

Fall 2001

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Recommended Citation

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COMMENTS

WEB OF MANIPULATION: THE LEARNED INTERMEDIARY DOCTRINE AND DIRECT- TO-CONSUMER ADVERTISING ON THE WORLD WIDE WEB

APRIL L. FOREMAN*

*And this distilled liquor drink thou off:
When, presently, through all thy veins shall
A cold and drowsy humour; for no pulse
Shall Take thou this vial, being then in bed,
keep his native progress, but surcease:
No warmth, no breath, shall testify thou liv'st;
The roses in thy lips and cheeks shall fade
To paly ashes; thy eyes' windows fall,
Like death, when he shuts up the day of life;
And in this borrow'd likeness of shrunk death:
Thou shalt continue two-and-forty hours,
And then awake as from a pleasant sleep.'*¹

INTRODUCTION

This exchange between Juliet and Friar Lawrence illustrates that a recipient's need for a drug provider's warning is nothing new.² Unlike today, in Juliet's time an apothecary both made and

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1. William Shakespeare, *Romeo and Juliet*, in WILLIAM SHAKESPEARE COMPLETE WORKS 1065, 1091 (William Allan Neilson & James Orchard Halliwell-Phillips eds., 1925). In this section of Mr. Shakespeare's play, Friar Lawrence is warning Juliet about the effects of the vial she will take later that evening. *Id.*

2. In our culture there are many legends about and relating to drugs. RICHARD RUDGLEY, ESSENTIAL SUBSTANCES: A CULTURAL HISTORY OF INTOXICANTS IN SOCIETY, 105-37 (1993). Sources suggest our belief in flying witches is a result of medieval storytellers' usage of hallucinogenic drugs. *Id.* at 105-09; H. SIDKY, WITCHCRAFT, LYCANTHROPY, DRUGS AND DISEASE, 189-214 (1997). See 1 HENRY E. SIGERIST, A HISTORY OF MEDICINE: PRIMITIVE AND ARCHAIC MEDICINE 205, 205 (1987) (discussing uses of ancient Cherokee medicinal rites and rituals, specifically in this instance the "Spirit of the

marketed his own pharmaceutical wares.³ As both the creator and distributor, Friar Lawrence was the one to warn Juliet about the effects of ingesting the tiny vial.⁴

Today, however, the prescription drug industry is trifurcated.⁵ Mammoth pharmaceutical companies manufacture drugs, doctors prescribe drugs, and pharmacies⁶ distribute them.⁷ With all these parties participating in the process the question becomes: whose duty is it to warn the modern-day Juliet about a drug's effects?⁸ Today, while an "unwarned" Juliet may have a cause of action against the doctor who prescribed her a drug if he failed to warn her of its effects, the drug manufacturers, the modern-day apothecaries of the potent vial, can shield themselves from attack behind the outdated Learned Intermediary Doctrine.⁹

Weasel"). For a history of medicine and drugs divided by geographical region, see generally, ROY PORTER, *THE GREATEST BENEFIT TO MANKIND: A MEDICAL HISTORY OF HUMANITY* (1997).

3. For a history of apothecaries see OXFORD, *WESTERN MEDICINE: AN ILLUSTRATED HISTORY* 18, 62-63, 68-69, 73, 81-82, 86, 90-91 (Irvine London ed., 1997).

4. See generally Shakespeare, *supra* note 1. The text of the play does not state whether Friar Lawrence made the contents of the vial. The readers can glean from the text that the good Friar did have a herb garden, and knowledge of the herbs' poisonous and medicinal powers. *Id.* at 1076.

5. See ALFRED BURGER, *DRUGS AND PEOPLE: MEDICATIONS, THEIR HISTORY AND ORIGINS, AND THE WAY THEY ACT* 21-23, (revised ed., 1986) (explaining how the pharmaceutical drug companies advertise directly to doctors hoping to sell more of "their drugs"). See generally JOHN P. SWANN, *ACADEMIC SCIENTISTS AND THE PHARMACEUTICAL INDUSTRY: COOPERATIVE RESEARCH IN TWENTIETH-CENTURY AMERICA* 15 (1988).

6. See, e.g., *In re Diet Drugs* (Phentermine/Fenfluramine/Dexfenfluramine) Products Liability Litigation, No. 1533, 2000 WL 1886594, at *3-4 (E.D. Pa. Dec. 7, 2000) (discussing the fluxuating state of the law and duties imputed within the Learned Intermediary Doctrine for pharmacists and pharmacies). While the duties of a pharmacist to warn the end consumer and how that interacts with doctors and manufacturers is a fascinating topic, this Comment unfortunately cannot cover all the new aspects of the Learned Intermediary Doctrine.

7. See generally BURGER, *supra* note 5; SWANN, *supra* note 5. See also Lisa Friedman Miner, *How Drugs Ads Influence Your Health*, DAILY HERALD, Apr. 24, 2000, § 3 at 1 (noting that in our society we use drugs to escape the stress of emotional and physical maladies).

8. See BURGER, *supra* note 5, at 18 (discussing how "no drug has just one effect"). When using drugs one must balance between the drug's clinical effects and its toxic results. *Id.* Taking Mr. Burger's statements into account, one sees the need for warnings about the balanced "toxic effects" with the hoped for clinical results. *Id.*

9. See, e.g., *Vitanza v. Upjohn Co.*, 214 F.3d 73, 79 (2nd Cir. 2000) (barring plaintiffs' suit because of the Learned Intermediary Doctrine); *Alexander v. Smith & Nephew, P.L.C.*, 98 F. Supp. 2d 1299, 1309 (N.D. Okla. 2000) (holding that in Oklahoma the "Learned Intermediary Doctrine is an exception to the duty to warn" and that the drug manufacturer's duty to warn only extends to the doctor); *Anderson v. Sandoz Pharm. Corp.*, 77 F. Supp. 2d 804, 806 (S.D. Tex. 1999) (holding that the plaintiff's doctor was a Learned Intermediary and

Part I explores both the background and evolution of direct-to-consumer (DTC) advertising, from the Federal Drug Agency (FDA) moratorium on DTC advertising to the present day, and the history and basis for the Learned Intermediary Doctrine. Part II explores prescription drug advertising on the World Wide Web and how Internet advertising contradicts the premises upon which the Learned Intermediary Doctrine is based. Part II also specifically concentrates upon how this type of advertising is undercutting the doctor-patient relationship. Part III proposes using a sliding-scale test to measure the interactivity of web sites to determine which sites are undercutting the doctor-patient relationship upon which the Learned Intermediary Doctrine is based.

