Claims Against Manufacturers

"[I]f a prescription drug or medical device causes personal injury, plaintiffs typically seek a deep pocket and sue the manufacturer, employing a variety of legal theories and claims."⁹⁹ In prescription drug actions, the LID

can have a significant impact upon the ultimate resolution of key issues raised in a failure-to-warn claim, including the adequacy of warnings and causation. Unlike in most products liability actions, the adequacy of the warning . . . is judged according to its adequacy for the physician, and not the user of the product.¹⁰⁰

Most litigation concerning pharmaceuticals does not center around whether any warning was provided at all, but rather on the adequacy of that manufacturer's provided warning.¹⁰¹ Thus, considering the LID, a plaintiff bringing a product liability claim against a drug manufacturer must first show the manufacturer failed to adequately warn the physician of a product risk of which the physician was otherwise unaware.¹⁰² A plaintiff must also show a manufacturer's failure to warn was both the cause in fact and proximate cause of the resulting injuries.¹⁰³ However, manufacturers typically raise the LID defense in a motion for summary judgment, "essentially concluding that: [t]he warnings provided were adequate for the physician; and [e]ven if a different or better warning had contained the information allegedly absent from the warnings already with the product, it would not have altered the physician's decision to prescribe it."¹⁰⁴

An adequate warning to physicians, and likely to be argued by manufacturers, is defined as one "sufficient to apprise the general practitioner as well as the 'unusually sophisticated medical man' of the dangerous propensities of the drug."¹⁰⁵ However, plaintiffs are likely to argue that a

99. Pham, *supra* note 47, at 16.

100. Robinson, Jr. & Calcagnie, *supra* note 78, at 1-2.

101. Woodside, III & Maggio, *supra* note 3, at 1 ("Unlike other areas of products liability where a case may be based upon a product that was improperly manufactured and does not meet specifications, a drug that is subject to litigation is generally properly made in accordance with manufacturing standards.").

102. See Guidry v. Aventis Pharm., Inc., 418 F. Supp. 2d 835, 840-41 (M.D. La. 2006).

103. Woodside, III & Maggio, *supra* note 3, at 1.

104. Robinson, Jr. & Calcagnie, *supra* note 78, at 5.

105. *Id.* (citing Parke-Davis & Co. v. Stromsodt, 411 F.2d 1390, 1400 (8th Cir. 1969)); Jury Instructions, Cona v. Merck & Co., 2005 WL 3965213, at *5, *9 (N.J. Super. Ct. Law Div. 2005) ("To be adequate, the warning or instruction must be the kind of warning or instruction which a reasonable prudent manufacturer in the same or similar circumstances would have provided to the prescribing physician. . . . When deciding if an adequate warning was given by the defendant you should look at the totality of the information given to the physicians about the drug and its risks, including information given in the package insert, in the published articles, in the promotional materials and the information provided by Merck's sales representatives.").

manufacturer has a duty to warn of *all* potential product dangers it knows or should know exist, and “that a warning must be correct, complete and fully descriptive, and it must convey updated information as to all of the drug’s known side effects.”¹⁰⁶ Further, the mere mentioning of a side effect will not relieve the defendant from liability if the degree of the associated risk is inadequately conveyed.¹⁰⁷

A plaintiff must also establish the element of causation, “that an adequate warning would have persuaded the physician not to prescribe the drug.”¹⁰⁸ Naturally, manufacturers will argue the warning was not the proximate cause of the claimant’s injuries and that a varied warning would not have dissuaded the physician from prescribing the drug.¹⁰⁹ If a manufacturer meets its burden of proof regarding a warning’s adequacy, without some evidence to the contrary, “courts are not reluctant to grant summary judgment.”¹¹⁰

Therefore, the LID only provides an affirmative defense to manufacturers if *adequate* warnings have been provided to *prescribing physicians*. However, various circumstances demand exceptions to the LID be created where manufacturers cannot be absolved from liability.

C. *Exceptions to the Learned Intermediary Doctrine*

Various exceptions to the LID have been written into the *Restatement (Third)* and adopted by courts.¹¹¹ With each exception to the doctrine, the manufacturer is required to warn consumers directly.¹¹² First, warnings must be provided directly to consumers when “the manufacturer knows or has reason to know that health care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.”¹¹³ Courts and the *Restatement* specifically recognize this exception in the circumstance of a mass immunization.¹¹⁴ Courts recognize the provider is not acting “in the same learned intermediary role” as when prescribing drugs to an individual

106. Robinson, Jr. & Calcagnie, *supra* note 78, at 5 (citing *Martin v. Hacker*, 628 N.E.2d 1308 (N.Y. 1993); *Krasnopolsky v. Warner-Lambert Co.*, 799 F. Supp. 1342, 1345-46 (E.D.N.Y. 1992) (stating the manufacturer’s duty to warn continues even after the product has reached the market, i.e. there is a duty to warn of risks discovered after market release)).

107. *See id.* (citing *Stahl v. Novartis Pharms. Corp.*, 283 F.3d 254, 267 (5th Cir. 2002); *McDonnell v. Chelsea Mfrs. Inc.*, 687 N.Y.S.2d 172, 174 (N.Y. App. Div. 1999)).

108. *Id.* at 6; *see also West v. Searle & Co.*, 806 S.W.2d 608, 613 (Ark. 1991) (stating patients rely on physicians’ judgment in selecting and using drugs).

109. Robinson, Jr. & Calcagnie, *supra* note 78, at 6.

110. *Id.* (citing *Carter v. TAP Pharms. Inc.*, 2004 WL 2550593 (W.D. Tex. 2004)).

111. *See generally* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. e (1998).

112. *See* Nadal, *supra* note 10, at 463.

113. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d)(2) (1998).

114. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d)(2) cmt. e (1998).

patient¹¹⁵ and that "no physician-patient relationship is created and 'the drug is not administered as a prescription drug.'"¹¹⁶ Thus, the physician is not acting as a learned intermediary in instances of mass immunization and the LID will not protect manufacturers against claims for product liability.

The *Restatement (Third)* suggests two other exceptions to the LID,¹¹⁷ though qualifying that "[t]he Institute leaves to developing case law whether exceptions to the learned intermediary rule, in these or other situations, should be recognized."¹¹⁸ The first of the *Restatement's* proposed exceptions to the LID would apply where FDA regulations require direct warnings be given to consumers.¹¹⁹ As an example, comment e notes that birth control pills are required to be sold with a "patient package insert" listing product warnings, and therefore the LID would not apply to these products.¹²⁰ The proposed FDA mandate exception has been recognized by a handful of courts who determined oral contraceptives differ from ordinary prescriptions because the patient herself chooses which contraceptive to take, and she does not largely depend on the prescribing physician.¹²¹

115. Karns, *supra* note 74, at 278 (citing *Allison v. Merck & Co., Inc.*, 878 P.2d 948, 959 (Nev. 1994); *Cunningham v. Pfizer & Co., Inc.*, 532 P.2d 1377, 1381 (Okla. 1975); *Brazzell v. United States*, 788 F.2d 1352, 1358 (8th Cir. 1986); *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1275-76 (5th Cir. 1974)).

116. Karns, *supra* note 74, at 276.

117. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. e (1998) ("Although the learned intermediary rule is generally accepted and a drug manufacturer fulfills its legal obligation to warn by providing adequate warnings to the health-care provider, arguments have been advanced that in two other areas courts should consider imposing tort liability on drug manufacturers that fail to provide direct warnings to consumers. In the first, governmental regulatory agencies have mandated that patients be informed of risks attendant to the use of a drug. A noted example is the FDA requirement that birth control pills be sold to patients accompanied by a patient package insert. In the second, manufacturers have advertised a prescription drug and its indicated use in the mass media. Governmental regulations require that, when drugs are so advertised, they must be accompanied by appropriate information concerning risk so as to provide balanced advertising.").

118. *Id.*

119. *Id.*

120. *Id.*; see also *Wagner & Peterson*, *supra* note 25, at 236.

