THE LOST CHILD OF PRODUCTS LIABILITY: NEW THOUGHTS ABOUT ADVERTISING AND THE LEARNED INTERMEDIARY DOCTRINE

> Blessed is he, who in the name of charity and goodwill, shepherds the weak through the valley of darkness for he is truly his brother's keeper and the finder of lost children.[1]

INTRODUCTION

Each and every day the American public is bombarded by the images, slogans, and stories of advertising. One would have to live in a shack in the Montana hinterlands to effectively escape the regular onslaught of advertising. Yet, the general public *seems* quite able to block out the "white noise." Whether ignoring print ads while flipping through a magazine or turning the dial when a station goes to commercial, most Americans have gained a thick shell to this necessary by-product from the world of industry and consumption.[2]

This apparent immunity to advertising, however, masks a more insidious truth. Our "immunity" is less than total. The truth is that advertising, in some form, affects everyone. Advertising firms and the companies that pay them have grown savvier and more aware of what makes an effective campaign and more importantly, what will penetrate the shell of the targeted consumer.[3] The average advertisement reflects a deep understanding of psychology, social science, and an unsettling number of details about the targeted audience.[4] For every ad that we ignore, another hits its mark. We refuse to succumb to the late night temptation of the fast-food commercial, but at the grocery store we impulsively purchase snack food that we recognize from a print ad. This is the purpose of advertising,

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1. QUENTIN TARANTINO, Speech delivered by Jules Winnfield, *in* PULP FICTION (Miramax Pictures 1994) (attributing it falsely to *Ezekiel* 25:17).

2. A far more radical critique of the advertising industry suggests that advertising and marketing have effectively usurped the role of manufacturing and become the main engine of the United States' economy. *See* STUART EWEN, CAPTAINS OF CONSCIOUSNESS: ADVERTISING AND THE SOCIAL ROOTS OF THE CONSUMER CULTURE (1976) (tracing the rise of consumerism and advertising in the twentieth century).

3. VANCE PACKARD, THE HIDDEN PERSUADERS 18–30 (1957). Although Packard's book was written nearly fifty years ago, his work captures the foundational "truths" of advertising criticism that are still in use today. *See generally* Alan M. Perlman, *Book Summary and Critique: The Hidden Persuaders* (criticizing the flaws in Packard's argument but finding his thesis and description of techniques to be still important to understanding advertising), *at* http://www.alanperlman.com/source/samples/booksum_pursuade.html (last visited Feb. 23, 2003); *see also* ERIC CLARK, THE WANT MAKERS: THE WORLD OF ADVERTISING: HOW THEY MAKE YOU BUY (1988) (updating Packard's investigations into the advertising world).

4. PACKARD, *supra* note 3, at 186–93.

to create a pitch aimed perfectly at consumers that does not attention to itself but creates a subtle need or desire for that product.[5]

It follows that if manufacturers use advertising, which subtly manipulates its audience, to promote their products, they should be responsible for its content. Such is the case when promises made in advertising become the source of warranty under the Uniform Commercial Code.[6] But, a more complex issue arises when plaintiffs argue that a product is defective because the manufacturer's advertising failed to properly warn them.[7] This potential affirmative duty raises a serious question for manufacturers as to what they must include in their advertising and when.

While the general duty to warn has been firmly established in the Third Restatement of Torts,[8] its elements have been challenged in state courts.[9] Perhaps no part of this duty is more controversial than the duty to warn associated with pharmaceutical products.[10] This is due to the unique nature of drugs and health care in our society. For most other products, the duty to warn exists between only the consumer and the manufacturer.[11] If the manufacturer breaches the duty, then it has, by definition, failed to warn or properly instruct the *consumer* about the product. Courts have recognized, however, that the pharmaceutical relationship is not strictly buyer to seller.[12] Standing between every drug maker and taker in this country is a

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5. To make a legal analogy, the perfect advertisement is like direct examination, controlling the tone and pace of the presentation while directing the attention of the jury toward the witness/product. *See* THOMAS A. MAUET, TRIAL TECHNIQUES § 5.1 (6th ed. 2002) ("Consequently, direct examinations should let the witness be the center of attention. The lawyer should conduct the examination so that he does not detract from his witness.").

6. *See, e.g.*, Cate v. Dover Corp., 790 S.W.2d 559, 560 (Tex. 1990) (analyzing the effectiveness of a warranty and disclaimer in a page of advertising). Explicit warranty cases from advertising are usually governed by the Uniform Commercial Code. U.C.C. § 2-313(1)(a) (2002) (defining express warranty as "affirmation of fact or promise made . . . which relates to the goods and becomes part of the basis of the bargain"). For cases where the advertising is on the product, the U.C.C. provides another source of warranty under § 2-314(2)(f), which creates an implied warranty of merchantability that does not require any buyer reliance. U.C.C. § 2-314(2)(f) (2002) (tying the warranty's merchantability standard to the promise on the package).

7. RESTATEMENT (THIRD) OF TORTS § 2(c) (1998) (creating a category of defective products based on a manufacturer's failure to properly warn or instruct consumers).

8. *Id.* § 2(c) reporter's note i ("Commercial product sellers must provide reasonable instructions and warnings about risks of injury posed by products.").

9. Anderson v. Owens-Corning Fiberglas Corp., 810 P.2d 549, 550 (Cal. 1991) (concluding that a duty-to-warn claim sounded in strict liability under California law).

10. *See* Caroline L. Nadal, Note, *The Societal Value of Prescription Drug Advertisements in the New Millennium: Targeted Consumers Become the Learned*, 9 J.L. & POL'Y 451, 451–54 (2001) (describing the shifting attitudes in courts and scholars toward pharmaceutical manufacturer liability).

11. RESTATEMENT (THIRD) OF TORTS § 2(c).

12. Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966).

physician who must make the decision to prescribe based on her medical training, knowledge of pharmaceuticals, and individual diagnosis.[13]

This "learned intermediary" between consumer and manufacturer has led to the exemption of pharmaceuticals from the duty to warn consumers. Known widely as the Learned Intermediary Doctrine (LID), this exemption is a court-created limit that proscribes plaintiffs from bringing duty-to-warn suits against pharmaceutical manufacturers.[14] As with other product liability doctrines, the LID represents a policy decision by the court to reallocate, or in this case refuse to reallocate, the burdens that befall consumers.[15] And until recently, the LID was a relatively settled area of the law.[16]

Things began changing in the 1990s with three related developments. First, the Food and Drug Administration (FDA) issued new regulations allowing pharmaceutical manufacturers to advertise directly to consumers in print and media, leading to a boom in pharmaceutical advertising.[17] Soon afterwards, the New Jersey Supreme Court issued a decision in *Perez v. Wyeth Laboratories, Inc.* that restricted the application of the LID where the manufacturer had advertised directly to the consumer.[18] These developments combined with the Third Restatement's refusal to take a stand on the issue[19] to create a sudden surge of debate in the LID.[20]

It is with some irony then that the emerging debate surrounding the LID has all too often glossed over the issue of advertising.[21] Instead, legal

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13. This Note will focus primarily on prescription drugs. Over-the-counter medications raise a very different set of duty-to-warn issues that are beyond the scope of this Note. *See, e.g.*, Roger Enriquez, Note, *I'm Warning You: Over-the-Counter Drug Manufacturers That Advertise in Spanish Should Warn in Spanish*, 4 J. GENDER RACE & JUST. 353, 361–65 (2001) (arguing for an extension of the duty to warn to cover advertisements that reach out to a new market, which cannot be covered by existing warnings).

14. *Sterling Drug*, 370 F.2d at 85.

15. RESTATEMENT (THIRD) OF TORTS § 1 cmt. a (1998).

16. JAMES A. HENDERSON, JR. & AARON D. TWERSKI, PRODUCTS LIABILITY: PROBLEMS AND PROCESS 433–34 (4th ed. 2000).

17. *See infra* Part I.C.

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

19. RESTATEMENT (THIRD) OF TORTS § 6(d) cmt. e (1998) ("The Institute leaves to developing case law whether exceptions to the learned intermediary rule in these or other situations should be recognized.").

20. *See, e.g.*, Bradford B. Lear, *The Learned Intermediary Doctrine in the Age of Direct Consumer Advertising*, 65 MO. L. REV. 1101 (2000); Nadal, *supra* note 10; Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141 (1997).

21. *See, e.g.*, Michelle D. Ehrlich, *Doctors Can "Just Say No": The Constitutionality of Consumer-Directed Advertising of Prescription Drugs*, 12 HASTINGS COMM. & ENT. L.J. 535 (1990) (focusing exclusively on regulatory control of pharmaceutical advertising); Amy D. White, Note, *The Mass Marketing of Prescription Drugs and Its Effect on the Learned Intermediary Doctrine*, 25 OKLA.

commentators have chosen to focus on issues of federalism, the pragmatic realities of the health care system, and the original purposes of the LID.[22] The result is that pharmaceutical advertisements have established a firm foothold in the marketplace without a focused discussion of how they affect the patient as the ultimate user and what, if any, warnings they must contain.[23] Certainly, there has been some discussion about the effects of direct-to-consumer (DTC) advertising,[24] but this has failed to push the connection between DTC advertising, the consequential shift in doctor-patient relationships, and any resulting duty to warn the consumer.[25] State courts have by and large ignored DTC advertising and its effects when deciding cases involving the LID.[26] With one exception,[27] most courts in the past five years have either delayed making a decision about the LID or voted to reaffirm it, in spite of the changing nature of pharmaceutical DTC advertising.[28]

The purpose of this Note is to reclaim the initiative of the Third Restatement and examine the applicability of the LID to pharmaceuticals that are marketed directly to consumers. When the FDA issued new regulations for drug makers to advertise to consumers in 1997,[29] the days of broad application of the LID seemed numbered.[30] But five years later, the

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CITY U. L. REV. 745, 745–48 (2000) (listing the text or transcript of several pharmaceutical advertisements without any analysis of how they affect consumers).

22. This is especially true of articles that defend pharmaceutical companies or argue for the preservation of the LID. *See* Justin Lee Heather, *Liability for Direct-to-Consumer Advertising and Drug Information on the Internet*, 68 DEF. COUNS. J. 412 (2001) (arguing that the criticism of the LID centers on federal preemption and changes in health care).

23. Currently, FDA regulations do require pharmaceutical advertisements to contain several warnings. Prescription-Drug Advertisements, 21 C.F.R. § 202.1 (2002); *see also infra* Part I.C.

24. *See* Jon D. Hanson & Douglas A. Kysar, *Taking Behavioralism Seriously: A Response to Market Manipulation*, 6 ROGER WILLIAMS U. L. REV. 259, 262–63 (2000) [hereinafter Hanson & Kysar, *A Response to Market Manipulation*] (discussing the problem of manufacturers' use of advertising to lower consumer appreciation of a product's true risk).

25. *Perez*, 734 A.2d at 1255 ("[W]ith rare and wonderful exceptions, the 'Norman Rockwell image of the family doctor no longer exists.'" (citation omitted)).

26. Texas, for example, recently elected to continue using the LID in a case very similar to *Perez*. *In re* Norplant Contraceptive Prod. Liab. Litig., 1997 WL 81092 *1 (E.D. Tex. 1997).

27. *Perez*, 734 A.2d at 1247, *see infra* Part II.

28. The Connecticut Supreme Court's recent decision upholding the LID is indicative of the delaying technique. Vitanza v. Upjohn Co., 778 A.2d 829, 846–47 (Conn. 2001). The court went to great lengths to outline the continuing policy basis for the LID while suggesting at the end that it might, given the proper facts, create an exception for DTC advertising. *See id.* (recognizing the *Perez* decision as one of six possible exceptions that courts have recognized). For an example of a court reaffirming the LID, see *In re Norplant*, 1997 WL 81092.

29. Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements; Availability, 62 Fed. Reg. 43,171 (Aug. 12, 1997) (codified at 21 C.F.R. pt. 202.1); *infra* Part I. C.

30. In addition to *Perez*, which was decided in 1999, most law review articles challenging the LID date to 1997 or later. *See* Noah, *supra* note 20, at 141–45 ("In several respects, 1997 represented a

LID is alive, well, and being applied in the same broad manner it was in 1990 when pharmaceutical advertisements began to expand.[31] While there has never been a call for the elimination of the LID, scholarship in this area has strongly called for reform and limits to its application.[32] But to convince courts and legislatures, advocates will need to establish and explore the transformation that a product, especially a pharmaceutical, undergoes when it enters the world of marketing and advertising. To that end, this Note represents a first step in laying bare the manipulations and motivations that advertising firms use for their clients.

In Part I, this Note describes the history and underlying policy considerations behind the Learned Intermediary Doctrine and the rapid rise in pharmaceutical advertising. Part II describes how the New Jersey and Connecticut Supreme Courts have dealt with the issue of DTC advertising and prescription drugs. Part III explores three paradigms of advertising analysis: behavioralism, motivational research (MR), and media analysis, as well as the art of public relations, which demonstrate the level of manipulation that companies will engage in to promote their products. Finally, Part IV argues that pharmaceutical advertising creates a situation where the LID should not apply and examines how courts in comparable situations have struck down deeply held common-law principles when the factual situations could not support the application. This Note seeks to influence courts and legislatures to amend the LID to allow for liability when a pharmaceutical firm reaches beyond the intermediary and makes promises directly to the consumer.

I. THE NOT-SO-ODD COUPLE: THE LEARNED INTERMEDIARY DOCTRINE AND PHARMACEUTICAL ADVERTISING

At thirty years, the Learned Intermediary Doctrine is a relatively new concept to the common law.[33] In fact, the doctrine may be slightly older

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watershed for pharmaceutical company promotions of prescription drugs directed to lay consumers.").

31. In the early 1990s, Upjohn began a sweeping marketing campaign for its prescription-only hair-loss drug, Rogaine, which can be seen as the prototype for many of the "lifestyle" drugs that have followed. *See* Bruce Horovitz, *Ad on Fighting HIV Draws Mixed Reaction*, L.A. TIMES, Nov. 14, 1990, at D1 (describing Upjohn's 1990 minoxidil campaign), *available at* http://www.aegis.com/news/lt/1990/LT901105.html.

32. Nadal, *supra* note 10, at 501–02 (advocating an exception to the LID without a rebuttable presumption); *see also* Wayne L. Pines, *A History and Perspective on Direct-to-Consumer Promotion*, 54 FOOD & DRUG L.J. 489, 508–12 (1999) (describing the arguments that allies and opponents to DTC advertising have raised).