I. THE "STAR-CROSSED LOVERS:"¹⁰ DIRECT-TO-CONSUMER ADVERTISING AND THE LEARNED INTERMEDIARY DOCTRINE

This Section discusses the evolution of DTC advertising in the pharmaceutical drug industry over the last twenty years and the history of the Learned Intermediary Doctrine. This Section also depicts conflicts between the two, which arise as a result of pharmaceutical advertising on the Internet.

A. *Direct-to-Consumer Advertising*

1. *FDA Standards and Guidelines*

Until the early 1980s prescription drug manufacturers typically advertised to medical professionals, but not to end consumers.¹¹ Shortly after the dawn of DTC advertising, on September 2, 1983, the FDA issued a statement requesting that the pharmaceutical industry hold a voluntary moratorium on product-specific DTC advertising.¹² The FDA reasoned that this moratorium would allow time for the "consumers, health professionals and industry" to discuss the relevant issues, and allow time to research the effects of DTC advertising.¹³ On September 9, 1985, the FDA withdrew the moratorium, stating

was in a position to warn her of the impending risks, and the drug company's duty to warn only extended to the doctor); *Ramos v. Sterling Drug, Inc.*, No. 04-98-01009-CV, 1999 WL 1261527, at *1 (Tex. App. Ct. Dec. 29, 1999) (applying the Learned Intermediary Doctrine denying that a pharmaceutical company had a "duty to warn the deceased").

10. Shakespeare, *supra* note 1, at 1065.

11. Thomas M. Moore & Mario Horwitz, *Consumer Directed Broadcast Advertising: Erosion of the Learned Intermediary Doctrine?*, FOR THE DEFENSE, Sept. 1998, at 20-21; Noah Lars, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 141 (1997).

12. Moore & Horwitz, *supra* note 11, at 20; Lars, *supra* note 11, at 142-43.

13. Moore & Horwitz, *supra* note 11 at 20; Lars, *supra* note 11, at 142-43.

that it achieved its purpose and that the current laws were sufficient to govern DTC broadcast advertising.¹⁴

Although the FDA lifted the moratorium, the pervasive sentiment in the industry gathered from the FDA's action was that it still discouraged all DTC advertising.¹⁵ Ten years later, however, on August 16, 1995, the FDA announced a hearing on the "DTC 'promotion' of prescription drugs."¹⁶ The hearing brought together the interested parties to gather information.¹⁷

On August 12, 1997, the FDA relaxed its stance and issued a *Draft Guidance* for the industry concerning consumer-directed broadcast advertisements¹⁸ (including radio, television, systems which communicate through phone lines, or telephone communication systems).¹⁹ Then, in August of 1999 the FDA released a final *Guidance for Industry* concerning broadcast advertising.²⁰ This subsequent *Guidance* is very similar to the *Draft Guidance*,²¹ and reinforces the FDA's view that when using

14. Moore & Horwitz, *supra* note 11, at 20; Direct-to-Consumer Advertising of Prescription Drugs; Withdrawal of Moratorium, 50 Fed. Reg. 36,677 (Sept. 9, 1985).

15. Draft Guidance for Industry; Consumer Direct Broadcast Advertisements Availability, 62 Fed. Reg. 43,171 (Aug. 12, 1997) [hereinafter *Draft Guidance for Industry*]; Moore & Horwitz, *supra* note 11, at 20-21. See also CENTER FOR DRUG EVALUATION AND RESEARCH, FOOD AND DRUG ADMIN., GUIDANCE FOR INDUSTRY, CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS (Aug. 1999), available at <http://www.fda.gov/cder/guidance/1804fnl.htm> (last visited Jan. 18, 2001) [hereinafter GUIDANCE FOR INDUSTRY] (illustrating the FDA's sentiment about DTC advertising, albeit slightly relaxed is still very consumer oriented and still strongly encourages the prescription drug industry to provide consumers with "nonpromotional, consumer-friendly product information" in their advertisements). The FDA also suggests that the pharmaceutical industry submit data and research on the effects DTC advertising has on consumers. *Id.*

16. Direct to Consumer Protection; Public Hearing, 60 Fed. Reg. 42,581 (Aug. 16, 1995); *Draft Guidance for Industry*, *supra* note 15, at 43,172. See also Moore & Horwitz, *supra* note 11, at 22-23 (discussing six specific issues about which the FDA expressed interest for its 1995 hearings).

17. Moore and Horwitz, *supra* note 11, at 20-21; James M. Johnstone, *Direct-to-Consumer Advertising: An Industry Perspective*, 47 FOOD & DRUG L.J. 63, 65 (1992); *Draft Guidance for Industry*, *supra* note 15, at 43,172. The actual FDA hearing was held on October 18th and 19th of 1995 in Silver Spring, MD. *Id.* The FDA published a follow-up document to alleviate public concerns about pre-clearance of DTC promotional materials. Direct-to-Consumer Promotion, 61 Fed. Reg. 24,314, 24,314-15 (May 14, 1996).

18. *Draft Guidance for Industry*, *supra* note 15, at 43,171.

19. Michael C. Allen, Comment, *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, 115 (1997); *FDA Eases Rules for Televised Drug Ads*, THE NEWS & OBSERVER, (Raleigh, N.C.), Aug. 9, 1997, at A1.