121. See *Nadal*, *supra* note 10, at 466-69 (citing *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.E.2d 352, 356-57 (Ill. 1996); *Cobb v. Syntex Labs.*, 444 So. 2d 203,

More importantly for the focus of this comment, the *Restatement* suggests an argument is being made, in light of increasing DTC advertising, that the LID should not apply when manufacturers advertise directly to the public.¹²² “This exception to the [LID] mandates a change in the warning standard. Warnings must be pitched toward the reasonably prudent patient-consumer rather than the prescribing physician.”¹²³ The DTC exception was the focus of *Perez v. Wyeth Laboratories, Inc.*,¹²⁴ where the New Jersey Supreme Court was the first to create an exception to the LID for manufacturers who engage in DTC advertising.¹²⁵

D. *Perez v. Wyeth Laboratories, Inc.*

In 1999 the New Jersey Supreme Court became the first court to hold the LID does not apply to pharmaceutical companies who engage in DTC advertising.¹²⁶ In *Perez v. Wyeth Laboratories, Inc.*, several women who underwent surgical insertion of Norplant, a contraceptive employing six caplets implanted under the skin of the upper arm, brought product liability claims against the manufacturer for failure to warn of potential side effects.¹²⁷

Wyeth began an advertising campaign in 1991 that directed the contraceptive at women, rather than physicians, on television and in magazines “such as *Glamour*, *Mademoiselle*, and *Cosmopolitan*.”¹²⁸ Many women allegedly suffered pain and scarring due to the implants and claimed aggressive consumer directed advertising influenced their decision to seek Norplant.¹²⁹

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 (Wash. 1978); *In re Norplant Contraceptive Prod. Litig.*, 165 F.3d 374, 379 (5th Cir. 1999); *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 91-92 (2d Cir. 1980)).

122. See *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245, 1251 (N.J. 1999); *Wagner & Peterson*, *supra* note 25, at 237; *Karns*, *supra* note 74, at 285.

123. *Karns*, *supra* note 74, at 285 (citing *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 68 (Mass. 1985)).

124. See *Perez*, 734 A.2d 1245.

125. See *Nadal*, *supra* note 10, at 457.

126. See generally *Perez*, 734 A.2d 1245.

127. See *id.* at 1247. The court also stated:

Plaintiffs’ principal claim alleged that Wyeth, distributors of Norplant in the United States, failed to warn adequately about side effects associated with the contraceptive. Side effects complained of by plaintiffs included weight gain, headaches, dizziness, nausea, diarrhea, acne, vomiting, fatigue, facial hair growth, numbness in the arms and legs, irregular menstruation, hair loss, leg cramps, anxiety and nervousness, vision problems anemia, mood swings and depression, high blood pressure, and removal complications that resulted in scarring.

Id. at 1248.

128. *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245, 1248 (N.J. 1999).

129. See *id.*

Plaintiffs further stated that no advertisement warned of the product's dangers but instead claimed its simplicity and convenience.¹³⁰ Wyeth, arguing based on the LID and the New Jersey Products Liability Act, claimed it had no duty to warn consumers directly, but instead was only required to provide warnings to physicians, which claimants failed to prove were inadequate.¹³¹

Relying on the LID, the trial court held "the physician retains the duty to weigh the benefits and risks associated with a drug before deciding whether the drug is appropriate for the patient" and that the plaintiffs failed to show the warnings provided to physicians were inadequate.¹³² The intermediate appellate court affirmed the trial court's grant of summary judgment on the basis of the learned intermediary doctrine.¹³³

The New Jersey Supreme Court reversed and held Wyeth in fact had a duty to directly warn consumers, stating:

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 consumers 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.¹³⁴

Thus, drug manufacturers making product claims directly to consumers could no longer satisfy their duty to warn by providing physicians with product warnings.¹³⁵ The court expressed general concerns regarding the practice of DTC advertising¹³⁶ and noted the marketing strategy was intended to pressure consumers to ask physicians for the specific products and that the advertisements rarely informed consumers of accompanying risks.¹³⁷

In reaching its decision, the court turned to the *Restatement (Third) of Torts* which left the DTC exception to "developing case law."¹³⁸ The court accepted the *Restatement's* invitation to create a DTC exception when interpreting section 6(d) language "when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings."¹³⁹

130. *Id.*

131. *Id.* at 1249.

132. *Id.* at 1248.

133. *Id.* at 1249.

134. *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245, 1247 (N.J. 1999).

135. Ausness, *supra* note 5, at 116.

136. *Perez*, 734 A.2d at 1251-53.

137. *Id.* at 1251-52.

138. *Id.* at 1253; *see also* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) cmt. e. (1999).

139. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d)(2) (1999).

The court also examined the four premises underlying the LID¹⁴⁰ and stated that changes in national health care, coupled with DTC advertising, resulted in several being inapplicable.¹⁴¹ Specifically, the court stated the traditional physician-patient relationship began to dissolve with the advent of managed care organizations (MCOs)¹⁴² and the doctrine of informed consent as patients and insurance companies began making more health care decisions.¹⁴³ Managed care programs reduced the physician's time with patients and thus his ability to adequately inform patients of drug risks.¹⁴⁴ Further, given the \$1.3 billion manufacturers spent on DTC ads in 1998, the court believed "drug manufacturers can hardly be said to 'lack effective means to communicate directly with patients' when their advertising campaigns can pay off in close to billions in dividends."¹⁴⁵

Thus, in concluding that the LID does not apply to manufacturers engaging in DTC advertising, the court stated:

When all of its premises are absent, as when direct warnings to consumers are mandatory, the [LID], "itself an exception to the manufacturer's traditional duty to warn consumers directly of the risk associated with any product, simply drops out of the calculus, leaving the duty of the manufacturer to be determined in accordance with the general principles of tort law."¹⁴⁶

140. The four underlying premises for the LID, as stated in *Perez* are: preserving the patient-physician relationship; physicians are in a better position to provide information to patients; drug manufacturers' lack of effective means to communicate to consumers; and given the complexity of risk information, manufacturers would be strained to provide adequate warnings to lay patients. See *supra* text accompanying notes 85-90.

141. See *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245, 1255 (N.J. 1999); see also *id.* ("Consumer-directed advertising of pharmaceuticals thus belies each of the premises on which the learned intermediary doctrine rests.").

142. MCOs, or Managed Care Organizations, are corporate organizations which contract physicians into preferred networks for their insured's use. In exchange for proving the MCO lower rates, physicians receive increased patient clientele. Specific types of MCOs include Health Management Organizations (HMOs) and Preferred Provider Organizations (PPOs).

143. See *Perez*, 734 A.2d at 1255; see also *id.* at 1257 ("Patient choice is an increasingly important part of our medical-legal jurisprudence. . . . Accordingly, a patient must be informed of material risks, which exist 'when a reasonable patient, in what the physician knows or should know to be the patient's position, would be 'likely to attach significance to the risk or cluster of risks' in deciding whether to forego the proposed therapy or to submit to it.'" (citation omitted)).

144. See *id.* at 1255; see also Bernard J. Garbutt, III and Melinda E. Hoffman, *Recent Developments in Pharmaceutical Products Liability Law: Failure to Warn, The Learned Intermediary Defense, and Other Issues in the New Millennium*, 58 FOOD & DRUG L.J. 269, 274 (2003) ("As a result of this new system, patients have less freedom in their choice of doctors, and doctors have monetary incentives to reduce costs of treatment and to crowd more patients into their schedule, thereby lessening the amount of time spent with each patient.").

145. See *Perez*, 734 A.2d at 1255-56 (citing Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 158 (1997)).

146. *Id.* at 1256 (quoting *Edwards v. Basel Pharms.*, 116 F. 3d 1341, 343 (10th Cir. 1997)).

Attempting to prevent manufacturers from facing absolute liability when engaging in DTC advertising, the *Perez* court adopted a rebuttable presumption that if a manufacturer complied with FDA advertising and warning regulations, it would not fail its duty to warn.¹⁴⁷ "The court thus recognized that a pharmaceutical manufacturer's compliance with FDA regulations, including regulations related to DTC marketing campaigns, may shield it in a failure to warn case."¹⁴⁸

E. Arguments in Favor a Direct-to-Consumer Exception to the LID

Critics to the LID advance several arguments against applying the doctrine to manufacturers employing DTC. Specifically, they argue DTC advertising has eroded the traditional patient-physician relationship because patients no longer passively defer to their physicians regarding treatment suggestions and orders.¹⁴⁹ Accordingly, the increased disjoint is attributable to DTC advertising in that "drug companies have given consumers better access to information about treatment options."¹⁵⁰ Also contended is that the rise of the managed care era has further deteriorated the traditional patient-physician relationship.¹⁵¹ Because MCOs bargain with drug manufacturers for lower prices in exchange for excluding competitors' products, MCO physicians have less discretion in choosing which drugs to prescribe.¹⁵² Also a perceived product of DTC advertisements is that patients pressure MCO physicians to prescribe specific medications on threats of seeking treatment elsewhere.¹⁵³

Proponents of the exception also argue that drug manufacturers should not be held to a lesser duty than manufacturers of all other consumer goods.¹⁵⁴ They also argue that the marketing schemes employed by manufacturers resemble those of all other consumer goods.¹⁵⁵ Specifically, critics purport the marketing of lifestyle drugs "plays upon the personal insecurities and vanities of listeners or viewers."¹⁵⁶

147. Woodside, III & Maggio, *supra* note 3, at 12.

148. *Id.*

149. Ausness, *supra* note 5, at 120.

150. *Id.* (stating that drug manufacturers also provide potential customers with free videos, brochures and information packets about products along with having websites and toll free numbers available twenty-four hours a day).