33. *See* Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966) (finding that as a matter of law the doctor's role as a "learned intermediary" relieves the defendant drug company of any duty to warn).

since some commentators attribute its origins to a 1948 New York Supreme Court decision, *Marcus v. Specific Pharmaceuticals, Inc.*[34] Either way, the LID predates the emergence of pharmaceutical advertising, which did not begin until at least twenty years after the LID had been established.[35] Furthermore, the LID, regardless of its formation date, was established at a time when pharmaceutical companies advertised predominately to doctors.[36] During this period, pharmaceutical companies would send representatives, known as "detail men," to individual doctors.[37] The detail men would use various methods of inducement to convince a physician to adopt their line of drugs as their primary choice for prescriptions.[38] The rationale was and is that a physician can interact with various detail men, develop a full understanding of the drug involved, and still make an independent judgment. As Judge Steuer in *Marcus* stated:

> There is no reason to believe that a physician would care to disregard his own knowledge of the effects of drugs . . . and substitute for his own judgment that of a drug manufacturer. Nor is there any reason to expect that if a doctor did choose to rely on the information given by the manufacturer he would prescribe without knowing what that information was.[39]

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34. Marcus v. Specific Pharm. Inc., 77 N.Y.S.2d 508, 509–10 (N.Y. Special Term 1948) (refusing a claim based on the manufacturer's failure to notify the consumer and establishing that the physician is the only person the manufacturer needs to inform). *Compare* Jeffrey J. Wiseman, *Another Factor in the "Decisional Calculus": The Learned Intermediary Doctrine, the Physician-Patient Relationship, and Direct-to-Consumer Marketing*, 52 S.C. L. REV. 993, 999 (2001) (tracing the LID to Judge Steuer's emphasis in *Marcus* of the physician's centrality in the dispensing of medication), *with* Nadal, *supra* note 10, at 451 n.2 (asserting that the LID dates back to *Sterling Drug*).

35. Pines, *supra* note 32, at 491–92 (noting that pharmaceutical companies began to run some advertising as early as the late 1970s and early 1980s).

36. *See Sterling Drug*, 370 F.2d at 85 (emphasizing the central role of the physician in receiving information about a pharmaceutical); *see also* Laurie K. Marshall, Comment, *Keeping the Duty to Warn Patients of the Risks and Side Effects of Mass-Marketed Prescription Drugs Where It Belongs: With Their Physicians*, 26 U. DAYTON L. REV. 95, 101–02 (2000) (listing the traditional policy arguments surrounding the central nature of the physician); White, *supra* note 21, at 755–57 (discussing the expansion of pharmaceutical advertising to the consumer).

37. Scott Hensley, *More Than Ads, Drug Makers Rely on Sales Reps Known as 'Detail Men,' They Now Hawk Harder, Earlier; Allergy Drugs in January?*, WALL ST. J., Mar. 14, 2002, at B1. The article points out that the detail men are still alive and well, busy promoting pharmaceuticals to doctors. *Id.*

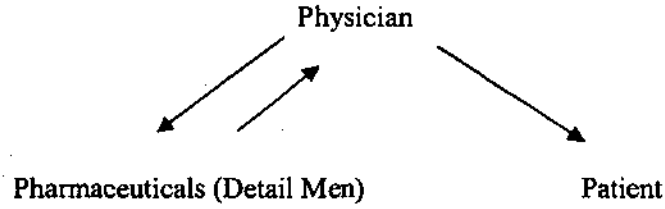
38. *Id.* These methods vary from outright pressure to more subtle forms of inducement such as lunches, complimentary golf games, and paraphernalia, pens, note pads, t-shirts, soap dispensers, etc. Personal interview with a Pharmaceutical Sales Representative who wished to remain anonymous (Sept. 22, 2002) (on file with author).

39. *Marcus*, 77 N.Y.S. at 509–10.

Thus, the physician's learned status has been the basis for the LID, allowing her to bear the pressure of pharmaceutical advertising in place of the uneducated consumer. Whether true or not, courts have relied upon this distinction as the primary basis for the LID ever since.

A. The LID: The Policy Support

Nearly every manufacturer has a duty to warn the user of their product about any dangers associated with the product that cannot be reasonably eliminated.[40] The LID was created to circumvent this duty to warn because "[i]f 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."[41] Under the LID, the doctor is the center of the medical relationship. She receives factual information from the pharmaceutical companies in the form of studies and promotional literature. From the patient, she receives symptoms and details about the illness. But everything is ultimately subservient to her medical opinion that is at once absolute and final. In this classic LID paradigm, the physician picks the proper cure (drugs or therapy) for the individual patient.



The policy supporting this structure, and thereby the LID, is based on four basic premises: that the physician is the most powerful member in the patient–physician–drug relationship; that the loss of liability preserves the physician–patient relationship; that it is difficult or impossible for a pharmaceutical company to make meaningful direct contact with the patient/consumer; and that pharmaceuticals are too important to society to burden with costs and liabilities.

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40. RESTATEMENT (THIRD) OF TORTS § 2 cmt. i (1998); Michael C. Allen, *Medicine Goes Madison Avenue: An Evaluation of the Effect of Direct-to-Consumer Pharmaceutical Advertising on the Learned Intermediary Doctrine*, 20 CAMPBELL L. REV. 113, 117 (1997).

41. *Sterling Drug Inc.*, 370 F.2d at 85.

1. Primacy of the Physician

Physicians decide what medications their patients will take.[42] No matter how badly a patient may want a prescription for Viagra, it is the physician who will ultimately make the diagnosis and prescribe the proper medication. In this respect, patients do not have the same freedom of choice that other consumers enjoy. A car buyer, for example, is restrained only by her own priorities. If she wants to drive a dune-buggy across the Yukon Territory mid-winter, she can, and the car company is only liable to the extent that this action is either foreseeable (and susceptible to a warning) or encouraged and not disclaimed by their advertising.[43] Certainly, the car dealer is not implicated in this scenario. For the patient/consumer, choice lies outside of herself with the physician who in turn is limited by on any number of factors dictated by chemistry, biology, and the physician's personal knowledge.[44] Even within this system, however, there are usually several options for treatment, and often it is through a collaborative physician–patient effort that the choice of treatment is made.[45] In such situations the primacy of the physician remains important but not absolute. The patient, as co-arbiter of treatment and ultimate user of any medication, benefits from at least some information on treatment alternatives. But, if pharmaceutical companies choose to provide this information, they must accept the accompanying, reciprocal duty to warn.

2. Preservation of the Doctor–Patient Relationship

The second basis for the LID comes from the doctor–patient relationship.[46] Apart from the issue of control, the LID serves to focus the patient and manufacturer on preserving the physician–patient relationship.

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42. Davis v. Wyeth Labs. Inc., 399 F.2d 121, 130 (9th Cir. 1968); *see also* Teresa Moran Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 FOOD DRUG COSM. L.J. 829, 830 (1991) (listing reasons for the evolution of the LID).

43. *See* RESTATEMENT (THIRD) OF TORTS § 2 (1998).

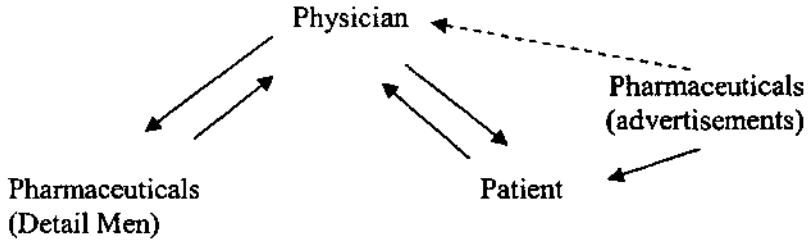
44. This last factor is especially important to physicians who may be leery of prescribing a drug with which they are unfamiliar. In this respect, detail men serve an important educational function by introducing and educating physicians on the qualities and side-effects of new or lesser known medications.

45. *See* Forest Lang, M.D., Editorial, *The Evolving Roles of Patient and Physician*, 9 ARCH. FAM. MED. 65, 65–66 (2000) (describing how physicians are now encouraging their patients to take a more active role in their treatment); *see also* Nancy Shute, *That Old-Time Medicine*, U.S. NEWS & WORLD REP., April 22, 2002, at 54, 55–56 (reporting on new trends in medicine including the "return" to a more patient-oriented system).

46. *See* Schwartz, *supra* note 42, at 830 (listing the responsibility of a doctor to a patient as one reason for the LID rule).

According to the rationale, no matter how much a physician allows a patient to participate in or control her treatment, the physician, and not the drug company, retains primacy in the relationship and controls what information flows to the patient.[47] In other words, a patient can never be autonomous, and the LID functions to reinforce the patient's reliance on the physician as chief healer and dispenser of information as well as medication. To that extent, the patient must trust the physician and her guidance. Conversely, this motivates physicians to stay up to date on pharmaceuticals by putting the legal onus on them.

By moving the duty to warn from consumer to physician, the LID also creates incentive in a pharmaceutical company to inform the physician.[48] Informed patient consent then works on the principle that any prudent patient–pharmaceutical company relationship remains secondary and disposable to the primary patient–physician relationship.[49] Once a pharmaceutical company promotes or creates a direct relationship with the consumer, however, it crosses a potential Rubicon by influencing treatment choices and patient information, and by creating a situation where the physician–patient relationship can be subverted. Visually, the changed dynamics of influence look like:



The new paradigm shows the physician receiving input from the detail men and the patient, like before, but now the physician receives a new, shadow pressure through the patient. If the patient has been influenced by a

47. *Id.* This idea of physician primacy is laterally supported by recent placebo studies, which have demonstrated that the information a patient is told by a physician coupled with the individual's attitude can have a greater than previously thought effect on their recovery. *See* John E. Dodes, *The Mysterious Placebo*, SKEPTICAL INQUIRER, Jan.–Feb. 1997 ("Spontaneous remission and the placebo effect . . . are significant phenomena that have great impact on consumers and health-care professionals."), *available at* http://www.csicop.org/si/9701/placebo.html (last visited Mar. 24, 2003).

48. RESTATEMENT (THIRD) OF TORTS § 6(d)(1) (1998) (establishing the formal duty to warn that pharmaceutical companies owe to all treating physicians); *id.* at cmt. d (discussing the liability from a failure to warn the physician and its associated reason of informed decision making); *see also* Basko v. Sterling Drug, Inc., 416 F.2d 417, 426 (2d Cir. 1969) (discussing the common law duty to warn for physicians).

49. Schwartz, *supra* note 42, at 830–31.

pharmaceutical company, she will bring that to bear on her relationship with the physician. The physician is now presented with information from a third party that she cannot directly refute or probe. In theory, the physician should be able to follow the dictates of Judge Steuer and rely solely on her extensive training and professional opinion.[50] In reality, the physician faced with a patient who has been primed by an outside party may be forced to convince the patient that she is wrong,[51] refuse further treatment,[52] or compromise.[53] Any of these options subvert the physician–patient relationship into a negotiation where a patient, relying on outside counsel, acts against the primacy of the physician to oversee the treatment of her illness. There is further danger that the patient will shop around for doctors only on the basis of whether she will prescribe the medication sought because the patient is convinced that it is the right one. On a more subtle level, the physician in a third-party-influence situation cannot with any certainty determine whether or how any advertising may have influenced the patient's description of her symptoms and aliments.

3. Difficulties in Providing Warnings and Informed Consent

Implicit within any physician–patient relationship is the understanding that the patient has consented to be treated and medically counseled by the physician.[54] This "informed consent," granted by the patient to the physician, confers on the doctor the primary responsibility for taking the necessary factors into consideration and then making a rational treatment decision.[55] It is the physician's job to communicate these decisions to the patient and to explain the reasoning and factors behind the diagnosis and prescription. To assist physicians with their tasks, pharmaceutical companies employ detail men to educate and warn the physician about the benefits and uses for various drugs as well as their side effects and limitations.[56]

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50. *Marcus*, 77 N.Y.S.2d at 509–10.

51. David E. Dukes et al., *What You Should Know About Direct-to-Consumer Advertising of Prescription Drugs*, 68 DEF. COUNS. J. 36, 37 (2001).

52. White, *supra* note 21, at 758 (discussing how physicians are unlikely to turn away patients' requests for medication out of fear that they will take their business elsewhere).

53. *See* Dukes et al., *supra* note 51, at 37 ("[P]hysicians will face an economic incentive to relax their prescribing criteria in an effort to retain patients.").

54. *See* Nadal, *supra* note 10, at 462 (explaining how the physician–patient relationship includes "important deference and reverence that patients cede to doctors").

55. *See* Schwartz, *supra* note 42, at 830 (describing the patient's involvement in a treatment decision as dependent on a physician's description of such treatment).

56. Although beyond the scope of this Note, there are serious questions about the "informing" nature of detail men and their influence over physician decisions. CLARK, *supra* note 3, at 203.

Pharmaceuticals and their defenders have argued that extending the duty to warn to consumers would be impossible.[57] As one commentator argued, "meaningful communication between the everyday prescription consumer and the pharmaceutical manufacturer would be best characterized as difficult."[58] Individual patients, after all, have individual needs and the physician with her knowledge and the informed consent of the patient is the best person to invest with any duty to warn.[59] Again, the LID supports this concern by limiting the pharmaceutical manufacturer's duty to warn to the physician alone and then allowing her to release the relevant information to the patient on an individual basis.

The argument that companies are unable to effectively communicate with patients is undercut by their push to use DTC advertisements. As a communication channel, advertisements are among the most effective ways to reach out to individuals. The issue then shifts from the ability to communicate, to a question of how much information the companies can communicate to how many people and how effectively. As Part III will show, advertisements can be quite effective in communicating to a broad audience but continue to fall short of effectively making the individual warnings that an informed physician delivers to individual patients.[60] Still, advertising shifts the balance of information by giving pharmaceutical companies direct lines of communication to individuals. This communication already carries promotional and warning information about their products and should include a relatively proper amount of liability.

4. The Importance of Pharmaceuticals in Society

The three previously described policies supporting the LID are closely aligned. Some scholars, however, divide the three into further, more

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> The truth, according to professionals who market to doctors, is not like that at all. Doctors, they say, are vulnerable to the same kind of techniques and pressures as any other group of individuals. Perhaps the major difference, they add, is the degree of pretence that is necessary: doctors resent being thought of as irrational and open to emotional persuasion . . . . The pharmaceutical admen that I saw . . . were in no doubt about the nature of their task. "They [doctors] think they decide on scientific grounds," said a man from one of the major American agencies. "They don't. They choose drugs the same way consumers choose goods."

Id.

57. Wiseman, *supra* note 34, at 1004.

58. *Id.*

59. *Id.* at 1003.