20. GUIDANCE FOR INDUSTRY, *supra* note 15.

21. CENTER FOR DRUG EVALUATION AND RESEARCH, FOOD AND DRUG

broadcast media, the industry must provide information about the risks of each prescription drug through a "major statement" in the advertisement.²² Both the 1997 *Draft Guidance* and 1999 *Guidance for Industry* allow drug manufacturers who advertise through broadcast media to use adequately distributed approved package inserts (inside the product itself)²³ as an alternative to the already required brief summary²⁴ of "side effects, contraindications, and effectiveness" of the prescription drug.²⁵

2. Product-Specific Advertising

Rogaine was the first subscription drug to be directly advertised to consumers.²⁶ Rogaine, a prescription drug used for male pattern baldness, was the model test drug for DTC advertising because it was easily analogized to the birth control exception to the Learned Intermediary Doctrine.²⁷ Since Rogaine's

ADMIN., GUIDANCE FOR INDUSTRY CONSUMER-DIRECTED BROADCAST ADVERTISEMENTS QUESTIONS AND ANSWERS, (Aug. 1999), available at <http://www.fda.gov/cder/guidance/1804q&a.htm> [hereinafter QUESTIONS & ANSWERS] (describing the differences between the *Draft Guidance* issued in 1997 and the final *Guidance for Industry* issued in August of 1999).

22. See GUIDANCE FOR INDUSTRY, *supra* note 15 (defining a major statement as a needed statement of a prescription drug's major risks during the audio or visual presentation when a company advertises in broadcast media rather than print).

23. *Id.*; The Federal Food Drug and Cosmetic Act, 21 U.S.C. § 352(n) (2000). The statute that governs advertising for prescription drugs in humans and animals is § 502(n) of the Federal Food, Drug and Cosmetic Act. *Id.* This statute requires that biological products include a "brief summary." *Draft Guidance For Industry*. 21 CFR §§ 202.1 require further that the brief summary also include all "risk-related information" in a "product's approved package labeling." *Draft Guidance For Industry*. As the *Draft Guidance* and *Guidance for Industry* rules further explain, this can be either a package insert or a product package insert. *Draft Guidance for Industry, supra* note 15, at 43,172. See also Moore & Horwitz, *supra* note 11, at 22-23 (suggesting that the *Draft Guidance* (which is very similar to the *Guidance for Industry*) along with other requirements requires that the package insert "be provided directly to 'the majority of a potentially diverse audience.'").

24. The Federal Food, Drug, and Cosmetic Act 21 U.S.C. § 352(n) (2000).

25. *Id.*; GUIDANCE FOR INDUSTRY, *supra* note 15.

26. John D. Hanson & Douglas A. Kysar, *Taking Behavioralism Seriously: Some Evidence of Market Manipulation*, 112 HARV. L. REV. 1420, 1456 (1999). See also *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245, 1251 (N.J. 1999) (describing the unique role of a cosmetic drug for male pattern baldness heralding the entrance of direct-to-consumer advertising); Tim S. Hall, *Bypassing the Learned Intermediary: Potential Liability for Failure to Warn in Direct-to-Consumer Prescription Drug Advertising*, 2 CORNELL J.L. & PUB. POL'Y 449, 462-64 (1993) (characterizing early prescription drug campaigns as informative and not product specific).

27. *Perez*, 734 A.2d at 1251 (discussing that the "[a]dvertising for Rogaine was just the tip of the iceberg"). See also Hall, *supra* note 26, at 27 (suggesting that Upjohn's selection of Rogaine to be the first drug to be used in product-specific advertising was "ideal" because it was cosmetic, and easily

debut on the advertising stage, prescription drug manufacturers have inundated consumers with product-specific advertising.²⁸ Though the first DTC advertisements, while product-specific, did not mention the drug's purpose,²⁹ consumers are now daily regaled with advertised medications for everything from smoking cessation to erectile dysfunction.³⁰ This advertising freedom allows pharmaceutical industries to launch successful and lucrative campaigns.³¹

Recently, the pharmaceutical industry marketing campaigns crossed over into cyber-advertising.³² To date, the FDA has not issued further regulation of this advertising medium subsequent to the 1999 *Guidance for Industry*.³³ And more disturbingly, the

analogized to the birth control exception of the Learned Intermediary Doctrine). See *infra* Part I(B)(1)(b) of this Comment for further explanation.

28. *Draft Guidance for Industry*, *supra* note 15, at 43,171; Miner, *supra* note 7, at 1. See also Perez, 734 A.2d at 1251 (describing Claritin, a histamine blocker, that contributed to the explosion of DTC advertising of prescription drugs).

29. Perez, 734 A.2d at 1251. Perez comments on the viewers confusion after watching many of the first product-specific advertisements as to exactly what Claritin treated or for what its use. *Id.*

30. See Miner, *supra* note 7 (illustrating by chart the amount of profit made by various manufacturers using DTC advertising).

31. Perez, 734 A.2d at 1251-52; Lars, *supra* note 11, at 141. See also Robert Pear, *Drug Companies Getting F.D.A. Reprimands for False or Misleading Advertising*, N.Y. TIMES, Mar. 28, 1999, at 28 (discussing how prescription drug companies spend 1.3 billion dollars on consumer directed advertising in 1998); Miner, *supra* note 7, at 1 (illustrating by chart the millions of dollars spent on various advertised prescription drugs).

32. See Robert Pear, *Marketing Tied to Increase In Prescription Drug Sales*, N.Y. TIMES, Sept. 20, 2000, at A18 (describing the various sources where consumers now get their healthcare information). For example, many drug advertisements on the Internet are histamine-blockers. See also Aventis, *Clartin Products, Claritin 10 mg Tablets (Loratadine) For Seasonal Allergy Relief*, at <http://www.claritin.com> (last visited Jan. 18, 2001); Eli Lilly and Company, *Flonase (Fluticasone Propionate) Nasal Spray, 50 mcg*, at <http://www.flonase.com> (last visited Jan. 18, 2001); GlaxoWellcome Webmaster *Once-Daily Allegra Fexofenadine HCL 180 mg Tablets*, at <http://www.allegra.com> (last visited Jan. 18, 2001); Merck & Co., Pfizer Inc., *Prozac Fluoxetine Hydrochloride*, at <http://www.prozac.com> (last visited Jan. 18, 2001); Warner-Lambert Co., *Lipitor.com . . . Your Personal Source for Cholesterol Information: Lipitor Atorvastatin Calcium*, at <http://www.lipitor.com> (last visited Jan. 18, 2001); Zocor (Simvastatin) *It's your future. Be There.*, at <http://www.zocor.com> (last visited Jan. 18, 2001); Zyrtec (R) (Cetirizine HCL): *Lots of Allergies. Just One Little Pill*, at <http://www.zyrtec.com> (last visited Jan. 18, 2001).