151. Chester Chuang, Note, *Is There A Doctor in the House? Using Failure-to-Warn Liability to Enhance the Safety of Online Prescribing*, 75 N.Y.U. L. REV. 1452, 1455 (2000).

152. Charles J. Walsh et al., *The Learned Intermediary Doctrine: The Correct Prescription for Drug Labeling*, 48 RUTGERS L. REV. 821, 876 (1995).

153. See Yonni D. Fushman, *Perez v. Wyeth, Inc.: Toward Creating a Direct-to-Consumer Advertisement Exception to the Learned Intermediary Doctrine*, 80 B.U. L. REV. 1161, 1172 (2000).

154. Ausness, *supra* note 5, at 122.

155. *Id.*

156. *Id.*

Many arguments are also advanced as to how DTC advertising furthers the public good and how a DTC exception would create more harm than good.¹⁵⁷ According to a 2003 statement by the Federal Trade Commission:

[DTC advertising] can empower consumers to manage their own health care by providing information that will help them, with the assistance of their doctors, to make better informed decisions about their treatment options. . . . Consumers receive these benefits from DTC advertising with little, if any, evidence that such advertising increases prescription drug prices.¹⁵⁸

A 2002 survey by *Prevention Magazine* found 24.8 million Americans consulted with their physician regarding medical conditions for the first time as a result of seeing a DTC advertisement.¹⁵⁹ Further, a 2002 FDA survey showed 43% of respondents sought additional information about a drug, conditions it treats, or general health after viewing a DTC advertisement.¹⁶⁰ The largest source of the additional information was the patient's physician.¹⁶¹

No doubt the rise of MCOs and DTC has impacted the patient-physician relationship and awareness of ailments and available treatments. However, to argue changes in advertising techniques and health coverage have so augmented the relationship as to require manufacturers to individually warn each consumer of the list of product hazards is impracticable. Further, research shows DTC advertising increases patient-physician contact and questions regarding conditions and general health. Thus, DTC advertising appears to have helped promote the public's general health.

Although marketing schemes and insurance plans have changed, the physician's role as final decision-maker in writing the prescription has not and

157. See Laurie K. Marshall, *Keeping the Duty to Warn Patients of the Risks and Side Effects of Mass-Marketed Prescription Drugs Where it Belongs: With Their Physician*, 26 U. DAYTON L. REV. 95, 97 (2000).

158. FEDERAL TRADE COMMISSION, Doc. No. 2003N-0344, COMMENTS BEFORE THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION, IN THE MATTER OF REQUEST FOR COMMENTS ON CONSUMER-DIRECTED PROMOTION 3 (2003).

159. FEDERAL TRADE COMMISSION, Doc. No. 2002N-0209, COMMENTS OF THE STAFF OF THE BUREAU OF ECONOMICS, THE BUREAU OF CONSUMER PROTECTION, AND THE OFFICE OF POLICY PLANNING OF THE FEDERAL TRADE COMMISSION, IN THE MATTER OF REQUEST FOR COMMENT ON FIRST AMENDMENT ISSUES 3 (2002) (citing *Prevention*, *Fifth Annual Survey: Consumer Reaction to DTC Advertising of Prescription Medicines 2001/2002* at 3 ("Consumer surveys suggest that DTC advertising has stimulated discussions between doctors and patients, encouraged consumers to learn more about previously undiagnosed conditions, and not prevented doctors from recommending non-drug therapies.")).

160. KATHRYN J. AIKIN ET AL., EXECUTIVE SUMMARY: PATIENT AND PHYSICIAN ATTITUDES AND BEHAVIORS ASSOCIATED WITH DTC PROMOTION OF PRESCRIPTION DRUGS—SUMMARY OF SURVEY RESEARCH RESULTS 3 (2004).

161. *Id.* Also stating that "[t]he most commonly reported sources of this additional information were healthcare providers. Eighty-nine percent (89%) of respondents reported obtaining information from their doctors." *Id.*

"the justifications for the doctrine are as valid today as they were when it was created."¹⁶² If a DTC exception was universally adopted, and drug companies were to warn individual consumers, the exception would first be premised on the fact that consumers would read the warning and refrain from taking the product if they deem it unsuitable.¹⁶³ A doubtful result.

V. POST *PEREZ V. WYETH LABORATORIES, INC.*

Following the *Perez* decision, courts in jurisdictions around the country have been reluctant, at best, to heed the invitation of the *Restatement* to delineate an exception to the LID on the basis of manufacturers engaging in DTC advertising. The court in *In re Meridia* addressed the fact that few courts have followed in New Jersey's footsteps and stated, "[f]ive years have passed since the New Jersey Supreme Court decided *Perez*. In the intervening period, no other state has followed New Jersey's lead. The court thus could not apply *Perez's* logic even if it desired to do so."¹⁶⁴ The exception recognized in *Perez* has yet to be recognized by any other court. Although the *Perez* decision remains a strong plaintiff's argument, most jurisdictions have yet to address the applicability of the LID to manufacturers engaging in DTC advertising.¹⁶⁵

Facing an almost identical situation as *Perez*, the court in *In re Norplant Contraceptive Products Liability Litigation* explicitly declined to create a DTC exception to the LID and granted the defendant manufacturer's motion for summary judgment.¹⁶⁶ In the class action suit, the court stated, "the overwhelming majority of jurisdictions to address the issue apply the [LID] to define a pharmaceutical company's duty to warn of risks associated with the use of a prescription drug."¹⁶⁷ The plaintiffs argued the LID was not applicable to their claim because Wyeth engaged in DTC advertising.¹⁶⁸ The court disagreed with the plaintiffs and stated, "This argument. . . lacks merit in

162. Woodside, III & Maggio, *supra* note 3, at 13.

163. Ausness, *supra* note 5, at 137.

164. *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 812 n.19 (N.D. Ohio 2004).

165. Pham, *supra* note 47, at 17; *In re Norplant Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 805 (E.D. Tex. 2002).

166. *In re Norplant*, 215 F. Supp. 2d at 833-34 ("Plaintiffs have failed to produce evidence overcoming the doctrine in that they do not show that the purportedly inadequate warnings on Norplant's labeling were either a producing cause of and/or proximately caused Plaintiffs [sic] subsequent injuries. Nor do they proffer evidence confirming that any of Plaintiffs' treating healthcare providers would not have prescribed Norplant had the labeling been different. Defendants, however, provide the affidavit of Dr. Anita Nelson, which establishes that the healthcare providers who prescribed Norplant were aware of the 26 'Adverse Reactions. . . . [T]his motion is GRANTED as to all Plaintiffs who claim they suffer any of the 26 'Adverse Reactions.'").

167. *Id.* at 805 (court provides a list of states, and the controlling authority, that have adopted the LID).

168. *See id.* at 827.

all jurisdictions, except New Jersey. . . . apart from New Jersey, [DTC] advertising does not negate the applicability of the [LID].”¹⁶⁹ However, ten plaintiffs’ claims out of the 2,966 were governed by New Jersey substantive law and were exempt from the summary judgment motion.¹⁷⁰ The court held the LID did apply and focused its discussion on the fact that “[p]laintiffs did not create a fact issue on causation because the evidence fails to show that any of the healthcare providers cited by the Plaintiffs were unaware of the 26 side effects.”¹⁷¹ The court in an earlier 1999 Norplant opinion gave special attention to the fact that the physician played an integral role in prescribing the drug and educating patients about risks and benefits of using the Norplant contraceptive.¹⁷²

Further, the court in *Albertson v. Wyeth, Inc.* stated, “it would be improvident to accede to plaintiffs’ argument that a limited exception to the learned intermediary doctrine should be created based upon direct-to-consumer advertising.”¹⁷³ The court believed that dissemination through the media concerning the drugs does not increase the patient’s ability to acquire the drugs because a prescription is still required.¹⁷⁴ As has been seen by “developing case law,” courts have not followed, and correctly so, the *Restatement’s* suggestion that a DTC exception to the LID be created.

VI. FEDERAL REGULATIONS OF PHARMACEUTICAL ADVERTISEMENTS

A. *Current FDA Regulation of Prescription Drug Advertisements*

The Food and Drug Administration’s (FDA) authority to regulate the sale, manufacture, and distribution of drugs exists under the Federal Food, Drug and Cosmetic Act (FDCA).¹⁷⁵ Specifically, FDCA section 502(n), codified as 21 U.S.C. § 352(n), grants the FDA the authority to regulate prescription drug advertisements.¹⁷⁶ Implementation of the advertisement regulation authority

169. *Id.*

170. *Id.* at 829.

171. *In re Norplant Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 826 (E.D. Tex. 2002).

172. *In re Norplant Contraceptive Prod. Liab. Litig.*, 165 F.3d 374, 379 (5th Cir. 1999).