60. Jack B. Harrison & Mina J. Jefferson, *"[S]ome [A]ccurate [I]nformation is [B]etter than [N]o [I]nformation [A]t [A]ll": Arguments Against an Exception to the Learned Intermediary Doctrine Based on Direct-to-Consumer Advertising*, 78 OR. L. REV. 605, 625 (1999).

distinct permutations of policy.[61] The problem with this method is that the strength of the LID comes from the sensibility and interrelatedness of its supporting policies. As a common-law exception to a general rule, the LID is justified by the logic of its underlying policy judgments. There is then, perhaps no greater policy justification than the argument that the LID protects pharmaceutical companies from liability, which leaves them free to invest in research and to develop new medications.[62]

This policy argument taps into the altruistic and utilitarian quality that truly sets pharmaceuticals apart from other consumables. Both the Second and Third Restatements of Torts have treated pharmaceuticals separately from other products based in part on this reasoning.[63] Indeed, the policy allows courts to avoid situations where the enforcement of the strict liability duty to warn would lead to the removal of a lifesaving product or decreased funding for research. The use of the LID, at least as a shield for pharmaceutical companies, is therefore ultimately dependent on the value society places on pharmaceutical products, important lifesaving drugs notwithstanding. Over the past few years, however, many of the best-selling and most highly-prescribed drugs have been from a category known as "lifestyle" drugs.[64] "Lifestyle" drugs are distinguished from the more "serious" drugs because their focus is predominantly to enhance or ease socially debilitating maladies, rather than cure life-threatening diseases.[65] Most lifestyle drugs have only been on the market for a few years.[66] Drugs like Viagra,[67] Rogaine,[68] and the recently recalled drug combination known as Fen-Phen[69] are representative of the new generation of drugs. Their

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61. *See* Marshall, *supra* note 36, at 101–02 (arguing that the LID is supported by four policies: physician primacy, the physician as the source of all patient information, preserving the physician–patient relationship, and manufacturers' inability to effectively communicate with patients).

62. Wiseman, *supra* note 34, at 1002.

63. The LID is an exception to the general rule requiring manufacturers to warn the consumer and rests on the premise that drugs are different and their manufacturers deserve protection from the law. *See generally* James A. Henderson, Jr. & Aaron D. Twerski, *Drug Designs* Are *Different*, 111 YALE L.J. 151 (2001) (explaining the differences and similarities between the Second and Third Restatements' coverage of prescription drugs).

64. Temma Ehrenfeld, *Treating a Drug-Price Headache*, NEWSWEEK, May 6, 2002, at 66.

65. Joseph Weber et al., *The New Era of Lifestyle Drugs: Viagra and Other Blockbusters Are Transforming the $300 Billion Industry*, BUSINESS WEEK, May 11, 1998, at 92, 92 (reporting on the growth in lifestyle drugs and their impact on the pharmaceutical industry) *available at* http://www.businessweek.com/1998/19/ b3577001.htm. The article defines lifestyle drugs as those drugs developed to treat discomforts and less-than-painful medical conditions that enhance life and keep chronic problems in check, but not necessarily cured. *Id.* at 94.

66. *See id.* (listing several lifestyle drugs, including those for impotence, arthritis and cholesterol, all introduced on the market between 1996 and 1999).

67. *Id.*

68. Pines, *supra* note 32, at 493.

69. Catherine Arnst, *Lost Warnings Could Have Prevented the Fen-Phen Mess*, BUSINESS

existence, popularity, and extensive marketing raise questions about the greater societal-purpose argument that has extended the LID to all drugs.[70] Even those who benefit from such drugs must admit that the benefits, while great, are from secondary self-esteem boosting than any direct lifesaving qualities. This is not to lessen the debilitating natures of impotence, baldness, and being overweight that prevent suffers from enjoying some of the basic dignities of life.

Still, lifestyle drugs are by their nature about life enhancement and making chronic problems socially bearable.[71] While they may be "lifesavers" to some, they are not designed or intended to be the magic bullets that other pharmaceuticals are.[72] To argue that lifestyle drugs should not fall under the protection of the LID is not to argue against the drugs themselves. Rather, the argument that the courts and legislatures must examine is whether lifestyle drugs deserve protection under the LID. It could be argued that neither has any business segregating specific drugs. Such separation could result in another litigation hurdle that attorneys could exploit to delay or dismiss a case, since the distinction is largely factual and far from bright line.[73] Yet, if the LID is dependent upon its supporting

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WEEK, August 28, 1998, *available at* http://www.businessweek.com/bwdaily/dnflash/aug1998/nf80828c.htm. Fen-Phen was pulled from the market in September 1997 after it was found to have serious side effects, including heart and lung failure. CTR. FOR DRUG EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMIN., FEN-PHEN SAFETY UPDATE INFORMATION, *at* http://www.fda.gov/cder/news/feninfo.htm (last updated Mar. 27, 2001).

70. At the same time, this is not to say that the "serious" drugs are not marketed. In fact, a recent best-selling drug is Lipitor, a cholesterol reducer, that is heavily marketed by its manufacturer, Pfizer Pharmaceuticals. *See* Ehrenfeld, *supra* note 64; *see also* Barbara J. Tyler & Robert A. Cooper, *Blinded by the Hype: Shifting the Burden When Manufacturers Engage in Direct to Consumer Advertising of Prescription Drugs*, 21 VT. L. REV. 1073, 1094 n.174 (1997) (citing to the release of a 1992 prostate cancer drug that Merck Pharmaceuticals, Inc. spent ten million dollars promoting). For utilitarian arguments of societal good, there is a strong point to be made in the distinction between lifesaving and lifestyle drugs as a basis for the LID.

71. Weber, *supra* note 65, at 94.

72. *See* DR. ERLICH'S MAGIC BULLET (Warner Bros. Pictures 1940) (dramatizing the discovery of formula 606, an early but complete cure for syphilis). *Compare* Weber, *supra* note 65; *with* Tyler & Cooper, *supra* note 70, at 1094.

73. What makes a drug a lifestyle drug as opposed to a more serious drug is not clear. Aside from a distinction between the type of ailment to be cured (life threatening or merely socially debilitating), factors for a court to consider might include the type of cure (complete or partial), the marketing strategy (including where it was advertised, targeted groups, and level of promotion), and the purpose for the drug's existence (is there a solid scientific reason for the drug or is it an attempt by the company to create a cash-rich product). Such comparisons can draw the court into an analysis of the product and its marketing as a preliminary matter and may open a Pandora's box for evidence and trial procedure problems. *See, e.g.*, Charles F. Thompson, Jr., *Juries Will Decide More Discrimination Cases: An Examination of* Reeves v. Sanderson Plumbing Products, 26 VT. L. REV. 1, 1–3 (2001) (detailing the evidentiary issues and trial problems arising from rebuttable presumption standards created by a series of Supreme Court cases).

policies, courts and legislatures would be remiss to ignore such a significant development and shift in the purpose of some pharmaceuticals. To ignore the change is to ignore the purpose of the exception. This would create an LID based not on facts or necessity, but on tradition and changing, unsupported principles. Such doctrines in the common law can be very dangerous and easily misapplied.[74]

B. Established Exceptions to the LID

There are currently two widely-established exceptions to the LID that courts have either acknowledged or applied.[75] These exceptions are narrowly drawn, applying only to oral contraceptives and mass immunizations.[76] Both exceptions arise out of factual situations where the policies of the LID were not found to be supported by its application.[77] In the case of mass immunization, courts found that there was no physician–patient relationship in the rote, assembly-line process of injecting hundreds of patients, and that the manufacturers owed a duty to warn people directly.[78] This exception has since been broadened to cover a number of mass immunization situations.[79] The effect of this exception was to shift the duty to warn back onto the manufacturer in a situation where neither manufacturer nor doctor could expect to communicate with the patient. In anticipation of liability extending to manufacturers of mass immunizations, Congress recently neutralized this exception for small pox vaccine manufacturers through Section 304 of the Homeland Security Act of 2002.[80] While broadly applicable to any claims under design or

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74. *See, e.g.*, Vicki C. Jackson, *Narratives of Federalism: Of Continuities and Comparative Constitutional Experience*, 51 DUKE L.J. 223, 223 (2001) (discussing recent Supreme Court decisions that show focus on precedent and are radically altering the relationship between state and federal government).

75. Tyler & Cooper, *supra* note 70, at 1083–89 (discussing *Davis v. Wyeth Labs. Inc.*, 399 F.2d 121 (9th Cir. 1968) and *Reyes v. Wyeth Labs., Inc.*, 498 F.2d 1264 (5th Cir. 1974) as examples of the LID exception for immunizations, and *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65 (Mass. 1985), as an exception to the LID for oral contraceptives); *see also* HENDERSON & TWERSKI, *supra* note 16, at 441–44 (listing the polio exception established in *Reyes* and the oral contraceptives exception in *Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352 (Ill. 1996) as two primary examples).

76. Tyler & Cooper, *supra* note 70, at 1083–89.

77. *Id.*

78. *Reyes*, 498 F.2d at 1276. The court also mentions a line of Texas cases that conclude since the product would harm a substantial number of people, even when properly prepared, manufacturers have a duty to warn. *Id.* at 1278.

79. *See* Tyler & Cooper, *supra* note 70, at 1084–87 (discussing the wide range of mass immunization exceptions created in the federal courts).

80. Homeland Security Act of 2002 § 304, (codified at 6 U.S.C. § 184 (2003)) (limiting liability for small pox vaccinations and establishing a standard that would preempt state law standards). The problem with limiting liability in this situation is that the small pox vaccine has a high potential to

manufacturing defects as well as the duty to warn, Section 304 creates a federal exception to the common law duty to warn that parallels the LID.[81] Counter legislation proposed by Representative Henry Waxman points out that this exception represents a shift of responsibility from the manufacturer or intermediary to the future victims, who would be without legal remedy if the vaccine was properly applied, regardless of the severity of their reaction.[82]

Courts have created a second exception to the LID for oral contraceptives on the basis that female patients seek contraceptives for personal (read: lifestyle) rather than medical reasons, and that as such, the patient makes many of the decisions in selecting her oral contraceptive.[83] Another reason behind this exception is that "patients who take oral contraceptives usually do not have ongoing traditional physician–patient relationships."[84] Some courts, however, have been very willing to find the LID applicable where there is any physician–patient relationship.[85] Other courts have been more generous to plaintiffs and have found an exception to the LID for other types of birth control devices.[86] Recently, the Connecticut Supreme Court announced through dicta that Connecticut recognizes up to six exceptions to the LID.[87] The six include the commonly accepted exceptions of mass immunizations and oral contraceptives as well as contraceptive devices, drugs advertised directly to the consumer, over-

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be harmful or fatal to a large percentage of the population (over 1%) who would have no legal recourse. Edward P. Richards, Op.Ed., *Smallpox Vaccine Casualties: Who Pays?*, JURIST (Nov. 29, 2002) [hereinafter Richards, *Smallpox Law Project*], *available at* http://www.jurist.law.pitt.edu/forum/forumnew77.php; *see also* Edward P. Richards, *Smallpox Vaccine Injury Law Project* (listing internet links to new documents and research regarding smallpox vaccination), *at* http://biotech.law.lsu.edu/blaw/bt/smallpox.htm (last visited Mar. 4, 2003).

81. *See* CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T OF HEALTH & HUMAN SERVS., *Legal & Liability Issues, Questions and Answers: Section 304 of the Homeland Security Act* (Dec. 13, 2002), *at* http://www.bt.cdc.gov/agent/smallpox/vaccination.

82. Smallpox Vaccine Compensation and Safety Act of 2003, H.R. 865, 108th Cong. (2003); Rep. Henry A. Waxman, Statement of Rep. Henry A. Waxman on the Introduction of the Smallpox Vaccine Compensation and Safety Act of 2003, (Feb. 13, 2003), *at* http://biotech.law.lsu.edu/blaw/bt/smallpox/Congress/pdfhomelandsecurity_legis_state.pdf. The threat of injury or death from mass smallpox immunization is very real for a significant number of people. *See* Richards, *Smallpox Law Project*, *supra* note 80.

83. Tyler & Cooper, *supra* note 70, at 1087–89 (citing MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 69 (Mass. 1985)).

84. Tyler & Cooper, *supra* note 70, at 1088 (citing *MacDonald*, 475 N.E.2d at 69).

85. *See* Martin v. Ortho Pharm. Corp., 661 N.E.2d 352, 353, 356–57 (Ill. 1996) (refusing to abrogate the LID because the plaintiff became pregnant while taking birth control and was in regular contact with her physician).

86. Hill v. Searle Labs., 884 F.2d 1064, 1070–71 (8th Cir. 1989) (finding an exception to the LID applied to other forms of birth control under certain situations where the patient played an active role in the choice that the oral contraceptive).

87. Vitanza v. Upjohn Co., 778 A.2d 829, 846–47 (Conn. 2001); *see also infra* Part II.

promoted drugs, and drugs withdrawn from the market.[88] While several of these exceptions are far from universally accepted, they all share common elements. Each exception is rooted in facts and situations where the policies of the LID are not supported by its application. Thus, the Connecticut Supreme Court appears to say that despite any attachment to continuity and uniformity in applying the LID,[89] we should not apply it blindly. Any new exception that the court or legislature chooses must reflect or enunciate the important policies and values of society.[90] The preservation or consistency of the LID is secondary.

C. A Brief History of Pharmaceutical Advertising and Federal Preemption

In 1982 a storm was brewing. In that year of deregulation and corporate expansion, Arthur Hull Hayes, Jr., Commissioner of the Food and Drug Administration (FDA), made a speech to the Pharmaceutical Advertising Council stating that pharmaceutical advertisements to the consumer were inevitable and that he foresaw their expansion in the coming years.[91] The pharmaceutical companies took the Commissioner at his word and used the speech as a green light for the advertising and mass marketing of prescription medication.[92] A year later, the FDA had to call for a voluntary moratorium on DTC advertising.[93]

For the next fourteen years, the FDA, pharmaceutical companies, advertising firms, and public relations firms debated the manner and form pharmaceutical advertising would take as it continued to emerge in greater amounts.[94] Still, forbearance prevailed and only a few pharmaceutical

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88. *Vitanza*, 778 A.2d at 846–47. The Connecticut Supreme Court culled these exceptions from other jurisdictions and did not actually apply any of them in the case. *Id.* The recognition of so many exceptions, however, is remarkable and represents at least willingness by this court to consider the policy behind the LID.

89. Marshall, *supra* note 36, at 105–07 (describing the general reluctance of courts to create new exceptions to the LID).

90. Even using the term *exception to the LID* is misleading since the LID is itself an exception. Calling oral contraceptives an exception to the exception is just another way of saying that the exception (the LID) does not apply and the general rule does. Such nomenclature arguments smack of pedantic exercise, but they do reinforce the idea that the LID is an exception sustained only because of policy concerns.