33. See Kelly N. Reeves, *Direct-to-Consumer Broadcast Advertising: Empowering the Consumer or Manipulating a Vulnerable Population?*, 53 FOOD & DRUG L.J. 661, 676 (1998) (pointing out the *Draft Guidance's* lack of elaboration on Internet web site advertising "except to note that the web site must provide the approved product labeling"). See also GUIDANCE FOR INDUSTRY, *supra* note 15 (illustrating the FDA's sentiment about DTC advertising, albeit slightly relaxed is still very consumer oriented and still

web has become another interactive tool of the pharmaceutical industry to ensnare more consumers.³⁴

B. The Learned Intermediary Doctrine: History

The Learned Intermediary Doctrine evolved in case law during the mid-1960s.³⁵ This doctrine is a defense used by prescription drug and medical device manufacturers in product liability cases to the extent that a plaintiff's claim is based upon the failure to warn doctrine.³⁶ The Learned Intermediary Doctrine relieves the drug manufacturers of their duty to warn the end consumer about the risks of a prescription drug, but preserves the manufacturers' duty to warn the physician, who must in turn warn the end consumer.³⁷ Under this doctrine, courts position doctors as educated middlemen between the final consumer and the prescription drug manufacturers.³⁸ Courts justify the allocation of duties by noting that doctors are in a better position

strongly encourages the prescription drug industry to provide consumers with "nonpromotional, consumer-friendly product information" in their advertisements). The 1999 *Guidance For Industry* also lacks further explanation about the Internet. *Id.*

34. Pear, *supra* note 31, at 18.

35. See *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966) (holding that a drug manufacturer had a duty to warn a Learned Intermediary about the possible side effects a drug could have on some patients); Teresa Moran Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 FOOD DRUG COSM. L.J. 829, 830-31 (describing the evolution of the Learned Intermediary Rule). See generally *Love v. Wolf*, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (Dist. Ct. App. 1964).

36. See *Baraukas v. Danek Med., Inc.*, No. 6:97CV00613, 2000 WL 223508, at *4 (M.D.N.C. Jan. 13, 2000) (applying the Learned Intermediary Doctrine to a medical device that is used in an experimental back surgery). See also *IDA G. DOX ET AL., ATTORNEY'S ILLUSTRATED MEDICAL DICTIONARY* P17 (1997) (describing a pedicle of the vertebral arch as one of two bars of bone that extends backwards from the body of each vertebra, these pedicles are parts of the vertebral arch that surround the spinal cord). For further information, diagrams and pictures see *GRAY'S ANATOMY: THE ANATOMICAL BASIS OF MEDICINE AND SURGERY*, 511-28 (38th ed. 1995) (discussing the various parts of the skeletal system).

37. *Baraukas*, 2000 WL 223508, at *4. See also *Vitanza v. Upjohn Co.*, 214 F.3d 73, 76 (describing a manufacturer's duty to warn only physicians); *Ramos v. Sterling Drug, Inc.*, 1999 WL 1261527, at *1 (limiting prescription drug manufacturers' duty to only the physicians and not end consumers); *Alexander v. Smith & Nephew, P.L.C.*, 98 F. Supp. 2d 1299, 1321 (requiring the manufacturers, under Oklahoma law, to warn physicians rather than patients); *Anderson v. Sandoz Pharm. Corp.*, 77 F. Supp. 2d 804, 806 (extending a manufacturers' duty to warn only to doctors and not to patients); *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245, 1255 (describing the exception to product liability concept of the "ultimate purchaser" within the Learned Intermediary Doctrine).

38. *Baraukas*, 2000 WL 223508 at *4; *Vitanza*, 214 F.3d at 76; *Ramos*, 1999 WL 1261527 at *1; *Anderson*, 77 F. Supp. 2d at 806; *Alexander*, 98 F. Supp. 2d at 1321; *Perez*, 734 A.2d at 1255.

than drug manufacturers to warn the end consumer about a drug's effects.³⁹

There are six basic premises underlying the Learned Intermediary Doctrine:⁴⁰ (1) doctors have the requisite experience and training, and they, not the patients or the drug companies, ultimately make the decision to prescribe or not to prescribe a drug;⁴¹ (2) in traditional doctor-patient relationships, patients rely heavily upon the doctor's advice and counsel concerning their health, not upon the advice of drug manufacturers;⁴² (3) courts hesitate to intervene into the doctor-patient relationship, and constrain a doctor's independent judgment about what should or should not be prescribed to patients;⁴³ (4) drug manufacturers do not have a relationship or other effective means to communicate

39. See *Anderson*, 77 F. Supp. 2d at 806 (holding that the plaintiff's doctor was a Learned Intermediary and was in a position to warn her of the impending risks, and the drug company's duty to warn only extended to the doctor); *Alexander*, 98 F. Supp. 2d at 1321 (holding that the Learned Intermediary Doctrine requires the drug manufacturer to warn the physician and a physician relying upon his own judgment should treat and warn the patient). See generally *Vitanza*, 214 F.3d at 76; *Ramos*, 1999 WL 1261527, at *1.

40. See *Perez*, 734 A.2d at 1255 (listing four premises for the Learned Intermediary Doctrine: "(1) reluctance to undermine the doctor-patient relationship; (2) absence in the era of 'doctor knows best' of a need for the patient's informed consent; (3) inability of the drug manufacturer to communicate with the patient; and (4) complexity of the subject"); Allen, *supra* note 19, at 120 (listing five reasons for the Learned Intermediary Doctrine, which describes why the doctor is in the best position to warn the end consumer including a physician's training and experience and the physician's professional evaluation of patient needs). See also *Alexander*, 98 F. Supp. 2d at 1321 (discussing the premise that a physician needs his independent judgment); Schwartz, *supra* note 35, at 830-31 (characterizing physicians as the better to decide because: (1) physicians, not patients prescribe drugs, therefore patients have little need for risk benefit information; (2) physicians' have the responsibility to inform patients in order to obtain their "informed consent"; (3) by providing warnings directly to consumers, drug manufacturers could interfere with the doctor-patient relationship, deterring patients from taking prescribed medications; and (4) it is very difficult to provide adequate warnings to consumers about the risks and benefits of prescription drugs through a drug label or package insert that they can genuinely understand).