173. *Albertson v. Wyeth, Inc.*, 2003 WL 21544488, at *10-11.

174. *Id.*

175. 21 U.S.C. §§ 301-399 (2000).

176. Woodcock, *supra* note 41, at 35; 28 U.S.C. § 352(n) (2000) (“In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in paragraph (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under paragraph (e) of this section, and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be

rests with the Division of Drug Marketing, Advertising, and Communications (DDMAC), within the Center for Drug Evaluation and Research (CDER).¹⁷⁷ The specific rules and requirements promulgated to govern drug advertisements are contained in 21 C.F.R. § 202.1. However, "[c]onsistent with the First Amendment, FDA may only regulate prescription advertising that is false or misleading."¹⁷⁸ Nothing in the FDCA prohibits DTC advertising.¹⁷⁹

The FDA regulates advertisements and promotional materials created by the product's manufacturer, packer or distributor.¹⁸⁰ This includes materials placed in publication by product sponsors directed to consumers, including: "ads printed in magazines, journals and newspapers; ads broadcast over television, radio or telephone; brochures, letters and flyers sent through the mail; videotapes and pharmacy counter displays, billboards and patient compliance programs."¹⁸¹

The FDA regulates those advertisements that discuss a drug's effectiveness and use,¹⁸² which may include two of the three ads used by product sponsors to communicate to consumers, "product-claim" and "reminder" ads.¹⁸³ Advertisements stating a drug's benefits must also contain a "fair balance" of the drug's "risks and limitations of efficacy."¹⁸⁴ Product claim ads are those providing the product's name and use or make a representation about the drug.¹⁸⁵ Reminder ads are those disclosing the product's name and some piece of descriptive information, (i.e. dosage method or price information) but

issued by the Secretary in accordance with the procedure specified in section 371(e) of this title, except that (A) in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement, and (B) no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 52 to 57 of title 15. This paragraph (n) shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 321(m) of this title. Nothing in the Convention on Psychotropic Substances, signed at Vienna, Austria, on February 21, 1971, shall be construed to prevent drug price communications to consumers.").

177. Woodcock, *supra* note 41, at 33.

178. Behrman, *supra* note 48, at 11.

179. Woodcock, *supra* note 41, at 35.

180. *Id.* at 33.

181. *Id.*; 21 C.F.R. § 202.1(e) (1999) (providing a general description of the various types of regulated advertisements as well as a list of those that are exempt).

182. 21 C.F.R. § 202.1(e)(1).

183. Woodcock, *supra* note 41, at 34 ("The third type, 'help-seeking' ads, are not regulated by FDA. Help-seeking ads are those discussing a disease or condition and advising the audience to ask their doctor. These ads are not required to disclose any risk information because no product was mentioned or implied.").

184. *Id.*

185. *Id.*

cannot also disclose the product's use or "make any claims or representations about the product."¹⁸⁶ Thus, the FDA primarily regulates product claim ads.¹⁸⁷

FDA regulations under the FDCA require all prescription drug advertisements contain "information in brief summary relating to side effects, contraindications, and effectiveness" of the pharmaceutical.¹⁸⁸ To meet this mandate, the FDCA distinguishes between print and broadcast advertisements. Print advertisements must contain a brief summary of *all* risks associated with the product.¹⁸⁹ Manufacturers can meet FDA's brief summary requirement merely by printing the packaging insert information into the advertisement's text.¹⁹⁰

Advertisements for broadcast over television, radio, or telephone, on the other hand, must disclose the "major side effects and contraindications of the advertised drugs in the audio or audio and visual parts of the presentation."¹⁹¹

186. 21 C.F.R. § 202.1 (e)(2)(i) ("*Reminder advertisements.*, Reminder advertisements are those which call attention to the name of the drug product but do not include indications or dosage recommendations for use of the drug product. These reminder advertisements shall contain only the proprietary name of the drug product, if any; the established name of the drug product, if any; the established name of each active ingredient in the drug product; and, optionally, information relating to quantitative ingredient statements, dosage form, quantity of package contents, price, the name and address of the manufacturer, packer, or distributor or other written, printed, or graphic matter containing no representation or suggestion relating to the advertised drug product."); see Woodcock, *supra* note 41, at 33.

187. Ausness, *supra* note 5, at 102.

188. 21 C.F.R. § 201.1(e)(4)(i)(a) ("*Substance of information to be included in brief summary.*, An advertisement for a prescription drug covered by a new-drug application approved pursuant to section 505 of the act after October 10, 1962 or section 512 of the act after August 1, 1969, or any approved supplement thereto, shall not recommend or suggest any use that is not in the labeling accepted in such approved new-drug application or supplement. The advertisement shall present information from labeling required, approved, or permitted in a new-drug application relating to each specific side effect and contraindication in such labeling that relates to the uses of the advertised drug dosage form(s) or shall otherwise conform to the provisions of paragraph (e)(3)(iii) of this section."); see also 21 C.F.R. § 201.1(e)(3)(iii) ("The information relating to side effects and contraindications shall disclose each specific side effect and contraindication (which include side effects, warnings, precautions, and contraindications and include any such information under such headings as cautions, special considerations, important notes, etc.; see paragraph (e)(1) of this section) contained in required, approved, or permitted labeling for the advertised drug dosage form(s). . ."); Nadal, *supra* note 10, at 482; see generally U.S. DEP'T OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS (1999) [hereinafter GUIDANCE].

189. 21 C.F.R. § 201.1(e)(i); see Hill, *supra* note 46, at 364.

190. See Ausness, *supra* note 5, at 102.

191. 21 C.F.R. § 201.1(e)(i) (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

This is known as a "major statement." Thus, the "brief summary" requires disclosure of all information regarding *all* known side effects and contraindications whereas the "major statement" merely requires a statement of those *major* side effects. Although broadcast advertisements must only provide the major statement in the ad itself, advertisers are still required to make the brief summary or make one available.¹⁹² The short duration of broadcast advertisement medium, however, does not support the required "brief summaries" in the advertisements.¹⁹³ Sponsors, therefore, "must make an 'adequate provision for the [sic] dissemination of the approved package labeling in connection with the broadcast presentation.'"¹⁹⁴ Through the "adequate provision" requirement¹⁹⁵ sponsors must provide a means by which "most of a potentially diverse audience [would] have reasonably convenient access to the advertised product's approved labeling" (i.e. the brief summary).¹⁹⁶ Specifically, sponsors can meet this requirement by a disclosure in the advertisement of all of the following: a toll-free number consumers can call and obtain labeling information, an internet web page address providing access to the labeling, where to obtain a print advertisement containing the brief summary, and disclosure in the advertisement that healthcare providers can provide additional information.¹⁹⁷ "The regulations thus specify that the major statement together with adequate provision for dissemination of the product's approved labeling can provide the information disclosure required for broadcast advertisements."¹⁹⁸

B. *Development of Regulation of DTC Advertising*

With the passage of amendments to the FDCA in 1962, the FDA could officially regulate prescription drug advertising.¹⁹⁹ DTC advertising was used on a small scale prior to 1983, and was usually present via print advertisements as a result of the medium's ease and ability to provide a cost-effective means of disseminating the mandated brief summary.²⁰⁰ With manufacturers preparing DTC campaigns, the FDA imposed a two year moratorium on DTC advertising to "investigate the effects such advertising on consumers and the

summary of all necessary information related to side effects and contraindications.); *see also* GUIDANCE, *supra* note 189.

192. GUIDANCE, *supra* note 189, at 1.

193. Nadal, *supra* note 10, at 482.

194. *Id.* (citing 21 C.F.R. § 201.1(e)(1)).

195. GUIDANCE, *supra* note 189, at 1.

196. *Id.*

197. *Id.* at 2-3.

198. *Id.* at 1-2.