91. Pines, *supra* note 32, at 492–93 (detailing the impact of Hayes' speech and its retrospective importance).

92. *See id.* (noting that prior to Hayes' speech most pharmaceutical companies had not considered advertising prescription drugs).

93. Dukes et al., *supra* note 51, at 37.

94. *See* Pines, *supra* note 32, at 491–96 (recounting the history of direct advertising by pharmaceutical companies and FDA regulation).

advertisements were actually produced during this period.[95] In 1997, the FDA issued a draft of its regulatory guidelines.[96] Television, print, and Internet ads for pharmaceuticals exploded. Popular news magazines such as *Time* and *Newsweek* began to carry three or more pharmaceutical advertisements per issue.[97] Pharmaceutical television advertisements became ubiquitous, employing all of the traditional forms of advertising from humor to melodrama to celebrity spokespeople—including former Presidential candidates, popular television personalities, and famous sports figures[98]—to free promotional giveaways.[99] Over a short period of time, pharmaceutical ads have become a regular fixture in advertising and in the consciousness of the general public. But more importantly, this expansion occurred very quickly and without the government taking full measurement of its impacts on the market, the consumer, and the relationships underlying the product's use.[100]

It is also important to note that the federal rules governing pharmaceutical advertising cover many of the same areas as the common law duty to warn.[101] This close relationship between FDA regulations and state common law sets up an argument for federal preemption of any tort claims against pharmaceutical manufacturers.[102] Preemption occurs when a

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95. *Id.* Despite the voluntary moratorium, several pharmaceutical companies continued their advertising strategies and developed vague television ads that suggested among other things that people with stomach problems ask their physicians about "'available treatment programs, sponsored by Smith Kline, the ulcer experts.'" CLARK, *supra* note 3, at 226 (detailing the Smith Kline program and other campaigns of the same era).

96. Draft Guidance for Industry: Consumer-Directed Broadcast Advertisements: Availability, 62 Fed. Reg. 43,171 (Aug. 12, 1997) (codified at 21 C.F.R. pt. 202.1).

97. *E.g.*, AstraZeneca, Advertisement, *Nexium*, NEWSWEEK, May 6, 2002 at 9–10; Pfizer Inc., Advertisement, *Zyrtec*, NEWSWEEK, Apr. 29, 2002 at 17–18. Like its competitor, *Time* will carry several pharmaceutical ads and often the two magazines carry identical advertisements in the same week. The result is market saturation in at least a very basic sense. The number of pharmaceutical advertisements will vary from week to week and can be affected by the magazine's content. *See* TIME, Apr. 22, 2002 (featuring a cover story on human guinea pigs in drug research, and its potentially deadly results, and no pharmaceutical ads). The next week *Newsweek* ran three pharmaceutical advertisements and a notice for a "special advertising" section in the next issue. *See generally* NEWSWEEK Apr. 29, 2002.

98. *See* Lisa Belkin, *Prime Time Pushers*, MOTHER JONES, Mar.–Apr. 2001, at 31.

99. Schering Corp., Advertisement, *Nasonex*, BETTER HOMES AND GARDENS, May 2002, at 25.

100. *See* Melody Petersen, *Increased Spending on Drugs Is Linked to More Advertising*, N.Y. TIMES, Nov. 21, 2001, at C1 (reporting a link between increasing drug prices and the rise in drug marketing). *Cf.* Andrea J. Nordaune, *Sales and Advertising: Keeping the Promises We Make*, 27 WM. MITCHELL L. REV. 361, 367–68 (2000) (noting that DTC advertising has been very lucrative for pharmaceutical companies).

101. *Compare* Prescription-Drug Advertisements, 21 C.F.R. § 202.1 (2002), *with* RESTATEMENT (THIRD) OF TORTS § 2(c) (1998) (requiring manufacturers to include adequate warnings on advertisements).

102. Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049, 2074–84 (2000)

court finds that the federal government speaks so comprehensively in an area that the state has nothing left to control.[103] Such federal preemption would remove state law and common-law from litigation in this area and transform any remaining court action into an administrative process about the pharmaceutical company's compliance with regulations. The issue, however, is not as clear-cut as some might wish to portray it.[104] In fact, the regulations, while extensive, are not absolute and do not provide any legal recourse for patients or the government to seek damages from a company for injuries.[105]

Regulations concerning pharmaceutical products do not set clear standards for courts considering questions of liability, particularly those involving the use of the LID.[106] Certainly, the FDA regulations go into great detail establishing what ads must carry,[107] what they cannot say,[108] how they should be labeled,[109] and the elements of "true statements"[110] and "false" ones.[111] Such standards are arguably important when considering what the duty-to-warn standard entails, but the FDA regulations are different because they are a product of an administrative process that emphasizes compliance and minimum standards, not liability and the allocation of risk between parties. While the federal regulations are at once very important to the discussion, they are also irrelevant to any analysis of the underlying policy issues at stake. For this reason, the remainder of this

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(discussing the emerging theory of federal preemption arising from FDA regulations governing DTC advertising).

103. HENDERSON & TWERSKI, *supra* note 16, at 395. Short of express federal preemption, Henderson and Twerski suggest three factors courts use to find implied federal preemption. *Id.* Courts look to see if "(1) Congress has enacted a regulatory scheme so comprehensive that it leaves no room for state action, (2) state law obstructs Congress's pursuit of a dominant federal interest, or (3) state law and federal law conflict in a manner that makes compliance with both impossible." *Id. See generally* Rabin, *supra* note 102 (analyzing the history and arguments associated with federal preemption of state tort law).

104. HENDERSON & TWERSKI, *supra* note 16, at 395; *see* Rabin, *supra* note 102, 2053–60 (discussing how the regulatory scheme for prescription drugs established by the FDA interacts with state tort law). The difference between regulatory compliance and regulatory preemption is complex. *Id.* at 2053. Since Congress did not explicitly preempt state tort common law with FDA regulations, state courts are left to decide what kind of deference to give these regulations. *Id.* at 2054. If a state court decides to accept the FDA standard as establishing the common law duty requirement, then compliance with the regulation can form a defense, as opposed to a constitutionally preemptive effect. *Id.*

105. *See* 21 C.F.R. § 202.1.

106. Rabin, *supra* note 102, at 2075 ("[T]he tort system in assessing either a strict liability claim or a risk-benefit-driven negligence claim is not undertaking the same inquiry as a regulatory agency adopting a minimal standard of safety.").

107. 21 C.F.R. § 202.1(a)(1), (a)(2), (d)(2), (e)(3)(iii).

108. *Id.* § 202.1(a)(3)–(5).

109. *Id.* § 202.1(e)(4).

110. *Id.* § 202.1(e)(5).

111. *Id.* § 202.1(e)(6).

Note will emphasize the state law and policy aspects that are critical to the LID and are openly challenged by the DTC advertising of pharmaceuticals.

The question of what role pharmaceuticals will play in the consumer landscape grows more settled each day. As recent commentators have said, "DTC advertising of prescription drugs is here to stay."[112] But, it has come with all the baggage of commercial advertising. As such, analysis must begin with what advertising does to a product and the way consumers approach it. For example, some advertising works to create a pre-established range of choices that preclude other choices or considerations.[113] A recent Nasonex nasal spray ad carried the script, "You're sneezing. Your nose is running. Think you need an allergy pill? . . . Think again."[114] The implication is that there is now a choice between pills and sprays for a sneeze or a runny nose, which presumes seasonal or chronic allergies. In truth, such symptoms could come from any number of things and might respond to several cures or only one, hence the need for a physician to diagnosis and prescribe. But at the same time, the ad establishes to the targeted audience that the universe of causal factors and solutions is much more limited. With one notable exception, courts have by and large ignored this effect and its relationship to the continuing usefulness of the LID.[115] Courts cannot continue to do so and still honor the policies and values at stake.[116]

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112. Tyler & Cooper, *supra* note 70, at 1105.

113. A good example of this phenomenon was the "cola wars" of the 1980s. Marketing campaigns created the dichotomy of Coke versus Pepsi. *See generally* MARK PENDERGRAST, FOR GOD, COUNTRY, AND COCA-COLA: THE UNAUTHORIZED HISTORY OF THE GREAT AMERICAN SOFT DRINK AND THE COMPANY THAT MAKES IT (1993) (analyzing the history of Coca-Cola's marketing campaigns over the years and its competition with Pepsi-Cola). Advertisements pushed brand loyalty and encouraged people to identify with one or the other brand to the exclusion of all other colas. *Id.* At the same time, products like Mountain Dew and Mello Yellow never went head to head in the same manner. The advertisements, which centered around the "debate" over which cola was better, also precluded the idea that people might choose to not drink cola. *See* BERKELEY BREATHED, CLASSICS OF WESTERN LITERATURE: BLOOM COUNTY 1986–1989, at 89 (1990) (satirizing the false choices created by the major cola manufacturers).

114. Schering Corp., *supra* note 101.

115. Perez v. Wyeth Labs., Inc., 734 A.2d 1245, 1247 (N.J. 1999) (finding that the LID did not apply where the manufacturer advertised directly to the consumer). Certainly, other courts have not ignored the expansion of pharmaceutical advertising but their decisions reflect a cursory acknowledgment that belies a true understanding of the effects of pharmaceutical advertising to the policies behind the LID. *See, e.g.*, Lennon v. Wyeth-Ayerst Labs., Inc., 2001 WL 755944 *2 (Pa. Super. 2001) ("Media dissemination of information concerning the existence of these drugs does not enhance the public's ability to acquire them . . . ."). *But see* Allen, *supra* note 40, at 124 (using the FDA guidelines to point out that the government supports DTC advertising because it enables consumers to gain access to drug products that they might not otherwise know about).

116. Nor can courts continue to ignore the massive amounts of money being poured into DTC advertising. Over the past ten years advertising budgets have swelled geometrically as pharmaceutical companies have reached further and further into the American psyche through advertising. Pines, *supra*

II. *PEREZ* AND *VITANZA*: BREADCRUMBS FOR ADVERTISERS?

In 1999, the Supreme Court of New Jersey created a new exception to the LID with its decision in *Perez v. Wyeth Laboratories Inc.*[117] The impact of *Perez* has been undeniable. Since its issuance in 1999, the decision has become a lightning rod for commentary on the LID with commentators polarized between seeing the case as a rallying point, or an aberration that must be ignored.[118] The decision is perhaps best understood as one court's reaction to DTC advertising, which by 1999 had grown to over one billion dollars per year,[119] and to the Third Restatement of Torts.[120] Prior to the Third Restatement, the LID existed solely in the common law of some states and was not codified in the Second Restatement in any form.[121] In the Third Restatement, the reporters, James Henderson and Aaron Twerski, recognized that new exceptions were changing the LID. They attempted to avoid controversy, however, by refraining from codifying any exceptions, which were left to "developing case law."[122] The *Perez* decision is one such development.[123]

The plaintiffs in *Perez* were women who had experienced difficulties and side effects from Norplant contraceptive device.[124] The plaintiffs claimed that they suffered "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

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note 32, at 506–08.

117. *Perez*, 734 A.2d at 1247.

118. *See, e.g.*, Honorable William A. Dreier, *Direct-To-Consumer Advertising Liability: An Empty Gift to Plaintiffs*, 30 SETON HALL L. REV. 806–14 (2000) (containing an extended critique of *Perez*); Heather, *supra* note 22, at 414–16 (providing an example of how the defense counsel industry has viewed and wishes to view *Perez*); White, *supra* note 21, at 765–68 (providing a good summary of *Perez* and its potential ramifications). While pro-defense commentators have been quick to speak against the *Perez* decision or minimize its applicability, commentators in favor of its exemption have been a bit more leery. *See* Nadal, *supra* note 10, at 472 ("Perez, however, is only a limited victory for consumers.").

119. White, *supra* note 21, at 755 (reporting that pharmaceutical companies spent one billion dollars in the first ten months of 1998); *see also* Pines, *supra* note 32, at 506–08 (detailing the massive amounts of money involved in DTC advertising in the past decade).

120. RESTATEMENT (THIRD) OF TORTS § 6 (1998).

121. *See* RESTATEMENT (SECOND) OF TORTS § 402 A (1965) (discussing strict liability without any reference to the LID). To a certain extent Product Liability was an afterthought to the Second Restatement, which dedicates only one section to the idea of strict liability. *Id.* § 402 A. Additionally, the Second Restatement predates the first case to enunciate the LID as it is known today. *See* Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966) ("[T]he purchaser's doctor is a learned intermediary between the purchaser and the manufacturer.").

122. RESTATEMENT (THIRD) OF TORTS § 6 cmt. e (1998).

123. *Perez*, 734 A.2d at 1253 (discussing the LID provisions in the Third Restatement of Torts and its flexible philosophy for developing exceptions).

124. *Perez*, 734 A.2d at 1248.

nervousness, vision problems, anemia, mood swings and depression, high blood pressure, and removal complications that resulted in scarring."[125] They alleged that despite a large marketing campaign that targeted women, Wyeth Laboratories never provided the consumers with information on the potential side-effects of the product.[126] As consumers, the plaintiffs argued, Wyeth Laboratories owed them a duty to warn of these side effects, and since Wyeth reached out to the plaintiffs, it should not be protected by the LID.[127] Lower courts rejected plaintiffs' arguments and found that the LID barred liability.[128] The New Jersey Supreme Court granted certification shortly thereafter on the issue of exception to the LID.[129]

The New Jersey Supreme Court's opinion in *Perez* begins with a discussion of the LID in New Jersey.[130] Importantly, the court finds that it has been applied where "sufficient reasons exist[ed]."[131] The opinion moves to Section III with an outline and analysis of the effect of DTC advertising on consumers.[132] Section III is arguably the most important part of *Perez* because it recognizes that DTC advertising has a significant psychological impact on consumers that changes the relationship between the physician and patient.[133] It is these changes that warp the function of the LID from protecting important physician prerogatives to simply protecting manufacturers.[134] While the court does not elaborate on how advertising creates these fundamental changes, it does make clear that the manufacturers were aware of the changes and chose to continue marketing in search of higher profit margins.[135] Whether the court successfully addresses these issues is debatable. In the final section, the court shifts its

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125. *Id.* at 1248.

126. *Id.*; *see also* Dreier, *supra* note 118, at 809 (noting that the marketing campaign included advertisements on television and in women's magazines like *Cosmopolitan*, *Glamour*, and *Mademoiselle*).

127. *Perez*, 734 A.2d at 1248–49.

128. *Id.*

129. *Id.* at 1249–50.

130. *Id.* at 1250–51 (pointing out that the LID relieves manufacturers of a duty to warn where the duty is otherwise sufficiently discharged).