41. See *Perez*, 734 A.2d at 1255 (listing as a justification for applying the Learned Intermediary Doctrine the "complexity of risk information," reasoning that patients may not understand the information even if by the manufacturers relay the information); Allen, *supra* note 19, at 120 (listing the importance of a physician's training and experience).

42. See *Perez*, 734 A.2d at 1255 (suggesting that a premise to the Learned Intermediary Doctrine is that a patient's informed consent was not necessary because doctors knew best).

43. *Id.* See also *Alexander*, 98 F. Supp. 2d at 1321 (discussing the premise of a physician's independent judgment); *Anderson*, 77 F. Supp. 2d at 806 (characterizing the doctor-patient relationship); Schwartz, *supra* note 35, at 830 (discussing undermining the doctor-patient relationship).

with the end consumers because drugs are prescribed through doctors, and distributed by pharmacies; (5) even if drug manufacturers warned consumers, the complexity of the risks and warnings would be difficult to translate into understandable risk-conveying language for the untrained consumer;⁴⁴ and (6) if manufacturers directly warn uninformed consumers, they may deter patients from taking the prescribed medicines or following their doctor's advice.⁴⁵

Critics, however, take issue with these outdated premises.⁴⁶ First, while doctors are still in the unique position to prescribe drugs, patients today are often actively involved in the decision process about which drug to take. The Supreme Court of New Jersey stated that we are no longer in the era of "the Norman Rockwell" image of the family where the paternalistic family doctor exists.⁴⁷ The court reasoned that "patient choice" is now part of our medical-legal case law rather than the assumption that "doctor knows best."⁴⁸ Second, while patients often rely on their doctors' advice, busy modern physicians are under time constraints and may fail to relate and warn the patients of all the possible risks associated with the prescribed drug.⁴⁹ Critics of the Learned Intermediary Defense argue that this responsibility to warn the end consumer should not fall exclusively on the physician.⁵⁰ Third, requiring pharmaceutical companies to give additional warnings directly to consumers in the form of inserts or another medium would not take away from the doctor's autonomy, it would simply supplement the doctor's own warnings to the patient.⁵¹ Fourth, as a consequence of advertising, drug companies themselves have undercut the doctor-patient relationship because instead of relying upon a doctor's advice, patients now are asking their doctors for drugs by name.⁵² The critics argue that if the

44. Schwartz, *supra* note 35, at 830 (discussing undermining the doctor-patient relationship).

45. *Id.*

46. See, e.g., Paul D. Rheingold, *The Expanding Liability of the Drug Manufacturer to the Consumer*, 40 FOOD DRUG COSM. L.J. 135, 136; Reeves, *supra* note 33, at 675-76; Sheryl Gay Stolberg, *Faulty Warning Labels Add to Risk in Prescription Drugs*, N.Y. TIMES, June 4, 1999 at A27.

47. Rheingold, *supra* note 46, at 136.

48. *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245, 1255. See Reeves, *supra* note 33, at 671 (illustrating the shift from a doctor-choice to a patient-choice medical environment).

49. *Perez*, 734 A.2d at 1255; Stolberg, *supra* note 46, at A27 (discussing the results of a 1,000 patient survey which found that only one-third had received information from their physicians about the dangerous side-effects of the drugs the doctors prescribed to them).

50. *Perez*, 734 A.2d at 1255; Stolberg, *supra* note 46, at A27.

51. *Perez*, 734 A.2d at 1255; Stolberg, *supra* note 46, at A27.

52. *Perez*, 734 A.2d at 1256. See *Tamar v. Terzian, Direct-to-Consumer Prescription Drug Advertising*, 25 AM. J.L. & MED. 149, 157 (1999) (stating

rationale for the Learned Intermediary Doctrine is that a doctor is in the best position to warn end consumers because he or she can communicate with them, this reasoning should now extend to drug manufacturers because they also communicate with the end consumer via advertisement.⁵³ Consequently, drug manufacturers should no longer escape their duty to warn the consumer.⁵⁴ However, the law in this area is still developing, as evidenced by the Third Restatement of Torts' median stance.⁵⁵

1. *Exceptions to the Learned Intermediary Doctrine*

There are two exceptions to the Learned Intermediary Doctrine:⁵⁶ mass immunizations/vaccinations⁵⁷ and birth control/contraceptives.⁵⁸ At the root of both exceptions is the presumption that the Learned Intermediary, the doctor, has been bypassed in these situations. This bypass occurs either because of the method by which the patient receives the drug⁵⁹ or because of the patient choice involved in the prescription process.⁶⁰

that because of DTC advertising, patients are now coming to doctors with preconceived notions and information about prescription drugs, which can ultimately decrease doctors' treatment choices if they concede to their patients' requests). Ms. Terzian continues offering an example of what occurred when doctors gave patients the combination of two prescription drugs known as fentanyl. *Id.* Moreover, DTC advertising forces doctors between a rock and a hard place. *Id.* at 157-58. They must balance between their patients' uninformed and unprofessionally diagnosed wants and the possibility of losing patients. *Id.*; Steven R. Salbu, *The FDA and Public Access to New Drugs: Appropriate Levels of Scrutiny in the Wake of HIV, AIDS, and the Diet Drug Debacle*, 79 B.U. L. REV. 93, 98-99 (1999) (relating how a patient's ability to direct their own treatment is empowering, but this empowerment can turn into bullying of prescribing doctors, resulting in terrible side-effects).

53. *Perez*, 734 A.2d at 1255-56.

54. *Id.*

55. See RESTATEMENT (THIRD) OF TORTS § 6 (d) (1) (1998) (describing a prescription drug as unsafe when warnings and instructions are not given to either the health-care providers "in a position to reduce risk" or the patient if there is no one else in a position to reduce the risk of harm).