199. Hill, *supra* note 46, at 363.

200. *Id.* at 363-64.

efficacy of then-existing FDA regulations.”²⁰¹ In September 1985, the FDA lifted the moratorium on DTC advertising, concluding “current regulations governing prescription drug advertising provide sufficient safeguards to protect consumers.”²⁰² Thus, manufacturers could advertise directly to consumers under the then existing FDA regulations controlling marketing of prescription drugs to physicians.²⁰³

Prior to 1997, pharmaceutical manufacturers rarely employed broadcast advertisements as the FDA required full disclosure of side effects in the ad itself.²⁰⁴ “That made thirty-second spots difficult—and even counterproductive.”²⁰⁵ In 1997, however, FDA issued a draft guidance entitled *Guidance for Industry: Consumer-Directed Broadcast Advertisements*²⁰⁶ which described changes in the rules governing broadcast advertisements.²⁰⁷ Subsequently, advertisers were only required to provide the major statement to refer viewers to the four sources where consumers could obtain additional information (web address, print ad, physician and toll-free number) and where a full disclosure may be found.²⁰⁸ Following the 1997 change, “drug companies began to flood the airwaves with commercials about their latest drugs. Expenditures on DTC ads nearly tripled between 1997 and 2001, and the percentage accounted for by television increased from 25% to 64%.”²⁰⁹

Through a post-marketing submission requirement, advertisers are required by the FDCA to submit all DTC advertisements to the FDA when a new campaign is launched.²¹⁰ Some manufacturers, on the other hand, have agreed to submit promotions to the FDA before public release.²¹¹ Within the FDA, the Division of Drug Marketing, Advertising and Communications (DDMAC) is responsible for reviewing drug promotional materials.²¹² DDMAC ensures the promotions portray a “fair balance” of risks and benefits and contain “true statements” as required by the FDCA.²¹³ A fair balance exists “if the

201. *Id.*

202. William E. Holtz, *Consumer-Directed Prescription Drug Advertising: Effects on Public Health*, 13 J.L. & HEALTH 199, 202 (1999) (citing Direct-to-Consumer Advertising of Prescription Drugs; Withdrawal of Moratorium, 50 Fed. Reg. 36, 677 (1985)).

203. Hill, *supra* note 46, at 363.

204. ANGELL, *supra* note 47, at 123-24.

205. *Id.*

206. *See generally* GUIDANCE, *supra* note 189.

207. Hill, *supra* note 46, at 362-63.

208. GUIDANCE, *supra* note 189, at 1-3.

209. ANGELL, *supra* note 47, at 123-24.

210. Behrman, *supra* note 48, at 20.

211. *Id.*

212. *Id.* at 19.

213. Hill, *supra* note 46, at 365; 21 C.F.R. § 202.1(e)(1) (1999) (“All advertisements for any prescription drug . . . shall present a true statement of information in brief summary relating to side effects, contraindications, and effectiveness.”).

presentation of true information relating to side effects and contraindications is comparable in depth and detail with the claims for effectiveness and safety."²¹⁴ If an advertisement is false or misleading as to side effects or effectiveness, does not provide the mandated "fair balance," or fails to disclose risks of non-recommended uses of a drug, then the advertisement will not present the required "true statement."²¹⁵ DDMAC's options with regards to false or misleading advertisements include: (1) untitled letters providing notice of violations and a request that the violative materials be discontinued; (2) warning letters issued for more serious violations which may pose serious public health risks; (3) injunctions and consent decrees; (4) referrals for criminal investigation or prosecution; and (5) seizures.²¹⁶ DDMAC received for review roughly 31,600 promotional materials in 1999, 32,100 in 2000, 34,200 in 2001, 36,700 in 2002, 40,000 in 2003, and 52,800 in 2004.²¹⁷ Advertisements in violation of FDA regulations are subject to being immediately stopped and can also require the sponsor to release a remedial campaign to correct misrepresentations.²¹⁸

According to Janet Woodcock, Director of the FDA's Center for Drug Evaluation and Research, the purpose of FDA regulation of DTC advertising is ensuring the ads remain positively balanced.²¹⁹

[T]here are three important things to understand about FDA's authority in this area. First, the statute and the regulations focus on the content, not the existence, of prescription drug promotion. Second, the law does not make a distinction between target audiences. The law has never prohibited advertising prescription drugs to consumers. However, until the early 1980's this was just not done. Third, the act specifically forbids requiring preclearance of ads by the FDA, except under extraordinary circumstances.²²⁰

The FDA aims to ensure consumers are exposed to truthful, non-misleading ads which are easily understood.²²¹

214. 21 C.F.R. § 202.1(e)(5)(ii).

215. 21 C.F.R. § 202.1(e)(5)(i)-(iii); Hill, *supra* note 46, at 365.

216. Behrman, *supra* note 48, at 22. Behrman also stated that since the 1997 changes, the FDA has issued fifty-two untitled letters, six warning letters on broadcast advertisements, fifteen untitled letters on purported reminder broadcast advertisements, and three untitled letters for purported help seeking broadcast advertisements, and "[m]ost of the violations cited were because the ad was misleading, e.g. the ad overstated or guaranteed the product's efficacy, expanded the indication or the patient population approved for treatment, or minimized the risks of the product through either inadequate presentation or omission of information." *Id.*

217. *Id.* at 19

218. *Id.*

219. *Id.* at 29.

220. *Id.*

221. *See* Behrman, *supra* note 48.

VII. MERCK & CO. INC.'S VIOXX[®]A. *Development and Production of Vioxx[®]*

Approved by the FDA in May 1999, Rofecoxib, developed by Merck & Co. Inc. and sold under the name Vioxx[®], was an anti-inflammatory drug used to treat osteoarthritis, acute pain conditions, menstrual symptoms, and rheumatoid arthritis in adults and children.²²² Vioxx was a prescription Cyclooxygenase-2 inhibitor, a non-steroidal anti-inflammatory drug (NSAID).²²³ NSAID pain relievers also include several over the counter medications such as Advil (Ibuprofen) and Aleve (Naproxen Sodium).²²⁴ Vioxx “relieved pain by blocking the enzyme cyclooxygenase (COX), which is required for the production of prostaglandins—chemicals that mediate the pain response.”²²⁵ NSAIDs, besides inhibiting prostaglandins which are responsible for the pain sensation, also reduce swelling, inflammation and irritation which all worsen pain.²²⁶ NSAIDs have long been used for alleviation of “chronic or acute inflammation and pain associated with osteoarthritis, rheumatoid arthritis, and other musculoskeletal conditions”²²⁷ However, traditional NSAID treatments were accompanied by a significant increased risk of gastrointestinal perforations, ulcers, and bleeding.²²⁸ Researchers later determined the COX enzyme had two forms.²²⁹ COX-1 was found to affect production of prostaglandins which aid in protecting the stomach lining whereas COX-2 was found to affect production of

222. FDA.gov, COX-2 Selective and Non-Selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), <http://www.fda.gov/cder/drug/infopage/COX2/default.htm> (last visited Feb. 16, 2007) [hereinafter COX-2]; see generally W. John Thomas, *The Vioxx Story: Would it Have Ended Differently in The European Union?*, 32 AM. J.L. & MED. 365 (2006) (providing a thorough discussion of the rise and fall of Merck’s Vioxx and how the Vioxx issues would be resolved in the European Union).

223. COX-2, *supra* note 223.

224. *In re Vioxx Prods. Liab. Litig.*, 401 F. Supp. 2d 565, 570 (E.D. La. 2005).

225. Donna Scott-Tilley, *Advanced Practice Nursing Extra, New Drugs: Second COX-2 Inhibitor*, 99 AM. J. NURSING 24DDD, 24DDD (Oct. 1999); *In re Vioxx Prods. Liab. Litig.*, 401 F. Supp. 2d at 570 (“NSAIDs work by inhibiting cyclooxygenase (COX), an enzyme that stimulates the syntheses of prostaglandins, which are chemicals produced in the body that promote certain effects.”).

226. *Kennedy v. Merck & Co., Inc.*, No. 19591, 2003 WL 21658613, at *2 (Ohio Ct. App. 2003).

227. *In re Vioxx Prods. Liab. Litig.*, 401 F. Supp. 2d at 571 (proving a clear background of the creation of Vioxx and includes discussion of the development of COX-2 inhibitors); see also Paul D. Rheingold, *Merck’s Vioxx: A Lucrative Pathway to Problems*, 8 No. 8 ANDREWS DRUG RECALL LITIG. REP. 6, 1 (2005) (“The COX-2 inhibiting drugs came on the scene in the 1990s as a type of ‘super aspirin.’”).

228. *In re Vioxx Prods. Liab. Litig.*, 401 F. Supp. 2d at 571.

229. *Id.*

prostaglandins which are responsible for both pain and inflammation.²³⁰ Discovering the two forms of the COX enzyme "led scientists to hypothesize that 'selective' NSAIDs designed to inhibit COX-2, but not COX-1 could offer the same pain relief as traditional NSAIDs with the reduced risk of fatal or debilitating gastrointestinal perforations, ulcers, and bleeding."²³¹ The "selective" NSAIDs became known as "COX-2 Inhibitors," of which Vioxx was one.²³² At the same time Merck was developing Vioxx, Pfizer Co. was also developing its COX-2 inhibitor Celebrex, which beat Vioxx to the market by six months.