131. *Id.*

132. *Id.* at 1251–53. *But cf.* Lennon v. Wyeth-Ayerst Labs., Inc., 2001 WL 755944 *2 (Pa. Super. 2001) (dismissing arguments addressing DTC advertising in two sentences).

133. *Perez*, 734 A.2d at 1251–53.

134. *See id.* (citing to behavioralist studies, the pressure pharmaceutical companies put on consumers, and the American Medical Association's long standing opposition to advertising). The *Perez* court makes these issues more explicit in the next section when it creates a new exception to the LID. *Id.* at 1253–59. "Consumer-directed advertising of pharmaceuticals thus belies each of the premises on which the learned intermediary doctrine rests." *Id.* at 1256.

135. *Id.* at 1252. Part III of this Note will discuss some of the theories describing the effects of advertising that cause the physician–patient relationship to weaken.

analysis to the LID and its general purpose.[136] In very strong language, the court carves out an exception to the LID based upon its prior analysis of the changes wrought by the rise of DTC advertising and recent changes in the law.[137] To do this, the court does not cancel the LID but creates a rebuttable presumption based on federal regulations.[138] The court states that it would presume a pharmaceutical company has satisfied the duty to warn when it has complied with FDA regulations.[139] This presumption would be rebutted, however, if a plaintiff could show that the manufacturer did not fulfill its duty to warn.[140]

In the wake of *Perez*, reaction from the legal community was mixed. One commentator pointed out that the presumption solution of the New Jersey court ignored the letter of existing New Jersey Product Liability Law and created a conservative standard of proof that would not allow plaintiffs any more access to pharmaceutical companies than they had under the LID.[141] Instead of creating a duty to warn the consumer, the *Perez* court had simply substituted one standard (the LID) for another (FDA regulations).[142] On the other hand, *Perez* has gained equal infamy amongst the defense bar, which seeks to limit the decision as "the only state supreme court decision adopting an advertising exception to the learned intermediary doctrine."[143] Commentators have warned of the "chilling effect" liability might have on pharmaceutical companies' right to commercial speech.[144] Others have seen the court's decision as an acknowledgment of federal preemption and a way to push state courts out of the issue altogether.[145] What critics can agree on is that New Jersey, through its decision, stands alone as the only state to have officially recognized a third exception to the LID.[146] In this respect, perhaps the biggest criticism of *Perez* is that it failed to create an effective exception to the LID. Regardless of its failures in the eyes of some, *Perez* remains a ground-breaking case that goes to

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136. *Id.* at 1253–59.

137. *Id.* at 1247 ("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 of side effects of the product."); Drier, *supra* note 120, at 811.

138. *Perez*, 734 A.2d at 1259.

139. *Id.*

140. *Id.*

141. Drier, *supra* note 118, at 808.

142. *Id.*

143. Dukes et al., *supra* note 51, at 46.

144. Harrison & Jefferson, *supra* note 60, at 637.

145. Rabin, *supra* note 102, 2074–84.

146. *Cf.* Harrison & Jefferson, *supra* note 60, at 613 ("Over time, however, *Perez* may signal a sea change in the application of the learned intermediary doctrine where DTC advertising is present.").

great lengths to recognize the effect advertising has on the consumer even under a federally regulated system. Whether accepting or rejecting the *Perez* decision, courts facing this issue will have to deal with the conclusions of the New Jersey Supreme Court.

Vitanza v. Upjohn Co., a post-*Perez* case, demonstrates, despite its holding, that the concepts of *Perez* have taken hold.[147] In *Vitanza*, the plaintiff's wife received samples of Ansaid, a nonsteroidal anti-inflammatory drug, from her gynecologist.[148] The samples contained a warning insert in each box, but did not carry a warning on each individual blister-pack sample.[149] The samples were given specifically to Mrs. Vitanza following a pregnancy, but two years later, her husband, while suffering from a headache, found the samples in the medicine cabinet, took them, had an allergic reaction, and died.[150] In an answer to a certified question from the Second Circuit Court of Appeals, the Connecticut Supreme Court held that the LID applied in this situation.[151] Further, the Connecticut Supreme Court explicitly rejected the plaintiff's request to fashion a new exception for promotional drugs, which in the court's opinion was not warranted.[152] Instead, the court summarized six exceptions that other courts have created to the LID that reflected, "a lack of communication between patients and their physicians or where patients essentially control the selection of the product."[153] The exceptions are vaccine inoculations, oral contraceptives, contraceptive devices, drugs advertised directly to consumers, overpromoted drugs, and drugs withdrawn from the market.[154] The court refused to go any further toward formal recognition of any of these exceptions, but by merely listing these six as separate exceptions with a common underlying policy of protecting physician–patient communication, the court clearly suggests that it is willing to entertain arguments for exceptions. It also shows that the court will analyze future challenges to the LID based on its underlying policy and purposes. While by no means as radical as *Perez*, the *Vitanza* court does show that states are willing to explore the LID issue and may be persuaded

147. Vitanza v. Upjohn Co., 778 A.2d 829, 832–33 (Conn. 2001) (responding to certified questions on the LID in Connecticut).

148. *Id.* at 833–34.

149. *Id.*

150. *Id.* at 834.

151. *Id.* at 832–33.

152. *Id.* at 846–47.

153. *Id.*

154. *Id.* In addition to the common elements given by the court, the exceptions also reflect instances where the pharmaceutical company has made significant personal connections with the patient as a consumer, outside of the traditional medical paradigm. *See supra* Part I A.

by arguments appealing to the shift in control and communication that DTC advertisements create in the physician–patient relationship.

III. THIS PILL WILL CURE YOU!* AND IT'S FREE FOR TEN DAYS!

*Pill Not Guaranteed to "Cure" "People." May Cause
SIDE EFFECTS,† LOOK FOR OUR AD IN GOOD HOUSEKEEPING
†SIDE EFFECTS MAY INCLUDE: DIZZINESS, VOMITING, INSOMNIA, SWEATING, HOT FLASHES, SEIZURES, TENDENCY FOR YOUR LEFT EYEBALL TO ROLL, INABILITY TO DIGEST SOLIDS, TOOTH DECAY, ATHLETE'S FOOT, UNPOPULARITY, AND MALAISE. PILL SHOULD NOT BE TAKEN IN CONJUNCTION WITH ANY OTHER MEDICATION, FOOD, OR WATER. CONSULT YOUR PHYSICIAN BEFORE YOU EVEN THINK ABOUT TAKING THIS PILL.

Advertising is the way that pharmaceutical companies reach out to the consumer and make promises directly to her. Once the manufacturer crosses this line, it must forfeit some of the protection of the LID because such promises undermine the centrality of the physician as sole arbiter of the patient's medical diagnosis and prescriptions. Advertising alters the physician–patient relationship by giving information to the patient directly, regardless of the physician's assessment or the patient's individual history. Only when courts understand the very real effect of this on the nature of health care and the role of the physician will they be able to make a rational decision about the LID.

In the wake of *Perez* and *Vitanza*, the need to understand the effects and purpose of advertising has become all the more important. As the New Jersey Supreme Court showed in Section III of its *Perez* decision, courts will look to the nature of DTC advertising to create an exception in the LID.[155] But courts will only look to advertising if parties can show the connection between advertising and a change in the underlying relationships that the LID traditionally protects.[156] This Part of the Note discusses three different methods of analyzing advertisements: Behavioralism, Motivation Research, and Media Analysis. While all three are outside the traditional legal methodology, each is a powerful lens through which the effects of advertising become clear.[157]

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155. Perez v. Wyeth Labs. Inc., 734 A.2d 1245, 1251–53 (N.J. 1999).

156. *See, e.g.*, Lennon v. Wyeth-Ayerst Labs., Inc., 2001 WL 755944 *2 (Pa. Super. 2001) ("Media dissemination of information concerning the existence of these drugs does not enhance the public's ability to acquire them . . . .").

157. Marshall McLuhan's "mosaic" style of media analysis, for example, is somewhat daunting on first blush. When it was first introduced to the general public, the system generally created more confusion than enlightenment. *See* James C. Morrison Jr., *Marshall McLuhan: No Prophet Without Honor*, *in* BEYOND THE IVORY TOWER: PUBLIC INTELLECTUALS, ACADEMIA AND THE MEDIA (Saleem H. Ali ed.) (draft manuscript) ("[I]t is understandable why McLuhan's critics have found it difficult or impossible to comprehend or accept both his medium—aphoristic probes arranged in a mosaic

A. Behavioralism: Conditioning the Mind So That the Body May Follow

One advantage of DTC advertising, according to its advocates, is that "[c]onsumers can use the beneficial product information gained through the direct-to-consumer, mass-market advertisements to ask their doctor questions or identify potential problems with the usage of the drug thereby opening a dialogue with the physician regarding treatment options."[158] The argument is that pharmaceutical advertisements open a new world of information to patients connecting them to information they might never otherwise hear about.[159] Advocates of DTC advertising present their commercials and ads as cornucopias of drug information that broaden a patient's knowledge and enhance her participation in the physician–patient relationship.[160] The truth is quite a bit different. Hanson and Kysar, two of the leading legal scholars of behavioralism, have found that first and foremost, "individuals are vulnerable to manipulation by those in a position to influence the decisionmaking context."[161] In other words, commercials do not educate or stimulate but rather manipulate and persuade in a unilateral manner.

Behavioralism, according to Hanson and Kysar, is a term "legal scholars use to describe a mounting effort to incorporate the findings of cognitive psychology into orthodox law and economics."[162] As Hanson and Kysar argue in their research, in the area of motivations and decision processes, behavioralism makes perfect sense to companies as a method of maximizing their profitability by controlling their advertising to be as effective as possible.[163]

Behavioralism also contends that human decision-making is not rational or logical.[164] It is often driven by biases and personal beliefs, and it is consistent in its irrationality. Hanson and Kysar argue that it can be

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structure—and his message, because of the way our minds have been shaped by typography, invisibly and subliminally."), *available at* http://www.mit.edu/~saleem/ivory/ch2.htm (last visited Mar. 31, 2003).

158. Marshall, *supra* note 36, at 113.

159. Noah, *supra* note 20, at 178–79.

160. Allen, *supra* note 40, at 125.

161. Jon D. Hanson & Douglas A. Kysar, *Taking Behavioralism Seriously: Some Evidence of Market Manipulation*, 112 HARV. L. REV. 1420, 1426 (1999) [hereinafter Hanson & Kysar, *Some Evidence of Market Manipulation*].

162. Hanson & Kysar, *A Response to Market Manipulation*, *supra* note 24, at 263 n.9 (distinguishing behavioralism from "'behaviorism' (without the 'al'), which is the school of psychology that excludes cognitions from its analysis").

163. Jon D. Hanson & Douglas A. Kysar, *Taking Behavioralism Seriously: The Problem of Market Manipulation*, 74 N.Y.U. L. REV. 630, 743 (1999) [hereinafter Hanson & Kysar, *The Problem of Market Manipulation*].

164. Hanson & Kysar, *Some Evidence of Market Manipulation*, *supra* note 161, at 1425.

charted and predicted through study.[165] The natural result is that companies, either consciously or unknowingly, driven by the competitive forces of the market, utilize applications that "tap into" consumer perceptions to manipulate the market and propel their product.[166] As proof, Hanson and Kysar offer the fact that "[m]anufacturers spend $8 billion per year studying consumer behavior and psychology."[167] That money buys data and research that chart, track, and take apart consumers' decision-making processes to understand how targeted consumers choose and what motivates them to do so.[168] The result is a great deal of information about consumer habits that companies can and do use to manipulate those habits.[169]

Hanson and Kysar argue that pharmaceutical advertisements based on this system of behavioralism are far from effective in their claimed purpose of providing information.[170] Their arguments center around three main points: ineffective warnings, detrimental effects on the delivery of information to physicians, and a deterioration of the physician–patient relationship.[171]

First, the warnings in pharmaceutical advertisements are not effective.[172] Aside from the fact that television ads cannot carry enough information in thirty-to-sixty seconds to properly inform a consumer, print advertisements are simply too small, confusing, and generalized.[173]

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165. *Id.* at 1425–26.

166. *Id.* at 1427, 1469.

167. *Id.* at 1429.

168. *Id.* at 1429–30. It seems apparent that pharmaceutical companies participate in this kind of research. For example, in a random sampling of magazines in May, 2002, I found the heaviest concentration of pharmaceutical advertisements in the following magazines: *Better Homes and Gardens*, *Readers' Digest*, *Woman's Day*, *Cooking Light*, *Ladies Home Journal*, *O the Oprah Magazine*, *Parents*, and *Martha Stewart Living*. Each magazine had at least three prescription pharmaceutical advertisements per hundred pages. Both *Better Homes and Gardens* and *Readers' Digest* averaged about five to six per hundred pages. The following magazines contained one to two ads per issue: *Time*, *Newsweek*, *Self*, *Forbes*, and *Golf*. Additionally, the *Golf* magazine contained two advertisements, one for an asthma medication and one for Viagra with the text: "What happens if you don't talk to your doctor about VIAGRA? Nothing." Pfizer Inc., Advertisement, *Viagra*, GOLF, May 2002, at 43. Finally, the following magazines contained no pharmaceutical advertisements: *Popular Science*, *Business Week*, *Atlantic Monthly*, *Harpers*, *Entertainment Weekly*, *Outside*, *Backpacker*, and *Sound and Vision*. This suggests that these magazines a) have banned pharmaceutical advertising, b) are read exclusively by people who never get sick, c) are read exclusively by people who do not deserve to know about wonderful pharmaceutical products that they might otherwise never learn about, or d) reflect careful market research and surveys that showed people who read *Better Homes and Gardens* to be far more likely to use/want pharmaceuticals than the readership of *Outside*.

169. Hanson & Kysar, *Some Evidence of Market Manipulation*, *supra* note 161, at 1450.

170. *Id.* at 1455–59.

171. *See id.*; *infra* notes 172–183 and accompanying text.

172. Hanson & Kysar, *Some Evidence of Market Manipulation*, *supra* note 161, at 1456.

173. *Id.*

Consumers do not take the warnings seriously and consider them "general reassurance" rather than actual warnings.[174] It is at this point that a pharmaceutical company might argue that if people do not follow the warnings, then the company should not be held responsible.[175] But this criticism misses the larger, systemic critique that Hanson and Kysar level at the methods employed by advertisers, including the manipulation of consumers' risk perceptions.[176] No matter how they are written, the ads do not warn, but lull consumers into complacency and therefore fail to provide adequate information.[177]

The second issue is that the explosion in DTC marketing affects how detail men deliver information to physicians.[178] This is what Hanson and Kysar call the indeterminacy of perceptions.[179] Here doctors perceive themselves to be immune from advertising and the marketing-oriented promotions by the detail men, but in reality they are just as susceptible as consumers to advertising.[180] The result is that doctors may be influenced subconsciously , and this may consequently affect how they prescribe for their patients.[181]

The third major issue that Hanson and Kysar found through their research was the compound effect that DTC advertising had on existing strains in the physician–patient relationship.[182] They write that

> one should at least consider the possibility that the combination of direct-to-consumer advertising and promotional efforts targeted at physicians has resulted in suboptimal prescribing and

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174. *Id.*

175. *See* Webb v. Navistar Int'l Transp. Corp., 166 Vt. 119, 137–48, 692 A.2d 343, 353–60 (1996) (Johnson, J. *dissenting*) (arguing that companies have to account for people not reading detailed instructions). "Products should be designed to protect not only ideal consumers, but also careless, illiterate, ignorant, and inattentive ones as well." *Id.* at 147, 692 A.2d at 359.