56. See *Allen v. G.D. Searle*, 708 F. Supp. 1142, 1147-48 (D. Or. 1989) (discussing the birth control/contraceptive exception to the rule); Hall, *supra* note 26, at 462-64 (describing the exceptions to the Learned Intermediary Doctrine); Schwartz, *supra* note 35, at 832 (discussing the two exceptions to the Learned Intermediary rule). See, e.g., *Reyes v. Wyeth Labs., Inc.*, 498 F.2d 1264, 1276-77 (5th Cir.), cert. denied, 419 U.S. 1096 (1974) (holding that when a drug manufacturer knew or had reason to know that the prescription drug would not be administered by a physician, the manufacturer had a duty to warn the end consumer).

57. *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121 (9th Cir. 1969).

58. See Hall, *supra* note 26, at 452 (discussing how a patient's choice to use birth control is likely to be discretionary and "not fueled by medical necessity," thus limiting the need for a doctor to determine only the patient's initial eligibility).

59. *Davis*, 399 F.2d at 131.

60. Hall, *supra* note 26, at 463.

a. Mass Immunizations

After the evolution of the Learned Intermediary Doctrine, courts created an exception for mass immunizations.⁶¹ From the late 1960s through the early 1970s, the courts repeatedly decided that mass immunizations were an exception to the Learned Intermediary Doctrine.⁶² In the case of mass immunization, the courts reasoned that there was no Learned Intermediary consulting exclusively with the patient.⁶³ Patients receiving immunizations, often do so in clinics where the patient or his guardian decides whether he or she should receive the immunization.⁶⁴

b. Birth Control/Contraceptives⁶⁵

Some courts have also precluded manufacturers of birth control medications or contraceptive devices from using the Learned Intermediary Doctrine⁶⁶ because the role of the Learned Intermediary is circumvented in this setting by the patient's choice.⁶⁷ Usually, the patient is not in physical necessity of these drugs or devices, but chooses to use them: it is a personal decision.⁶⁸ Furthermore, because the patient typically only returns

61. Hall, *supra* note 26, at 463; Schwartz, *supra* note 35, at 832.

62. Reyes, 498 F.2d at 1276; Davis, 339 F.2d at 121.

63. See Davis, 339 F.2d at 131 (holding that when prescription drugs are dispensed like non-prescription drugs, the drug manufacturer has a duty to warn the end consumer). See also Reyes, 498 F.2d at 1276-77 (holding that in the Fifth Circuit, when a drug manufacturer knew or had reason to know that the prescription drug would not be administered by a physician it had a duty to warn the end consumer).

64. Davis, 339 F.2d at 121; Reyes, 498 F.2d at 1276-77.

65. For a discussion of contraceptive cases and tort liability see Virginia H. Castleberry, Hill v. Searle Laboratories: *The Decline of the Learned Intermediary Doctrine in Favor of Direct Patient Warnings of Drug Product Risks*, 43 ARK. L. REV. 821, (1990) (discussing how the Arkansas Supreme Court expanded a drug manufacturer's duty to warn by broadening the exceptions to the Learned Intermediary Defense in *Hill v. Searle Labs.*). See also Hill v. Searle Lab., 884 F.2d 1064, 1065, 1071 (8th Cir. 1989) (holding that the manufacturer of a copper intrauterine device owed a duty to the end consumer).

66. TERESA Moran Schwartz, *Consumer Warning for Oral Contraceptives: A New Explanation to the Prescription Drug Rule 41 FOOD DRUG COSM. L.J.* 241, 246-50 (1986); Stevens v. G.D. Searle, 602 F. Supp. 379, 380-81 (E.D. Mich. 1985). See also MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 68-70 (Mass. 1985) (holding that under Massachusetts law a manufacturer of birth control pills owes a duty to warn the end consumer of the pills side effects); Odgers v. Ortho Pharm. Corp., 609 F. Supp. 867, 878-81 (E.D. Wis. 1985) *modified*, 532 F. Supp. 211 (E.D. Wis. 1981) (holding that under Michigan law a manufacturer of oral contraceptives must warn the end consumer directly).

67. Allen v. G.D. Searle, 708 F. Supp. 1142, 1147-48.

68. See Perez v. Wyeth Labs., Inc., 734 A.2d at 125 (discussing patient choice in our "medical-legal jurisprudence").

on a yearly basis, lessening the chances for a doctor to warn her, the courts impose a duty to warn on the manufacturer.⁶⁹

C. Combining DTC and the Learned Intermediary Doctrine

Recently, DTC advertising and the Learned Intermediary Doctrine collided. On August 9, 1999, the Supreme Court of New Jersey held that "[t]he direct marketing of drugs to consumers generates a corresponding duty requiring manufacturers to warn of defects in the product."⁷⁰ Other courts, although not recognizing the manufacturers' duty in specific circumstances, are recognizing that when a prescription drug company participates in DTC advertising it may preclude itself from a defense under the Learned Intermediary Doctrine and have a duty to warn the end consumer.⁷¹

II. DTC ADVERTISING AND UNDERCUTTING THE DOCTOR-PATIENT RELATIONSHIP

Applying the Learned Intermediary Doctrine to prescription drug Internet advertising may have serious consequences for drug manufacturers and consumers. Section A defines and discusses the doctor-patient relationship, which is the main premise of the Learned Intermediary Defense. Then Section B discusses and evaluates the interactivity of advertising on various prescription drug web sites, including how these web sites are undercutting the doctor-patient relationship.

A. The Doctor-Patient Relationship: A Premise to the Learned Intermediary Doctrine.

Doctors are far more than an educated avenue for patients to acquire prescription drugs.⁷² Doctors are our teachers, counselors, negotiators, and sometimes our friends.⁷³ Today, the doctor-patient relationship includes greater patient autonomy than it previously did.⁷⁴ Self-help, patient participation and patient choice

69. See *MacDonald*, 475 N.E.2d at 69 (discussing the frequency with which oral contraceptive patients return to the doctor).

70. *Perez*, 734 A.2d at 1263. In *Perez*, the court held that there was a rebuttable presumption that a manufacturer fulfilled its duty if it had complied with the FDA standards for advertising. *Id.* at 1259. The current regulations however, do not expressly address Internet advertising; and thus, there is no presumed standard against which plaintiffs may rebut.