Vioxx was an improvement over traditional NSAIDs because it did not carry the same risk of gastrointestinal bleeding as COX-1 inhibitors; "[b]ecause the newest drugs block COX-2, and have minimal effects on COX-1, they are considered significant pharmacologic advances."²³³ In particular, six clinical trials showed Vioxx relieved joint pain and stiffness in patients with osteoarthritis.²³⁴

In order to receive FDA approval, Merck conducted the Vioxx Gastrointestinal Outcomes Research (VIGOR) study, through which the company intended to show that Vioxx caused fewer gastrointestinal problems than predecessor drug Naproxen.²³⁵ Merck submitted the VIGOR study results to the FDA in June, 2000. However, along with a reduction in gastrointestinal problems, the research also showed patients taking Vioxx had a rate of heart attacks five times greater than those taking the older Naproxen.²³⁶ Merck justified the results by stating that Naproxen had cardioprotective effects which aided in preventing heart attacks. Merck quickly followed the VIGOR study with their Adenomatous Polyp Prevention on Vioxx (APPROVe) study.²³⁷ Merck's APPROVe study confirmed the VIGOR findings that Vioxx carried with it an increased risk of heart attack and stroke.²³⁸

230. *In re Vioxx Prods. Liab. Litig.*, 401 F. Supp. 2d 565, 571 (E.D. La. 2005).

231. *Id.*

232. *Id.* ("In light of these scientific developments, Merck & Co., Inc. ('Merck') and several other pharmaceutical companies began the development of such drugs, which became known as 'COX-2 inhibitors' or 'coxibs.' Vioxx is a COX-2 inhibitor.")

233. Scott-Tilley, *supra* note 226, at 24DDD.

234. *Id.*

235. All About Vioxx Lawsuits, Vioxx Lawsuits—The VIGOR Study, <http://www.vioxx-lawyer-all-about.com/vioxx-vigor-study.html> (last visited Feb. 8, 2007); *see generally* C. Bombardier et al., *Comparison of Upper Gastrointestinal Toxicity of Refecoxib and Naproxen in Patients with Rheumatoid Arthritis*, 343 NEW ENG. J. MED. 1520 (2000).

236. All About Vioxx Lawsuits, Vioxx Lawsuits—The VIGOR Study, <http://www.vioxx-lawyer-all-about.com/vioxx-vigor-study.html> (last visited Feb. 8, 2007).

237. All About Vioxx Lawsuits, Vioxx Lawsuits—The APPROVe Study, <http://www.vioxx-lawyer-all-about.com/vioxx-approve-study.html> (last visited Feb. 8, 2007).

238. *Id.*

The studies showed that inhibiting COX-2 without the inhibition of COX-1 caused blood clotting, which led to the side effects creating the basis for the Vioxx litigation.²³⁹

What explains the clotting effect. . . is that inhibiting COX-2 allowed a pro-thrombotic factor, thromboxane (a vaso constrictor which induces blood clotting), to increase whereas allowing COX-1 to remain unrestrained stopped the prostacyclin whose job is to inhibit platelet aggregation (blood clotting). Thus the balance in users was switched toward clotting.²⁴⁰

Clotting increases risk of heart attack and stroke because clots block arteries and lead to ischemia (a restriction in blood supply) after the blockage.²⁴¹ Strokes result from blockages of cerebral arteries or carotid arteries feeding blood to the brain.²⁴² Further troubling for Vioxx is the risk of blockage is much higher in those with narrowed arteries, (i.e. the elderly and those with existing heart problems), which makes it easier for clots to lodge and block those arteries.²⁴³

In February 2001, the FDA advisory panel recommended the FDA require a change in Vioxx's packaging insert to relate the results of the VIGOR study of increased rates of heart attack and stroke.²⁴⁴ However, Merck continued aggressively marketing Vioxx to physicians and downplayed Vioxx's role in increasing stroke and heart attacks. In September 2001, the FDA sent Merck a warning letter stating "You have engaged in a promotional campaign for Vioxx that minimizes the potentially serious cardiovascular findings that were observed in the Vioxx Gastrointestinal Outcomes Research (VIGOR) study."²⁴⁵ In April 2002, the FDA required Merck to include the warning regarding increased stroke and heart attack in its packaging.²⁴⁶

On September 30, 2004, following publication of their APPROVe study, Merck announced an immediate voluntarily withdrawal of Vioxx from the market.²⁴⁷ Raymond Gilmartin, president and CEO of Merck at the time of the withdrawal, stated:

239. Rheingold, *supra* note 228, at 2.

240. *Id.*

241. *Id.*

242. *Id.*

243. *Id.*

244. Rita Rubin, *How Did the Vioxx Debacle Happen?*, USA TODAY, Oct. 12, 2004, at D1; W. John Thomas, *The Vioxx Story: Would it Have Ended Differently in The European Union?*, 32 AM. J.L. & MED. 365, 366 (2006).

245. GREIDER, *supra* note 56, at 102-03.

246. Thomas, *supra* note 245, at 366.

247. Press Release, Merck & Co., Inc., Merck Announces Immediate Worldwide Withdrawal of Vioxx® (Sept. 20, 2004), available at http://www.vioxx.com/rofecoxib/vioxx/consumer/voluntary_withdrawal_statement.jsp (last visited Apr. 6, 2007).

We are taking this action because we believe it best serves the interests of patients. . . . Although we believe it would have been possible to continue to market VIOXX with labeling that would incorporate these new data, given the availability of alternative therapies, and the questions raised by the data, we concluded that a voluntary withdrawal is the responsible course to take.²⁴⁸

As previously discussed, Vioxx was the most heavily advertised drug in 2000, with Merck spending \$160 million on marketing the new drug which netted a 360% increase in sales.²⁴⁹ Between May 1999 and the withdrawal of September 2004, 105 million Vioxx prescriptions were filled in the United States alone to an estimated 20 million patients.²⁵⁰ In 2003, Vioxx worldwide sales topped \$2.5 billion.²⁵¹

B. Current Vioxx[®] Litigation

Following Merck's voluntary withdrawal of Vioxx on September 30, 2004, thousands of individual lawsuits and roughly 160 class actions were filed in state and federal courts alleging tort and products liability claims.²⁵² "The latest mass tort, and perhaps one that will rival the fen-phen diet drug litigation, involves Vioxx. . . . Suits are being brought in many forums for heart attacks, sudden cardiac death and strokes, as well as for a number of other side effects."²⁵³ Due to the volume of suits, the Judicial Panel on Multidistrict Litigation designated the Vioxx Multidistrict Litigation (MDL) and ordered it consolidated into one court.²⁵⁴ Thereafter, all Vioxx suits filed in federal courts were transferred to the United States District Court for the Eastern District of Louisiana, for coordination of discovery and pretrial matters.²⁵⁵

Merck currently faces 27,000 individual Vioxx lawsuits nationwide.²⁵⁶ As of December 31, 2006, 4,025 Vioxx related claims had been dismissed before being scheduled for trial, more than 1,225 of which were dismissed with prejudice.²⁵⁷ Thirty-one Vioxx suits, as of March 27, 2006, had been scheduled for trial.²⁵⁸ Fourteen of the thirty-one were either dismissed or

248. *Id.*

249. GREIDER, *supra* note 56, at 102.

250. *In re Vioxx Prod. Liab. Litig.*, 239 F.R.D. 450, 452 (E.D. La. 2006).

251. *Id.*

252. *In re Vioxx Prod. Liab. Litig.*, 401 F. Supp. 2d 565, 571 (E.D. La. 2005); *In re Vioxx Prod. Liab. Litig.*, 239 F.R.D. at 452.

253. Rheingold, *supra* note 228, at 1.

254. *See In re Vioxx Prod. Liab. Litig.*, 401 F. Supp. 2d 565, 571 (E.D. La. 2005).

255. *In re Vioxx Prod. Liab. Litig.*, 239 F.R.D. at 452.

256. Adam Jadhav, *Vioxx Maker Wins First Case in Madison County, But Others Await*, ST. LOUIS POST DISPATCH, Apr. 9, 2007.

257. Press Release, Merck & Co., Inc., Merck Wins Product Liability Case in Madison County, Ill. (Mar. 27, 2007), available at http://www.merck.com/newsroom/press_releases/corporate/2007-0327.html (last visited Apr. 7, 2007).

258. *Id.*

withdrawn from the trial calendars by the plaintiffs, ten resulted in jury verdicts in Merck's favor,²⁵⁹ five verdicts in the plaintiff's favor and two ended with hung juries and remain unresolved mistrials.²⁶⁰

Claims against Merck allege a myriad of causes of action. Most prevalent is the failure of the duty to warn, which is therefore accompanied with the issues surrounding the LID and DTC advertising.²⁶¹ Claimants are attempting to circumvent the LID by claiming that Merck failed to provide adequate warning to their prescribing physicians.²⁶² Whether or not adequate warnings were provided to physicians is a question of fact, and the plaintiffs are therefore trying to reach the jury.²⁶³ However, one commentator noted, "[w]e think that the learned intermediary doctrine, the FDA approval process . . . and the statistical realities of the Vioxx record will combine to provide Merck with a potent defense."²⁶⁴

The combined jury instruction in *Cona v. Merck & Co., Inc.*, and *McDarby v. Merck & Co., Inc.*, provided that Merck, as manufacturer of Vioxx, had a duty to make a product that is reasonably safe, which required dissemination of adequate warnings of the product's risks.²⁶⁵ If a manufacturer fails to provide an adequate warning, the product is thus deemed defective under the law.²⁶⁶ Therefore, Merck had a duty to provide adequate warnings about the dangers of its product. "In the case of a prescription drug adequate warning must be given to the doctors who will prescribe the drug. This is true because it is the prescribing doctor who has to decide whether to prescribe a prescription drug to a patient."²⁶⁷ The judge's statement shows the jury was instructed to take into consideration the LID.