176. Hanson & Kysar, *The Problem of Market Manipulation*, *supra* note 163, at 743.

177. Hanson & Kysar, *Some Evidence of Market Manipulation*, *supra* note 161, at 1456. This "lulling effect" is often lost on attorneys who have some awareness of liability and personal injury law, but it is predictable that the average non-legal consumer will view the warnings as a sign that somebody has figured all the problems out. *See id.* ("Consumers often interpret such warnings as a 'general reassurance' that their condition can be treated, rather than as a requirement that 'specific vigilance' is needed to protect them from product risks.").

178. *Id.* at 1457–58.

179. Hanson & Kysar, *The Problem of Market Manipulation*, *supra* note 163, at 723.

180. Hanson & Kysar, *Some Evidence of Market Manipulation*, *supra* note 161, at 1457–59; CLARK, *supra* note 3, at 203.

181. *See* William C. MacLeod & J. Howard Beales, *Assessments of Pharmaceutical Advertisements: A Critical Analysis of the Criticism*, 50 FOOD & DRUG L.J. 415, 415 (1995). Doctors are, after all, human beings and despite their vast wealth of knowledge they are just as susceptible to pressure from patients, detail men, and the effects of advertising from private contact.

182. Hanson & Kysar, *Some Evidence of Market Manipulation*, *supra* note 161, at 1459.

> consumption of pharmaceutical drugs. When physical insecurities about baldness are consciously targeted in consumer ads, when fifty-seven percent of ads directed at physicians are judged to have little or no educational value, when physicians are rewarded with airline tickets for increasing the number of prescriptions they write—when those and other similar promotional efforts characterize the pharmaceutical drug market—one might justifiably surmise that the concomitant demand for medicines is excessive.[183]

At the bottom line, Hanson and Kysar simply argue that the consumer (whether doctor or patient) should be aware of gifts, offers, and advertising as a promotional tool because they often short change the warning or create a situation where the consumer is distracted from the warning.[184] The warnings are rendered ineffective, and the ad actually inhibits the passage of information from the pharmaceutical companies to the doctors or the patients, ultimately undercutting physician–patient relations.[185]

Hanson and Kysar have employed other behavioral frameworks to analyze the effects of advertising.[186] In particular, they argue that several "cognitive biases" affect the way individuals make choices.[187] Cognitive biases are mental devices that are not reasoning in the formal sense, but are a series of "mental crutches" that individuals use to augment their basic misunderstandings about the judgments they face.[188] "Their cumulative effect is to impair our appreciation of risk and uncertainty so severely that one commentator has termed the condition *probability blindness*."[189] These biases include general phenomena such as "belief perseverance," which is the rejection or dismissal of counter-evidence once a hypothesis or theory is

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183. *Id.*

184. *See id.* (noting that doctors often lack independent knowledge of the products and that some physicians are urging their peers to "continue to practice medicine based on scientific data and its appropriate dissemination by medical journals and not industry-sponsored promotional medical education programs and/or public relations-inspired media efforts"). For examples of such promotions, see Aventis Pharm. Inc., Advertisement, *Allegra*, LADIES HOME JOURNAL, May 2002, at 89 (offering a free foam cushion marked with the Allegra brand name if the reader fills out an informational card to join the "Allegra Extras Program"); Pfizer Inc., Advertisement, *Estrostep*, PARENT'S, May 2002, at 76 (promoting a birth control pill that gives the user clear skin and offering a $10 rebate); AstraZeneca LP, Advertisement, *Nexium*, READERS' DIGEST, May 2002, at 131 (promising a free seven-day supply if the reader gets a prescription from a doctor).

185. Hanson & Kysar, *Some Evidence of Market Manipulation*, *supra* note 161, at 1458–59.

186. *See* Hanson & Kysar, *The Problem of Market Manipulation*, *supra* note 163, at 645–72 (discussing two categories of behavioral decision making—"'scientific' and probabilistic judgments and those affecting the way in which individuals determine and exhibit their preferences").

187. *Id.* at 645–46.

188. *Id.*

189. *Id.* at 646.

formed, and "bad statisticians," which is a reliance on simplified statistics to make decisions rather than performing more complex assessments to reach conclusions.[190] Hanson and Kysar also include more subtle reasoning that reflects a deeper but equally flawed pattern by pointing out the phenomenon of representativeness, which is the idea that people tend to make judgments of frequency and likelihood based on the degree to which one thing resembles something else.[191]

This idea is also known as the representativeness heuristic or the principle of like to like.[192] Aristotle was an early champion of this form of reasoning.[193] Under this line of thinking, medieval physicians used the mandrake root to treat all types of ailments because of its resemblance to a human body.[194] After the advent of the scientific method, this reasoning was discredited and the mandrake was shown to be, in fact, poisonous.[195]

Hanson and Kysar recommend identifying and using these biases as diagnostic tools to determine the effect advertising has on the behavior and choices of a patient.[196] For example, the effect of cognitive dissonance, "the tendency to reject or downplay information that contradicts other, more favorable views about oneself,"[197] can be used to identify outside manipulation of a person's self-image.[198] Thus, when companies seek advertising opportunities that either massage self-image or help to justify purchasing decisions, they are creating a form of cognitive dissonance that can be identified in the individual. In this respect, behavioralism shows that pharmaceutical companies through DTC advertising are not only in direct contact with the patient, but also may be manipulating, albeit subtly, how the patient makes decisions.

A good example of this manipulation is a recent Adderall XR campaign.[199] Ostensibly for children suffering from attention deficit hyperactivity disorder, the drug is advertised squarely at the parents,

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190. *Id.* at 646, 662.

191. *Id.* at 664.

192. *Id.*

193. ARISTOTLE, RHETORIC § 1371b, *reprinted in* 9 GREAT BOOKS OF THE WESTERN WORLD 593, 615 (Robert Maynard Hutchins et al. eds., W. Rhys Roberts trans., 1952) ("And since what is natural is pleasant, and things akin to each other seem natural to each other, therefore all kindred and similar things are usually pleasant to each other . . . .").

194. Anthony Roe, *The Mandrake*, WHITE DRAGON (Spring 2001) *available at* http://www.whitedragon.org.uk/articles/mandrake.htm (last visited Mar. 23, 2003).

195. *Id.*

196. Hanson & Kysar, *The Problem of Market Manipulation*, *supra* note 163, at 645–46.

197. *Id.* at 658.

198. *Id.*

199. Shire US Inc., Advertisement, *Aderall XR*, BETTER HOMES & GARDENS, May 2000, at 37.

specifically the mother.[200] The captions and pictures portray the disease as an overwhelming problem.[201] The best mothers can hope for is a slightly extended cure that will enable bursts of normalcy on a day-by-day basis. The pitch is clearly aimed at the mother's motivated reasoning. By raising the stakes of the disease, the pharmaceutical company helps a conflicted mother, who may be questioning whether her child should even be on medication, justify her decision. Given that behavoralists can predict this interaction and its consequences, the consumer should be given full disclosure and an effective warning. It is the warning—cardiac damage as a possible side effect of prolonged use of Adderall XR[202]—that may change the mother's choice and inform her decision. The advertisement presents the mother with minimal warnings on the main page of the ad (they are buried in small print on a separate page), but prominently delivers a solicitation packed with a cognitive bias aimed directly at her.[203]

Such evidence of manipulation can be used to help support a plaintiff challenging the application of the LID in a particular situation. To be successful, the plaintiff must also demonstrate that this cognitive bias serves to weaken the physician–patient relationship.[204] In addition, the plaintiff must show the court that this manipulation and weakened relationship violate the policy behind the LID enough for the court to restrict its application. In essence, the plaintiff must argue to the court that if the pharmaceutical had given the plaintiff an effective warning, the accident would have been avoided. The advantage of using the behavioralism model of analysis is that it gives weight and scientific credence to the findings of the New Jersey Supreme Court in Section III of *Perez*,[205] and gives other courts a solid line of reasoning to follow when making a policy argument against a blanket application of the LID.

B. Motivation Research: Madison Avenue Creates the Need

As early as the 1950s, advertising as a trade, involving social science, art, and psychology, had reached a level of maturity and advanced development.[206] Beyond the basic behavioral manipulations, advertising

200. *Id.*

201. *Id.*

202. *Id.*

203. *See id.*

204. Hanson & Kysar, *Some Evidence of Market Manipulation*, *supra* note 161, at 1459.

205. Perez v. Wyeth Labs. Inc., 734 A.2d 1245, 1251–53 (N.J. 1999) (discussing the effects of direct advertising on consumers).

206. PACKARD, *supra* note 3, at 15–19. Packard's book and its subject of motivational research have since been disclaimed by a succeeding generation of advertising firms, but the principles and

firms began working on deeper manipulations of the public psyche.[207] The result was motivational research (MR).[208] The goal of MR was to discover the subconscious triggers in people's psyches and figure out how to market so that the triggers were activated.[209] By doing so, the MR people hoped to move beyond enticement to the point of creating need and desire for the product.[210] The three major techniques of MR are observation, focus groups, and depth interviews.[211] All involve close observation, like behavioralist studies, but instead of seeking the classifiable reactions that behaviorists quantify, MR seeks to understand the deeper connections consumers make with products.[212] The result is advertising that does more than provoke a reaction. With MR, advertisers can cross over to an unconscious response level that will catch the consumer without raising the consumer's awareness.[213] The ultimate goal is to stimulate desire and raise it to a point where the consumer identifies with the product, achieving brand loyalty.[214]

Packard, in his groundbreaking work on the psychology behind advertising, uses several examples to illustrate these principles of MR. One is the legend of the advertising executive who created a character, a non-rational symbol, and through advertisements and promotion turned them into a nationally recognized logo that boosted sales of a poor-selling line of shirts.[215] Similarly, there is the study conducted on housewives involving

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concepts reported by Packard have not disappeared. *See, e.g.*, CLARK, *supra* note 3, at 70.

> Today's advertising men often downgrade motivational research; like so many things in advertising they prefer to regard it as part of the alien foreign land of the past or as a wayward black sheep of the family no longer to be spoken of in polite company. Motivational research, says the textbook *Consumer Behavior*, was an 'invasion' that 'generated more heat than light' dismissing it to research history. But as David Bernstein points out, 'the very people who knock Ernest Dichter [the main promoter of motivational research and the subject of Packard's book] are the people who use his ideas, albeit in a modified form.' In fact 'motivation' research—and its impact on the persuasion industry—is as alive as ever. Because it is not politic to say so, it has simply changed its public face.

Id. Since Packard's analysis offers the simplest introduction to the subject of motivational research, this Note will use Packard's ideas and terminology.

207. PACKARD, *supra* note 3, at 15–19.

208. *Id.* at 19.

209. *Id.* at 18.

210. *See* EWEN, *supra* note 2, at 39 (analyzing the creation of life dissatisfaction by advertisers as a method of selling more products).

211. Jerry W. Thomas, *Motivational Research*, WHITE PAPERS, *available at* http://www.decisionanalyst.com/publ_art/motive.asp (last visited Mar. 23, 2003).

212. PACKARD, *supra* note 3, at 39.

213. *Id.* at 23–29.

214. *Id.* at 39.

215. *See id.* (describing the origins of the mustachioed figure with a black eye patch, used as a symbol for Hathaway shirts).

three boxes of laundry detergent.[216] The housewives were given three boxes, a yellow, a blue, and a yellow-blue full of laundry detergent.[217] The housewives were led to believe that each box contained a different detergent when in fact all three contained the same.[218] According to Packard, the results were that a number of the subjects reported that the yellow detergent was too strong and ruined some of their clothing.[219] As for the blue, they reported that it was too weak and left clothes dirty, but the mixed box of detergent worked just right.[220]

Such clever manipulations notwithstanding, MR looks to the whole consumer and guides marketers in targeting their advertising to the areas where consumers are most susceptible. Packard cites to a study conducted by Bufferin to determine what kind of people bought the product.[221] The study found that Bufferin users were mainly either hypochondriacs or "self-reliant Spartan types."[222] The response was a series of highly detailed ads that appealed to the hypochondriac with medical detail and to the Spartan with an implied ethic of self-information.[223] Sales rose as a result, allowing Bufferin to consolidate its place in the market.[224] The result of using MR is that marketing campaigns become disengaged from the purpose of the products. Following an MR process, a pharmaceutical is not sold based on its greatest good but rather on a series of fears, reassurances, and psychological images that draw more consumers into the ad and to ultimate identification with the product.

With pharmaceutical products, the psychological connection can be a very subtle appeal to guilt, shame, or secret desire. As a psychological method, MR analysis is often in the eye of the beholder and may not be apparent to every reader. MR's subtlety, however, does not mean that it does not exist. Rather, it represents the best attempts by the viewer or scholar to break down the reasoning behind the ad. For example, the Flonase allergy nasal spray ad portrays a house trapped in a large parking lot, suggesting that allergies have driven this family to pave over their yard or perhaps move the house to the parking lot of Disney World.[225] The goal is for the reader to identify with the family, and there is no specific allergy

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216. *Id.* at 11.
217. *Id.*
218. *Id.*
219. *Id.*
220. *Id.*
221. *Id.* at 58.
222. *Id.*
223. *Id.*
224. *Id.*
225. GlaxoSmithKline, Advertisement, *Flonase*, COOKING LIGHT, May 2002, at 56.

sufferer identified, thereby making the ad gender neutral.[226] At once the allergy sufferer both sympathizes with and envies the family, thinking *it is too bad to live in a parking lot.* But at the same time there is an inherently new and wondrous quality about a home in a parking lot that sparks the imagination. It is almost something out of children's literature—*a strange house in the parking lot, I wonder who lives there?* Thus, the people of the parking lot house are simultaneously pitiable and curiously envied by the targeted consumer, who becomes involved in the ad and is, hypothetically, triggered to seek out the product or at least identify with it when the opportunity arises.