71. *Doe v. Miles Inc.*, No. ED 75100, 2000 WL 667383, at *17 (Mo. App. Ct. May 23, 2000).

72. See generally J. ANDREW BILLINGS ET AL., *THE CLINICAL ENCOUNTER: A GUIDE TO THE MEDICAL INTERVIEW AND CASE PRESENTATION* 12-72 (2d ed. 1999).

73. See generally *id.*

74. *Id.* at 321-22.

in the scope of diagnosis, and treatment are now all part of an "ideal doctor-patient relationship."⁷⁵ The doctor-patient relationship is similar in many ways to the attorney-client relationship.⁷⁶ Both of these fiduciary relationships are based on trust and confidence.⁷⁷ Through this trust and confidence a doctor is able to acquire needed information and use that information for the patient's benefit.⁷⁸ A lack of information and communication between doctor and patient may hamper a doctor's ability to assist patients.⁷⁹ Through DTC Internet advertising, drug manufacturers may usurp the many roles of a doctor and undercut the doctor-patient relationship.

B. *The Interactive Advertisement—The Prescription Drug Web Sites*

The interactivity possible between consumers and prescription drug manufacturers through the Internet is far beyond the interaction possible through standard print, radio or television advertisements.⁸⁰ Using the Internet, drug manufacturers have increased capabilities to contact the consumer. Internet advertising is not hampered by time as are other mediums, enabling the manufacturer to provide the consumer continuous information. Many interactive web pages encourage repeat visits with their forecasts or other information

75. *Id.*

76. *See id.* at 287-93 (describing how a physician can undermine the basic trust of a patient through conduct or through breaching the duty of confidentiality).

77. BILLINGS, *supra* note 72, at 12-72. *See generally* ABA Center for Professional Responsibility, Model Rules of Professional Conduct, Introduction, & §§ 1.6 (1999) (describing the duties and premises behind an attorney-client relationship).

78. *See* BILLINGS, *supra* note 72, at 35 (explaining how doctors' "recognized role[s]" give them access to intimate information that should only be used for the patients' benefit).

79. *See generally id.* at 38-72, 113-62 (relating ways a doctor may approach a patient to elicit the needed information).

80. *See, e.g.,* Aventis, Clartin Products, *Claritin 10 mg Tablets (Loratadine) For Seasonal Allergy Relief*, at <http://www.claritin.com> (last visited Jan. 18, 2001); Eli Lilly and Company, *Flonase (Fluticasone Propionate) Nasal Spray, 50 mcg*, at <http://www.flonase.com> (last visited Jan. 18, 2001); GlaxoWellcome Webmaster *Once-Daily Allegra Fexofenadine HCL 180 mg Tablets*, at <http://www.allegra.com> (last visited Jan. 18, 2001); Merck & Co., Pfizer Inc., *Prozac Fluoxetine Hydrochloride*, at <http://www.prozac.com> (last visited Jan. 18, 2001); Warner-Lambert Co., *Lipitor.com . . . Your Personal Source for Cholesterol Information: Lipitor Atorvastatin Calcium*, at <http://www.lipitor.com> (last visited Jan. 18, 2001); *Zocor (Simvastatin) It's your future. Be There.*, at <http://www.zocor.com> (last visited Jan. 18, 2001); *Zyrtec (R) (Cetirizine HCL): Lots of Allergies. Just One Little Pill*, at <http://www.zyrtec.com> (last visited Jan. 18, 2001).

that changes daily.⁸¹ Through e-mail subscription lists, the drug manufacturers are not only encouraging consumer contact, but are also contacting consumers.⁸²

Many of the manufacturers of histamine blockers, HMG-CoA Reductase Inhibitors, and antidepressants have web sites advertising their prescription drugs.⁸³ These web sites vary in their levels of interactivity.⁸⁴ As these web sites increase in interactivity, the doctor-patient relationship is increasingly undermined; as well as the manufacturers' justification for using the Learned Intermediary Defense, by decreasing patients' willingness to properly inform their physician and, therefore, decreasing their reliance upon the physician's advice.⁸⁵

1. www.allegra.com: *The Histamine Receptor One Blocker Allegra*⁸⁶

Allegra is a tablet primarily used for remedying seasonal allergies.⁸⁷ The manufacturer's home web site allows consumers to acquire a five-dollar coupon for this prescription drug if they respond to a quiz, and learn about what allergies they might have.⁸⁸ The web site also explains to consumers why Allegra could be more beneficial for them than other prescription remedies.⁸⁹ The pages in the site also suggest that prior to leaving, the visitors view the pollen forecast in their geographic region.⁹⁰ Although this site is largely informative for consumers, teaching them about their allergies,⁹¹ it nevertheless undercuts the doctor-patient relationship. Because the manufacturer encourages consumers to spend time on the site, and establishes a separate relationship with the consumer, it weakens its Learned Intermediary Defense.

2. www.zyrtec.com: *The Histamine Receptor One Blocker Zyrtec*⁹²

Zyrtec is a daily one-dose pill, which remedies a variety of allergies.⁹³ The Zyrtec home web site does not differentiate

81. See, e.g., web sites cited *supra* note 80.

82. *Id.*

83. *Id.*

84. *Id.*

85. Miner, *supra* note 7, at 1.

86. Aventis, *Once-Daily Allegra Fexonfenadine HCL 180 mg Tablets*, at <http://www.allegra.com> (last visited Jan. 18, 2001).

87. *Id.*

88. *Id.*

89. *Id.*

90. *Id.*

91. Aventis, *Once-Daily Allegra Fexonfenadine HCL 180 mg Tablets*, at <http://www.allegra.com> (last visited Jan. 18, 2001).