259. The latest of the verdicts in favor of Merck and Co., Inc. was recently reached on March 27, 2007 in Madison County, Illinois, a jurisdiction renowned around the country for a history of excessively high jury verdicts. Press Release, Merck & Co., Inc., Merck Wins Product Liability Case in Madison County, Ill. (Mar. 27, 2007), available at http://www.merck.com/newsroom/press_releases/corporate/2007-0327.html (last visited Apr. 7, 2007). The jury in *Schwaller v. Merck and Co.*, No. 05-L-687, found Vioxx was not the proximate cause of a 72-year-old woman's heart attack death, but instead that obesity and other pre-existing health conditions were significant contributing factors in her death. *Id.* The jury also rejected the claim that Merck failed to adequately warn Schwaller's prescribing physicians of risks associated with Vioxx use. *Id.*

260. *Id.*

261. Calvert D. Crary, *Update: Merck's Vioxx Litigation*, LITIG. NOTES, Nov. 9, 2004, available at http://www.litigationnotes.com/litinotes_sample3.pdf.

262. *Id.*

263. *Id.*

264. *Id.*

265. Jury Instructions, *Cona v. Merck & Co., Inc.*, 2005 WL 3965213, at *5, *9 (N.J. Super. Ct. Law Div. 2005); *McDarby v. Merck & Co., Inc.*, No. L-1296-05, 2006 WL 3965213, at *5 (N.J. Super. Ct. Law Div. 2006).

266. *Id.*

267. *Id.*

In *McDarby*, the plaintiff's claim alleged that an increased risk of heart attack was known or knowable to Merck who failed to adequately warn physicians that patients with heart attack risk factors should not be prescribed the drug.²⁶⁸ Merck contended, however, that it provided adequate warning of any risks that were known or knowable when the plaintiff used Vioxx.²⁶⁹ "If the defendant proves that there was no risk or the other risk was not known or knowable during those times, then it had no duty to warn of any such risk and cannot be held liable for failure to do so."²⁷⁰

McDarby, for which the above jury instruction was written, resulted in a \$13.5 million plaintiff's award after the jury found that Vioxx was a substantial contributing factor to his heart attack.²⁷¹ Plaintiff's complaint alleged Merck failed to disclose potential dangers associated with the Vioxx use and also claimed misrepresentation to physicians and the public of any of the drug's dangers through advertisements.²⁷² The plaintiff, who provided records indicating four years of Vioxx use, claimed long term use of the drug was both the cause in fact and proximate cause of his heart attack.²⁷³ Merck, however, contended it met all FDA regulations concerning Vioxx by providing the FDA with all mandated information and therefore fulfilled its duty to warn.²⁷⁴ The jury disagreed with Merck and reached a unanimous verdict finding that the manufacturer failed to adequately warn the patient of an increased risk of heart attack associated with the drug and that their failure to warn proximately caused his injuries.²⁷⁵

Similarly, the jury in *Barnett v. Merck & Co., Inc.* awarded \$51 million in damages to the plaintiff, Barnett, who they found suffered a heart attack attributed to Vioxx use.²⁷⁶ Barnett began taking Vioxx in 1999 for chronic neck pain and subsequently suffered a heart attack three years later, but continued taking the drug until its 2004 withdrawal.²⁷⁷ Barnett claimed Merck was liable for failing to warn him of product dangers and was negligent in its representation and production of Vioxx.²⁷⁸ Merck, relying on the LID, argued

268. *Id.* at *6.

269. *Id.* at *5.

270. *Id.*

271. Jury Verdict, *McDarby v. Merck & Co., Inc.*, 2006 WL 1073402, at *2 (N.J. Super. Ct. Law Div. 2006) (New Jersey Vioxx User, Wife Received \$13.5 Million).

272. Jury Instruction, *Cona*, 2005 WL 3965213 at *9; *McDarby v. Merck & Co., Inc.*, No. L-1296-05, 2005 WL 3965213, at *5 (N.J. Super. Ct. Law Div. 2005).

273. Jury Verdict, *McDarby*, 2006 WL 1073402, at *3 (New Jersey Vioxx User, Wife Received \$13.5 Million).

274. *Id.*

275. *Id.*

276. Jury Verdict, *Barnett v. Merck & Co.*, 2006 WL 2742584, at *2 (E.D. La. 2006) (Judge Orders New Trial on Damages After Jury Awards \$51 Million for Vioxx Claim).

277. *Id.* at *3.

278. *Id.*

it discharged its duty by providing warnings to prescribing physicians and was therefore not liable.²⁷⁹ The jury found Merck did not fail to warn the plaintiff of the danger, but was negligent for failing to warn Barnett's prescribing physicians of the risks associated with Vioxx.²⁸⁰ Judge Fallon, presiding over Vioxx MDL litigation, found the award was "grossly excessive" and ordered a new trial for damages alone.²⁸¹

Ernst v. Merck and Co., Inc., provided the largest award to date for a Vioxx claim, awarding the family of a deceased Vioxx patient \$253.4 million in damages.²⁸² Ernst was prescribed Vioxx in 2000 to relieve tendonitis pain and died of a heart attack six months later.²⁸³ Ernst's family alleged Merck knew of the danger and continued to market Vioxx knowing it was unsafe and that Merck misrepresented Vioxx's safety to the public via marketing campaigns.²⁸⁴ Merck countered by arguing Vioxx was not inherently dangerous, that warnings provided both to patients and physicians were legal as approved by the FDA, that it did not knowingly mislead consumers, and that the patient's death resulted from pre-existing medical conditions.²⁸⁵ Contrary to the manufacturer's contentions, the jury found both marketing and design defects to be producing causes of Ernst's death and Merck's negligence as the proximate cause.²⁸⁶ Although the jury awarded the plaintiffs \$253 million, Texas punitive damages caps will reduce the award to roughly \$26 million.

In contrast, *Dedrick v. Merck and Co., Inc.* resulted in a quite different outcome.²⁸⁷ The plaintiff in *Dedrick* alleged he suffered a heart attack after taking Vioxx for six months.²⁸⁸ The plaintiff claimed Merck failed to adequately warn consumers and physicians of Vioxx's associated risks and also breached various implied warranties by misrepresenting material facts to his prescribing physician.²⁸⁹ Specifically, the plaintiff stated, "If not for those

279. *Id.*

280. *Id.* at *4.

281. *In re Vioxx Prods. Liab. Litig.*, 448 F. Supp. 2d 737, 741 (E.D. La. 2006). In explaining his reasoning, Judge Fallon states "The Court finds that the \$50 Million compensatory damages award is excessive under any conceivable substantive standard of excessiveness. The evidence suggests that the Plaintiff *may* have lost nine or ten years of life expectancy as a result of his use of Vioxx. . . .Therefore, no reasonable jury could have found that Plaintiff's total losses totaled \$50 Million." *Id.* at 740.

282. Jury Verdict, *Ernst v. Merck & Co., Inc.*, 2005 WL 2760303, at *2 (23d Jud. D. Tex. 2005) (Brazoria County Jury Awards Family of Deceased Vioxx User \$253.4 Million).

283. *Id.* at *3.

284. *Id.*

285. *Id.* at *4.

286. *Id.*

287. Jury Verdict, *Dedrick v. Merck & Co., Inc.*, 2006 WL 40077593, at *2 (E.D. La. 2006) (Merck Prevails After Jury Rejects Tennessee Man's Vioxx Claim).