This is the threat that MR poses to the traditional policies behind the LID. The use of MR encourages deep affiliation with certain products, creating brand loyalty. Medicine, however, cannot be treated the same way as other consumer products. Drugs are different.[227] While some patients do have better success with specific drugs, brand loyalty more often than not conflicts with the individualized nature of disease and with the physician's role as primary diagnostician. If a patient develops a loyalty to a specific drug that in the physician's learned opinion is not the right medication for the situation, the physician is put in a position where she must not only diagnose, but also persuade a patient who has already begun to make up his mind. Such a situation is precarious because the physician wants to cultivate a relationship of trust with the patient and does not want to slip into a situation where the patient perceives that the doctor is bullying him. At the same time, the patient, if challenged, may reject the physician's advice and seek comfort in the familiar product. This latter scenario is all the more possible in an HMO system where the physician may be seeing the patient for the first and only time. When brand loyalty is involved, the consumer is encouraged to identify with the product, making an attack on the product an attack on the individual.

To apply this argument in a litigation context, the plaintiff must be able to illustrate the nature of the relationship between the plaintiff and the pharmaceutical company. The plaintiff must show that the company's ad campaign seeks to manipulate the consumer into forming a long-term relationship with the product that may interfere with the physician–patient relationship. This can be demonstrated by the amount of research and targeted marketing the company has conducted and the amount of data the company has compiled to establish its target audience. Establishing

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226. *Id.*

227. *See generally* Henderson & Twerski, *supra* note 63 (arguing that drugs should be treated differently under the Third Restatement of Torts because of their unique role in society and their restrictive value as determined by the physician).

evidentiary presumptions based upon such information, however, would not be as clear as the bright line provided by federal regulations that define the rebuttable presumption developed in *Perez*.[228] Under this analysis, courts will have to find definitions and standards to determine when the relationship fostered by the pharmaceutical companies crosses the line and begins to damage or disrupt the physician–patient relationship. In this respect, MR analysis is very close to the spirit of *Perez's* Section III in that it forces courts to scrutinize the nature and extent of DTC advertising in order to determine how it has affected the policies underlying the LID.[229] MR shows that advertising is neither an information clearinghouse nor an accident of creativity. Rather it is the culmination of intensive research, which traces consumer purchasing psychology in order to generate a future need.

C. Media Analysis: Doctor Frankenstein! — Yes? — The Monster Is Us!

In 1951, Marshall McLuhan, a genial, unassuming literature professor from Toronto, Canada published his first book on the myths and images that modern advertising was creating in the world around him.[230] That book and the ones that followed changed how the world looks at media.[231] McLuhan's phrases continue to dominate perceptions of media from the "medium is the message" to the "global village" to the concepts of hot and cool media.[232] McLuhan created a new way of looking at media. While behavioralism and Packard's advertising critiques focused on the

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228. *See supra* Part II.

229. *See* Perez v. Wyeth Labs. Inc., 734 A.2d 1245, 1251–53 (N.J. 1999) (analyzing the effect and nature of DTC advertising on the relationships between physician, patient, and pharmaceutical companies).

230. MARSHALL MCLUHAN, THE MECHANICAL BRIDE: FOLKLORE OF INDUSTRIAL MAN v–vi (Beacon Press 1967) (1951) [hereinafter MCLUHAN, THE MECHANICAL BRIDE].

231. McLuhan's influence has traveled far beyond academics and into the popular culture. In his heyday, McLuhan's theories were the subject of intense discussion and essays by notables such as Tom Wolfe. Tom Wolfe, *Suppose He Is What He Sounds Like, the Most Important Thinker Since Newton, Darwin, Freud, Einstein, and Pavlov—What If He Is Right?*, *in* MCLUHAN HOT AND COOL: A PRIMER FOR THE UNDERSTANDING OF AND A CRITICAL SYMPOSIUM WITH A REBUTTAL BY MCLUHAN 15 (Gerald Emanuel Stearn ed., 1967). The phenomenon of McLuhan was best encapsulated in a brief scene in Annie Hall where Woody Allen produces McLuhan to stifle a boor who is droning on and on about McLuhan's media theories while waiting in line for the movies. ANNIE HALL (United Artists Pictures 1977). In the 1990s with the dawn of the information age, McLuhan's ideas have found a new audience and a general acceptance by academics. *See generally* FORWARD THROUGH THE REARVIEW MIRROR: REFLECTIONS ON AND BY MARSHALL MCLUHAN (Paul Benedeti & Nancy Dehart eds., 1997) (compiling essays by contemporary writers such as Lewis Lapham, Camille Paglia, Neil Postman, and Louis Rossetto about McLuhan's continuing influence and prescience).

232. *See* MARSHALL MCLUHAN, UNDERSTANDING MEDIA: THE EXTENSIONS OF MAN 23, 36, 93 (2d ed. 1964) [hereinafter MCLUHAN, UNDERSTANDING MEDIA].

quantifiable aspects of an ad and how consumers perceive it, McLuhan looked to the format and the metaphorical value latent in certain types of images. For example, he wrote about an ad for a car which featured a baby's rattle and the claim that the company could remove the unwanted car rattles just as easily as it could remove the baby's.[233]

> This kind of copy has really nothing to do with rattles. The copy is merely a punning gag to distract the critical faculties while the image of the car goes to work on the hypnotized viewer. Those who have spent their lives protesting about "false and misleading ad copy" are godsends to advertisers, as teetotalers are to brewers, and moral censors are to books and films. The protestors are the best acclaimers and accelerators. Since the advent of pictures, the job of the ad copy is as incidental and latent as the "meaning" of a poem is to a poem, or the words of a song are to a song.[234]

McLuhan's theories explore the subtext of advertising. By focusing on the peripheral parts of an ad, McLuhan sought to demonstrate that advertisements, like literature and art, use icons and symbolic imagery to convey messages that appeal to the same subconscious level that perceives and enjoys the "'meaning' of a poem" or the "words of a song."[235] McLuhan advances the idea that this subtext is both the point, and most effective part, of the ad.[236] In the baby rattle example, McLuhan observes that the company is not selling the idea that they remove rattles from cars; they are selling, through graphic imagery, the idea that their company is essential to achieving a certain lifestyle.[237] The company appeals not to the specific promise to repair, but to the general image of comfort and luxury that somehow comes to the consumer through the purchase of the product or service.

The Viagra ad from the May edition of *Golf* magazine provides a clear and simple prescription drug example for a McLuhan-type of analysis.[238] In the ad, the text is a pun on male erections and erectile dysfunction.[239]

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233. *Id.* at 205.

234. *Id.*

235. *Id.*

236. MCLUHAN, THE MECHANICAL BRIDE, *supra* note 230, at 13 ("It would be hard to know where to begin to peel back the layers of insentience and calculated oblivion implied in such an ad. And what would be found as one stripped away these layers, each marked with the pattern of sex, technology, and death? Exactly nothing.").

237. MCLUHAN, UNDERSTANDING MEDIA, *supra* note 232, at 205.

238. Pfizer Inc., *Viagra*, *supra* note 168.

239. *Id.*

"What happens if you don't talk to your doctor about VIAGRA? . . . Nothing."[240] The slight naughtiness of this double-entendre may distract as McLuhan would argue that it was intended to, and a closer look at the graphic rewards the observer with a richer image and a dirtier joke. The image shows a thirty-something man wearing an unbuttoned shirt with rolled up sleeves and a t-shirt underneath.[241] He smiles, but it is a closed-lip, half smile.[242] His eyes are clear and look out of the ad directly at the viewer.[243] He is positioned intimately on a couch, and one could imagine that if the ad were extended, one would see a confidant or lover sharing the couch.[244] The picture is cropped so that we only see one hand and nothing below his chest.[245] The crop is flat and parallel to the text, but in direct line with the man's genitals and to the left of the text, the white space below the picture bubbles up to include a picture of the pill.[246] Visually, the slightly raised pill and its layout suggest an erection with the Viagra pill as the seed within.[247] Thus, an apparently innocuous advertisement unpacks into a much more ribald image that belies the relative innocence of its text.

The idea of using this line of analysis in a litigation context is open to two criticisms. First, this analysis is very much open to interpretation or even the old criticism that only dirty minds see dirty pictures everywhere. Such arguments, however, ignore the relatively objective proof of the ad's true message. The idea is not to sell Viagra but intimacy. Whether the man in the ad is confidant or lover, he is part of an image of confidence, sexuality, and vigor. Again, as McLuhan describes the process:

> The need is to make the ad include the audience experience. The product and the public response become a single complex pattern. The art of advertising has wondrously come to fulfill the early definition of anthropology as "the science of man embracing woman." The steady trend in advertising is to manifest the product as an integral part of large social purposes and processes. With very large budgets the commercial artists have tended to develop the ad into an icon, and icons are not specialist fragments or aspects but unified and compressed images of complex kind.[248]

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240. *Id.*
241. *Id.*
242. *Id.*
243. *Id.*
244. *Id.*
245. *Id.*
246. *Id.*
247. *Id.*
248. MCLUHAN, UNDERSTANDING MEDIA, *supra* note 232, at 201.

The Viagra ad manipulates viewers to identify not with a specific cure or function, but rather to identify the drug with the very image of potency and intimacy. It is iconic because in McLuhan's analysis advertising must appeal to the larger image.[249] Thus, it is not a conspiracy or necessarily the fault of a company like Pfizer that makes and markets Viagra. Rather, it is the nature of the advertising beast. McLuhan's lesson is that all advertising shares in this format. The medium is the message.[250]

The second obvious criticism of using this line of analysis in a legal sense is that it is vague and theoretical. Such ideas as "the medium is the message," and "technology as an extension of [the] physical body,"[251] begin to spin away from the concrete details of personal injury and into the more nebulous realms of subtext, images, and archetypes.[252] Some might argue that the Viagra ad, as interesting as it is, would not necessarily yield any useful information to a court trying to discern whether the actions of the pharmaceutical company have disrupted a physician–patient relationship or otherwise violated the policy behind the LID. But the answer to this criticism lies in McLuhan's analysis, which goes deeper than a simple analysis of the actions of one advertiser or the effects on a single consumer. The importance of McLuhan's analysis is that it illustrates the level at which advertising changes how consumers interact with manufactures and how consumers choose products.

McLuhan's first attempt at media analysis, *The Mechanical Bride*, focused point blank on the advertising industry.[253] The best parts of this book remain its insights on sex and technology as the great driving forces of advertising.[254] According to McLuhan, these two themes are consistent throughout the advertising world.[255] The language of advertising is to link the new products with embedded images and thereby tap into the consumer's deeper consciousness.[256] In turn these "metaphors" come from literature and trace back to a much older psychological well-spring.[257]

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249. *Id.*

250. *Id.* at 23.

251. *Id.* at 23, 56.

252. This criticism is true of McLuhan's theories in general and is an important factor to realize when utilizing this form of advertising analysis. *See generally* Morrison, *supra* note 157 (outlining that McLuhan's theory was misconstrued into the idea that the content of any message is meaningless).

253. MCLUHAN, THE MECHANICAL BRIDE, *supra* note 230, at v–vi.

254. *See id.* at 98.

255. *Id.*

256. *Id.* at 101.

257. *Id.* at 100. This is perhaps the best way to understand McLuhan's interest in the area. As an English professor, he was motivated to analyze the deeper themes of modern media that appeared to spring forth from literature. *See* MARSHALL MCLUHAN, THE GUTENBERG GALAXY: THE MAKING OF TYPOGRAPHICAL MAN (1962) (exploring a similar shift of media and perception that occurred when

As the Viagra ad demonstrates, McLuhan's theory still applies as a principle for understanding advertising as a medium.[258] This may indeed be too nebulous and theoretical for a court to acknowledge, but as evidence of the essential nature of advertising, a properly conducted McLuhan analysis could educate a court. McLuhan's theory would be powerful in a legal sense because it does not require the plaintiff to show any proof of intent on the part of the pharmaceutical company in designing a manipulative ad. Simply designing an ad, according to McLuhan, manipulates the consumer and transmits information that is controlled by larger themes and the medium itself.[259] Within this framework, no regulation or minimum standards could change or truly regulate the message. The New Jersey Supreme Court in *Perez* constructed its rebuttable presumption based on FDA compliance as part of a balance with the "public interest in informing patients about new pharmaceutical developments."[260] It would be impossible to regulate the kind of "information" these subliminal messages convey because they have nothing to do with pharmaceutical development. It would, to draw a McLuhan metaphor, be like having Homer's Sirens perform computer workshops and then pleading innocence when the participants drowned themselves instead of learning Microsoft Word. The lesson for courts from this analysis is that advertising is going to deliver a type of message, which will not change simply because of regulatory content.

D. The Mystifying Manipulations of the Media Men in Public Relations

Although public relations people do not necessarily supervise advertisements, they are symptomatic of the larger marketing industry and an indispensable part of any serious discussion about the effects of advertising and the significance those effects might have in the litigation context. Public relations (PR) began in the nineteenth century when a few press agents took the lessons of their trade, coupled with lessons from P.T. Barnum, and began advising the rich and powerful on how to make

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"aural" man became literate, and projecting shifts that will occur as the electronic age arrives); *see also* JOSEPH CAMPBELL, THE HERO WITH A THOUSAND FACES 3–4 (2d ed. 1968) (analyzing the common themes that occur throughout cultures in their mythology and their psychological/Jungian connections as part of a human "monomyth").

258. Nor is it limited to Viagra, which is open to the charge that of course a sexual stimulant would appeal to consumers by using sex. An ad for Adderall XR, a drug for children with attention deficit hyperactivity disorder, seems to use a similar appeal to sex. *See* ShireUS Inc., *supra* note 200, at 37 (presenting the appeal of domestic peace, studious behavior, and a nurturing mother—who seems to have her arm in an awkward, yet vaguely phallic, position).

259. *See* MCLUHAN, UNDERSTANDING MEDIA, *supra* note 232, at 201–07.