288. *Id.*

289. *Id.* at *2-*3.

negligent misrepresentations, his physicians would not have prescribed the drug."²⁹⁰ Merck argued no evidence of increased risk of heart attack existed at the plaintiff's dosage level and that his pre-existing cardiovascular disease was the actual cause his injuries.²⁹¹ In December 2006, a jury found "Merck properly warned Dedrick's treating physician about known risks at the time, and that Merck's alleged failure adequately warn his physician was not the proximate cause of Dedrick's injuries."²⁹²

The LID plays a specific roll in regards to Vioxx cases during the pre-trial stages. Specifically, in *In re Vioxx Products Liability Litigation*, Merck, arguing on the grounds of the LID, successfully defended a certification motion for a national class of personal injury and wrongful death claims.²⁹³ In denying certification, the court focused on the lack of typicality among claimants.²⁹⁴ The court stated:

In this case, both the proposed class representatives and the putative class members assert various products liability claims against Merck under theories of negligence, strict liability, failure to warn, and defective design. While these claims involve common issues, they also involve individual issues such as injury, causation, *the learned intermediary doctrine* and comparative fault.²⁹⁵

Further, in *Kennedy v. Merck & Co., Inc.*, an Ohio appellate court affirmed a grant of summary judgment for Merck on the basis of the LID.²⁹⁶ Kennedy, on behalf of his deceased wife, claimed Merck failed to adequately warn her that anaphylactoid reactions could occur by taking Vioxx.²⁹⁷ Kennedy's wife was given free samples of Vioxx from her physician which contained a statement on the package to see accompanying packaging insert for product warnings. However, Kennedy's wife was not given the packaging insert from her physician. The court noted that Kennedy did not argue the warnings provided to the prescribing physician were inadequate, but that the warnings were inadequate due to the manner in which they were conveyed to his wife.²⁹⁸ The trial court found Merck had no duty to ensure advertisements and printed materials containing warnings provided directly to physicians reached the

290. *Id.*

291. *Id.* at *3

292. *Id.*

293. *See In re Vioxx Prod. Liab. Litig.*, 239 F.R.D. 450, 462 (E.D. La. 2006).

294. *Id.* at 462-63 ("Regardless, the PSC's reliance on mass accident class action is misplaced in this pharmaceutical litigation. The number, uniqueness, singularity, and complexity of the factual scenarios surrounding each case swamp any predominating issues.").

295. *Id.* at 460 (emphasis added).

296. *Kennedy v. Merck & Co., Inc.*, 2003 WL 21658613, at *6, *7 (Ohio Ct. App. 2003).

297. *Id.* at *2.

298. *Id.* at *5.

actual patient.²⁹⁹ Specifically, the appellate court, quoting the trial court, stated “[c]onstruing these facts and R.C. 2307.76(c) in a light most favorable to Mr. Kennedy, reasonable minds could only conclude that Merck discharged its duty to warn Mrs. Kennedy of the possibility of adverse reactions to Vioxx by warning Dr. Striebel of the risks.”³⁰⁰ The appellate court, affirming the trial court’s grant of summary judgment, held that “Under the [LID], there exists no requirement that Merck give any warnings for Vioxx to the consumer if the warnings provided to the physician are adequate.”³⁰¹

Thus, litigation regarding the LID and the duty to warn centers on a fact-determination of whether Merck provided an *adequate* warning to *prescribing* physicians. Specific attention, however, is being given to what Merck knew of potential adverse effects and when it knew of them. If juries find an inadequate warning was provided to physicians, the LID will be inapplicable and Merck will be subject to products liability claims for failure of the duty to warn.

VIII. ANALYSIS

The learned intermediary doctrine should continue to play a strong role even in the face of increased DTC advertising. Pharmaceutical companies should not face increased liability as a result of direct product advertising or be held liable for failing to provide *all* potential adverse effects in a thirty second television spot. The fact remains that physicians are more directly targeted by drug manufacturer marketing than consumers³⁰² and are the ones ultimately responsible for writing the prescription.³⁰³ Thus, there should be no change in the current allocations of the duty to warn as it should continue to fall on physicians to ensure the drugs being prescribed are in the patient’s best interest and that he is aware of any adverse effects accompanying treatment.

The bottom line is that pharmaceuticals themselves are not changing, and neither are the dangers with which they are accompanied. Patients still must have symptoms treated by the medication, and physicians still must make the decision to prescribe. What has changed, however, is the patient’s awareness of treatment options and his subjective opinion of his ailments. By requiring certain drugs be available only by prescription, the FDA reflects a policy statement that individual consumers cannot truly comprehend a drug’s effects

299. *Id.* at *5.

300. *Id.* at *4 (citation omitted).

301. *Id.* at *10.

302. U.S. GEN. ACCOUNTING OFFICE, REPORT TO CONGRESSIONAL REQUESTORS 03-177, PRESCRIPTION DRUGS: FDA OVERSIGHT OF DIRECT-TO-CONSUMER-ADVERTISING HAS LIMITATIONS 3 (2002) (stating that DTC advertising increased by 145% between 1997 and 2001, and that promotion to physicians accounted for 80% of the pharmaceutical companies promotional spending).

303. Woodside, III & Maggio, *supra* note 3, at 13.

and therefore, safe usage demands professional intervention.³⁰⁴ When prescribing, the duty rests on the physician to examine the patient and determine if a requested or needed treatment is appropriate in the circumstance. Therefore, the duty should remain on the physician to ensure the drugs prescribed are best suited for a patient who is fully aware of the associated risks. If the LID is an attempt to "preserve the primacy of the physician's role in making treatment decisions for patients, including the making of informed choices about prescription drugs,"³⁰⁵ courts should unequivocally continue to apply the doctrine. This holds especially true in an age of increased DTC advertising and usurpation by patients and MCOs of the physician's role in treatment decisions.

Those arguing that DTC advertising has changed the role of patient and physician are misguided.³⁰⁶ The patient-physician relationship has not been fundamentally changed by DTC advertising as critics purport. Instead, managed care organizations and a patient per hour rate increase should be considered when discussing physicians writing prescriptions for requested drugs. The LID is premised on the principle that prescribing physicians are in the best position to evaluate the patient's needs, to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a prescription based therapy.³⁰⁷ The fact that physicians are in the best position to evaluate the patient's needs remains unchanged regardless of the advertising dollars spent by drug manufacturers. For the basis of the LID, the fundamental relationship of ill patients needing prescriptions and physicians being required to write them, is unchanged.

With regard to impending Vioxx litigation, again, courts should not recognize a DTC exception to the LID. The duty should remain with the physician to warn potential patients of product hazards so long as reasonable warnings were supplied and made available by the manufacturer. Thus, jurors should only consider whether an *adequate* warning was provided to the *physician*, not the end consumer, when contemplating verdicts. Specifically, Merck complied with FDA regulations following the VIGOR study by including packaging inserts that were received by both patients and physicians.

304. *Id.* at 13-14.

305. Robinson, Jr. & Calcagnie, *supra* note 78, at 2.

306. *See generally* Perez v. Wyeth Labs., Inc., 734 A.2d 1245 (N.J. 1999) (holding drug manufacturers employing DTC are not protected by LID exception to the general duty to warn); Renee Matter, *Emerging DTC Advertising of Prescription Drugs and the Learned Intermediary Doctrine: Even in the Absence of a True Patient-Physician Relationship, Drug Manufacturers can Protect Themselves by Warning Consumers Directly*, 69 DEF. COUNS. J. 79, 87 (2005) (stating DTC advertising changed the roles and relationships of patients and physicians and undercut the premises of the LID as DTC removes the physician from the learned intermediary role and encourages patients to request certain pharmaceuticals).

307. Robinson, Jr. & Calcagnie, *supra* note 78, at 1.

Merck's liability should not simply rest on the fact that Vioxx was marketed directly to the consumers, but instead on whether meeting FDA mandates suffice to meet the manufacturer's duty to adequately warn prescribing physicians.

Considering increases in medical malpractice suits against doctors, and that the duty to warn should remain with those physicians, perhaps it is time for part of the burden of the duty to warn to fall on another group.³⁰⁸ Regardless of the duty imposed by state and federal regulations regarding product warning requirements, and likely to be an unpopular suggestion, perhaps the consumers should have the ultimate duty of inquiring into substances they ingest. Consumers are undoubtedly aware some risks and potential side effects are inherent in taking prescription drugs. The best tool for educating the public as to possible adverse effects of pharmaceuticals may be to place a share of the burden directly on the consumer himself to inquire into those effects. The question of "how might this *drug* affect me?" should be the first statement out of a patient's mouth after requesting any pharmaceutical treatment.

The doctrine of *caveat emptor* was once the predominate rule in purchasing products and property. Perhaps a revival of the doctrine, even to a slight degree, would be the best policy for ensuring consumers are aware of potential adverse effects of pharmaceuticals. To borrow a moderately applicable quote, "[m]y point is that you have to think for yourself. If your parents told you that chocolate was dangerous would you take their word for it? Exactly! So perhaps instead of acting like sheep when it comes to [pharmaceuticals] you should find out for yourself."³⁰⁹

COREY SCHAECHER*

308. Please note that it is far from this author's opinion that health care providers should face any increase in liability. In fact, it is unfortunate doctors are facing the current litigious climate which surrounds their profession. Also please note that patients should not have to rummage through obscure documents to be apprised of dangers associated with a prescription drug. Instead, the suggestion is that the patients should take *some* responsibility in being aware of the drug's possible adverse affects and contraindications.

309. THANK YOU FOR SMOKING (20th Century Fox, 2005).

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