260. Perez v. Wyeth Labs. Inc., 734 A.2d 1245, 1259 (N.J. 1999).

themselves and their industries more popular and influential with the general public.[261] PR hit its stride in the twentieth century when it expanded to work with industry, advertising, and politics.[262] The tobacco industry was an early user of PR to manipulate sales and public opinion.[263] For example, PR firms began advertising to women in the 1920's that they should smoke a cigarette instead of reaching for a "sweet" in an appeal to link smoking with health and weight consciousness.[264] Another large-scale PR campaign occurred in the 1950s when the "cancer scare" hit tobacco companies and sent sales plummeting.[265] PR firms developed campaigns to shift the tobacco companies' advertising to focus on the "health benefits" of certain tobacco brands, such as those that used filter tips.[266] In addition, PR firms created study groups to "look closer into the cancer problem" and funded "public" interest groups such as the "National Smokers Alliance."[267] The result was a dramatic shift upwards in sales and a similar change in public attitude, which, by the late 1950s, considered the cancer scare to be over.[268]

The lesson for anyone challenging pharmaceutical companies on their duty to the public is simple—be conscious of PR. PR has become an effective tool for companies seeking to sway public opinion and policy, especially in health care issues.[269] One could argue that the legal commentary following the *Perez* decision reflected the PR response, at least indirectly, in its strongly pro-LID tone.[270] This is not to suggest that PR

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261. JOHN C. STAUBER & SHELDON RAMPTON, TOXIC SLUDGE IS GOOD FOR YOU: LIES, DAMN LIES AND THE PUBLIC RELATIONS INDUSTRY 17–24 (1995). One example is the story that Ivy Lee, a PR advisor to John D. Rockefeller, told the billionaire to carry pocketfuls of dimes to give out to children whenever he went anywhere to soften his image with the public that associated him with the vicious monopolistic practices of Standard Oil. *Id.* at 19.

262. Mark Dowie, *Introduction* to STAUBER & RAMPTON, *supra* note 261, at 1–4.

263. *Id.* at 25.

264. *Id.* at 25–26.

265. *Id.* at 27-30; *see also* PACKARD, *supra* note 3, at 43, 48–49.

266. PACKARD, *supra* note 3, at 43.

267. STAUBER & RAMPTON, *supra* note 261, at 28–29 (discussing the "pretense of honest concern" put forth by the PR strategists).

268. *Id.* at 27–29 (discussing the "smoke and mirrors" PR campaign of the tobacco industry reacting to the cancer scare); *see also* PACKARD, *supra* note 3, at 43 (noting a 1800% increase in the purportedly "safer" filter-tip cigarettes and the upward trend of cigarettes as a whole in the mid-fifties).

269. STAUBER & RAMPTON, *supra* note 261, at 22–24.

270. *See* Dabney J. Carr IV & Bryony H. Bowers, *Recent Developments in Learned Intermediary Doctrine*, 31 THE BRIEF 20, 21–22 (A.B.A. Sec. Torts & Ins. Practice 2002) (discussing new developments in DTC advertising as a potential area for further exceptions to the LID); Harrison & Jefferson, *supra* note 60, at 606 (arguing that although DTC advertising has numerous advantages, its new exception does not justify abandoning the LID); Marshall, *supra* note 36, at 102–05 (listing the traditional policy arguments surrounding the central nature of the physician); Nordaune, *supra* note 100, at 367 (noting that DTC advertising has been very lucrative for pharmaceutical companies).

firms were involved with the scholarly discussion of the LID following *Perez*. Rather the discussions emerging from *Perez* create several rational approaches for defending the LID, which can and will be used by PR firms to affect public opinion.

In particular, certain themes have emerged from pro-LID articles. Several articles claiming to discuss the LID issue have focused only on the role of federal regulation to the exclusion of DTC advertising.[271] The articles that do discuss DTC advertising assert that the policies of the LID are preserved, in the continuing physician–patient relationship.[272] More importantly, many of the articles treat the LID in discussion as a sacred doctrine that cannot tolerate another exception.[273] Certainly, these themes reflect the basic arguments against limiting the LID in cases of DTC advertising, but they also present a coherent criticism of LID reform that pharmaceuticals could tap into to influence others. It is a simple fact for any litigator or legislator who questions the interests of a profitable industry that the industry will fight back.[274]

IV. *BRAUN V. SOLDIER OF FORTUNE* AND SUGGESTIONS FOR A DIFFERENT APPROACH

A remaining issue associated with creating an exception to the LID based on the effects of DTC advertising is free speech.[275] Unlike other LID exceptions for mass immunizations or oral contraceptives, the proposed DTC advertising exception involves behavior of the pharmaceutical company independent of the duty to warn.[276] As two commentators observed:

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271. *See, e.g.*, Dukes, et al., *supra* note 51, at 48–49 (providing advice on how to use FDA compliance as a defense in failure to warn cases); Rabin, *supra* note 102 (describing FDA regulation of prescription drugs). It is important to remember that DTC advertising is the entire reason the New Jersey Supreme Court considered the LID. *Supra* Part II.

272. *See, e.g.*, Marshall, *supra* note 36, at 113 (arguing that "[r]egardless of the advertisements, the physician is the only person who can effectively supply and individual patient-consumer with an adequate warning).

273. *See, e.g.*, Harrison & Jefferson, *supra* note 60, at 619 (setting forth five arguments against creating exceptions to the LID).

274. Other examples of the pharmaceutical PR campaign are seen in advertisements promoting the "higher purpose" of pharmaceuticals. *See* America's Pharmaceutical Companies, Advertisement, *New Medicines. New Hope.*, NEWSWEEK, May 27, 2002 at 19 (promoting the altruistic work of pharmaceutical companies through their individual researchers). Additionally, the "Special Advertising Sections" that appear in magazines further blur the line between news and promotions. *See* Coalition of National Cancer Cooperative Groups, Advertisement, *Cancer Clinical Trials: Your First Decision Counts*, NEWSWEEK, May 6, 2002, at C1 (featuring a series of "articles" about cancer treatments by the coalition which is composed of corporate and hospital interests).

275. Harrison & Jefferson, *supra* note 60, at 633–38.

276. *Cf.* Part I.C (discussing federal regulation of pharmaceutical advertising).

> While imposing a duty to warn on manufacturers may have potentially disastrous financial effects, it is also true that such a duty may unconstitutionally interfere with drug manufacturers' First Amendment rights. The advertising of prescription drugs is, after all, commercial speech, and the Supreme Court has long held that commercial speech merits First Amendment protection if it is truthful.[277]

Commercial speech, however, is not afforded the same protections as other types of speech.[278] More importantly, commercial speech jurisprudence provides a model for courts that may choose to take a different approach to DTC advertising. The following example shows that a court can balance concerns of speech with those of liability for injuries.

Braun v. Soldier of Fortune Magazine is a unique and powerful example for any court facing a challenge to the LID.[279] In the *Braun* case, a mercenary, Michael Savage, advertised his services in the personals section of *Soldier of Fortune* (SOF), which resulted in Bruce Gastwirth hiring him to murder Richard Braun, Gastwirth's business associate.[280] In August of 1985, Savage murdered Braun, and wounded Braun's son.[281] The victims' family filed a wrongful death and personal injury suit, placing blame for the incident on SOF for accepting the personal ad when, according to the plaintiff, it was reasonable to foresee a harmful result.[282] The challenge for the court lay in the sensitive relationship between liability and speech protections guaranteed under the First Amendment. The Eleventh Circuit Court of Appeals, however, found authority under the United States Supreme Court's decision in *Gertz v. Robert Welch, Inc.*[283] Based on *Gertz*, the *Braun* court determined "that the First Amendment permits a modified negligence standard . . . on publishers for injury caused by the

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277. Harrison & Jefferson, *supra* note 60, at 633 (citing *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748 (1976)).

278. *See generally* Lars Noah & Barbara A. Noah, *Liberating Commercial Speech: Product Labeling Controls and the First Amendment*, 47 FLA. L. REV. 63 (1995) (discussing federal regulatory limitations on the disclosure of truthful information to consumers, and setting forth a brief history of the Supreme Court's commercial free speech jurisprudence).

279. Braun v. Soldier of Fortune Magazine, Inc., 968 F.2d 1110 (11th Cir. 1992).

280. *Id.* at 1112.

281. *Id.*

282. *Id.* at 1112–13.

283. *Id.* at 1118 (citing to *Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 347 (1974)). *Gertz* concerned a defamation suit brought against a communist newspaper publisher for publishing an article in which the plaintiff was portrayed as a "Communist-fronter," a "Lenninist," and a participant in Marxist activities. *Gertz*, 418 U.S. at 325–28. The Court held that a commercial publisher who defamed a private figure could not claim constitutional privilege against liability for the injury inflicted. *Id.* at 345–48.

advertisements they print only if the ad on its face, without the need to investigate, makes it apparent that there is a substantial danger of harm to the public."[284] The court then applied a theory of negligence to SOF's actions.[285] The court held that SOF had a duty to the plaintiff under a risk-utility analysis and that the publication of the ad led to the plaintiff's death without any reasonably foreseeable intervening events.[286]

Braun is important in the context of pharmaceutical advertising because it subjected a highly protected area (free speech) to liability. Under *Braun*, publishers are free to publish what they choose, but they must also face the resulting liability for their actions. While pharmaceutical companies have enjoyed great success in advertising,[287] they have simultaneously avoided any broad liability for failing to warn or for misleading the consumer through advertising. At least one critic has suggested that challenging ads as misleading would be a more fruitful avenue to making pharmaceutical companies responsible for their DTC advertising.[288] New Jersey Judge William A. Dreier pointed out that the *Perez* court could have allowed the plaintiff's claim under a theory of fraud and misrepresentation.[289] Such a theory would tie pharmaceutical companies' liability to their actions as advertisers and force them to develop guidelines that would ensure commitment to responsible advertising.[290] The main arguments against such a theory of liability focus on the potential "chilling effect" such liability would have against pharmaceutical companies who would stop advertising out of fear of liability.[291] But as *Braun* points out, "[t]he advertiser's strong economic interest helps ensure that its particular message reaches the public, even in the face of restrictive regulations."[292] And certainly pharmaceutical companies, if nothing else, have a strong economic interest in their advertising.[293] Furthermore, *Braun* demonstrates that when the facts before the court demand that the law change, the court will change it. Even sensitive areas of the law demand reform and the LID is no exception. If change occurs, however, the courts

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284. *Braun*, 968 F.2d at 1118–19.

285. *Id.* at 1119–20.

286. *Id.* at 1121–22.

287. *See* Pines, *supra* note 32, at 506.

288. Dreier, *supra* note 118, 807–08.

289. *Id.*

290. Such a list of guidelines has already been conceived and may be in place in pharmaceutical companies. Nordaune, *supra* note 100, at 368–70 (listing sample guidelines for pharmaceutical companies to avoid liability).

291. *See, e.g.*, Allen, *supra* note 40, at 130–31 (discussing the chilling effect liability would have on pharmaceutical companies resulting in their loss of beneficial advertising).

292. Braun v. Soldier of Fortune Magazine Inc., 968 F.2d 1110, 1117 (11th Cir. 1992).

293. *See* Pines, *supra* note 32, at 506–08 (reciting the large amount of money at stake).

and legislatures must act in a manner that will realign or reconfirm the law's commitment to protecting its citizens by creating a doctrine that will promote responsibility where the greatest good can be served.

In *Braun*, the court found that lodging responsibility in the publication to foresee harm would serve to protect people by preventing individuals from using the *media* for their irresponsible and violent ends. Similarly, Judge Drier's suggestions could provide an alternative theory that would bypass the issue of the LID while tying liability directly to the pharmaceutical companies' actions. In theory this would "reward" careful companies that provided consumers with realistic, balanced information about their products, and "punish" companies that were irresponsible or misleading. Above all, it would force a court to carefully scrutinize pharmaceutical companies' advertising and to look at the number and types of connections pharmaceutical companies create with consumers.

A misrepresentation and fraud theory against a pharmaceutical company for their advertising is simply another way to provide liability for a failure to warn. As a theory, it is quite beguiling in that it preserves the LID as a viable doctrine, but limits where it can be applied. The major problem is that a claim for fraud and misrepresentation would require a higher level of proof than negligent failure to warn.[294] To date, however, no court has adopted this line of analysis for a pharmaceutical advertising case.

CONCLUSION

Pharmaceutical advertising has fully arrived, and in the complex way of progress, the results are mixed. Just exactly how companies communicate with the public is very important. As the manufacturer, pharmaceutical companies are in the best position to know the potential side effects and dangers associated with their products. The problem, in terms of the duty to warn, is defining the nature and extent of the duty. Despite federal regulations that govern parts of this decision,[295] state courts and legislatures retain discretion where manufacturers reach beyond physicians and manipulate individual patient/consumers. Once a manufacturer crosses this line and makes promises directly to the consumer, it must forfeit some of the protection of the LID because such promises undermine the centrality of physician as sole arbiter of the patient's medical diagnosis and prescriptions.

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294. *See* Dreier, *supra* note 118.

295. *See* Rabin, *supra* note 102, at 2074–84 (describing FDA regulation of prescription drugs and its interaction with tort liability).

The LID must be applied carefully as an exception where the facts support the underlying policy. By looking to the relationship created by manufacturers through their DTC advertising, courts can determine whether the connections are strong enough to create a normal duty to warn or whether the physician maintained control and autonomy over the patient and made her diagnosis free from undue patient/manufacturer influence. Holding pharmaceutical companies liable will also provide an effective, systematic check on the companies to be responsible in how they present their advertising. Since most duty to warn tort actions occur in state court, individual decisions will enable local communities to have a greater voice in controlling the levels of pharmaceutical advertisement. Courts, however, will not be able to make this nuanced decision without the tools to analyze advertisements and their effects. Whether a court looks to negligence, fraud or misrepresentation, or applies the *Perez* presumption, the litigator must point the court toward the details. Courts must see advertisements for what they are—manipulations that prey upon consumers in conscious and unconscious ways. Only then is there hope for a fair resolution that will check pharmaceutical advertising and allow both plaintiffs and pharmaceutical companies a fair opportunity to make their case.

For better or worse, pharmaceutical advertising is a part of our lives for the foreseeable future, and such information does improve our knowledge, medication, and treatment. At the same time, that information must come with responsibility. How we, as a society, choose to delegate that responsibility will shape how effective it is and how advertising develops as a result. As one commentator noted, "[b]eyond any new legal liabilities surrounding DTC advertising, companies that engage in such activities have certain social responsibilities dictated by their roles as corporate citizens in a business which has profound impact on the health and well being of the public."[296] Given the current state of affairs surrounding the LID and DTC advertising, society has not been successful in delegating this responsibility. But that is only reason to continue to forge a new way of getting at the "truth." In the end, the greatest danger is to forget that advertising is not "truth" in any sense, but a series of highly controlled persuasive promotions. To embody the greater truth and provide mechanisms for its protection is, or should be, the goal of any legislature or court, and they must step in to protect the lost child of products liability.

Daniel Richardson[*]

296. Audiey C. Kao & Erica Ozanne Linden, *Direct-to-Consumer Advertising and the Internet: Informational Privacy, Product Liability and Organizational Responsibility*, 46 ST. LOUIS U. L.J. 157, 171 (2002).

* The author wishes to thank Britt Richardson, Bruce Duthu, Rebecca Boucher, Lorin Parker, and Stephen Dycus for their invaluable support, feedback, and advice on this Note.