92. PHARMACOLOGY: LIPPINCOTT'S ILLUSTRATED REVIEWS, Index (Richard A. Harvey & Pamela C. Champe eds., 2d ed. 2000).

93. Pfizer Inc., *Zyrtec (R) (Cetirizine HCL): Lots of Allergies. Just One Little Pill*, at <http://www.zyrtec.com> (last visited Jan. 18, 2001).

between consumers and healthcare professionals.⁹⁴ The site allows the consumer to learn about Zyrtec: what it is, its benefits, how to take the drug, how to get the drug, personal stories, product information, and even how to pronounce the name.⁹⁵ Another link on the page is called "understanding your allergies."⁹⁶ This page provides consumers information on allergies, symptoms, allergens, allergy-prevention tips, and a quiz.⁹⁷ The web site allows consumers to receive a ten-dollar coupon if they fill out a survey mailed to them.⁹⁸ Consumers can also view a pollen count for their geographic area, subscribe to a pollen and allergy e-letter, or e-mail the web site to a friend.⁹⁹ The site also provides information on understanding treatment options and adapting to responses.¹⁰⁰ Another section of the web site encourages consumers to contact the manufacturer to share their Zyrtec experience because the manufacturer will listen.¹⁰¹ Thus, like Allegra's site,¹⁰² Zyrtec's site is informative; however, the manufacturer further assumes the traditional role of a doctor by encouraging consumers to talk about their Zyrtec experiences.

3. www.zocor.com: *The HMG-CoA Reductase Inhibitor Zocor*¹⁰³

Zocor's home site divides its initial links between consumers and healthcare professionals.¹⁰⁴ This site describes and defines cholesterol, heart disease, and the benefits of nutrition and exercise.¹⁰⁵ It contains a video and testimonial by a professional football coach.¹⁰⁶ This web site also has links to "healthful tools,"¹⁰⁷

94. *Id.*

95. *Id.*

96. *Id.*

97. *Id.*

98. Pfizer Inc., *Zyrtec (R) (Cetirizine HCl): Lots of Allergies. Just One Little Pill*, at <http://www.zyrtec.com> (last visited Jan. 18, 2001).

99. *Id.*

100. *Id.*

101. *Id.*

102. Aventis, *Once-Daily Allegra Fexofenadine HCL 180 mg Tablets*, at <http://www.allegra.com> (last visited Jan. 18, 2001).

103. PHARMACOLOGY, *supra* note 92.

104. Merck & Co., *Zocor (Simvastatin) It's your future. Be There.*, at www.zocor.com (last visited Jan. 18, 2001).

105. *Id.*

106. *See id.* (depicting the Dan Reeves' story in print and a film testimonial).

107. *Id.* Within this "Healthful Tools" link consumers have many options. *Id.* The heading of the page reads: "Where will you be when your grandson gets his first taste of the ocean?" *Id.* Consumers can link to a "Cholesterol I.Q." page and "[t]est their knowledge with this interactive page." *Id.* The second "Healthful Tool" contains goal cards that a consumer can print out from the web site. The goal cards allow consumers to keep track of their significant cholesterol information. *Id.* Consumers can also print out exercise journals to motivate them to stick to an exercise plan. *Id.* Another tool on this

a glossary, a subscription list for e-mail about the web site's updates, and prescription refill reminders.¹⁰⁸ It also offers consumers further information upon request.¹⁰⁹ Once again, although this web site informs consumers, it also establishes a relationship with them by encouraging continued contact, which undermines the doctor-patient relationship.

4. www.flonase.com: *The Corticosteroid Flonase*¹¹⁰

Flonase, a drug manufactured by GlaxoSmithKline, is a nasal spray.¹¹¹ The Flonase home web site offers informational links for healthcare professionals and patients.¹¹² The patient site links consumers to information about nasal allergies, a note to parents about children's allergies, an "allergytalk"¹¹³ newsletter, various resources, and a pollen count map.¹¹⁴ The consumer can even receive a free allergy kit.¹¹⁵ In the "allergytalk" link, the site discusses how to be a "Pollen Warrior," giving consumers advice such as not wearing their contacts, washing their nose out with salt water, grooming their pets, and making sure their nasal prescription is filled "before the allergy season arrives."¹¹⁶ While this web site gives out general information educating consumers about Flonase, it is also acting as a teacher or informer to consumers, which is one of the roles of a physician. A drug manufacturer using DTC Internet advertising in this manner is effectively advertising itself into the physician's role, both undercutting the doctor-patient relationship and the basis upon which the manufacturer demands the Learned Intermediary Defense.

5. www.prozac.com: *The Antidepressant Prozac*¹¹⁷

Prozac, an antidepressant, also has a home web site.¹¹⁸ The

page is the glossary of terms concerning heart disease terminology. *Id.* The last "Healthful Tool" is a "Risk factor assessment." *Id.* The site informs consumers that this quiz will help them identify the specific risk factors that are correlated with high cholesterol. *Id.*

108. *Id.*

109. *Id.*

110. PHARMACOLOGY, *supra* note 92.

111. GlaxoWellcome Webmaster, *Flonase (Fluticasone Propionate) Nasal Spray, 50 mcg*, at <http://www.flonase.com> (last visited Jan. 18, 2001).

112. *Id.*

113. *Id.*

114. *Id.*

115. *Id.*

116. GlaxoWellcome Webmaster, *Flonase (Fluticasone Propionate) Nasal Spray, 50 mcg*, at <http://www.flonase.com> (last visited Jan. 18, 2001).

117. PHARMACOLOGY, *supra* note 92.

118. Eli Lilly & Co., *Prozac (Fluoxetine Hydrochloride)*, at <http://www.prozac.com> (last visited Jan. 18, 2001).

site has a separate link for healthcare professionals.¹¹⁹ The consumer/patient site encourages consumer response to the web site.¹²⁰ Prozac's web site has, as do others, a consumer-oriented warning section.¹²¹ In its "Taking Control" link the site informs patients that the prescription process involves communicating with their doctor and provides questions the patients may want to ask their doctor.¹²² The other noteworthy function of this web site is the "Community" link.¹²³ Within this link consumers have an opportunity to share testimonials and other "written inspirations."¹²⁴ The page certainly interacts with the end consumer. The page's features create interaction, encourage a community atmosphere and multiple visits, and teach consumers what they should ask their doctor; therefore, undermining the doctor-patient relationship.

6. www.claritin.com: *The Histamine Receptor One Blocker Claritin*¹²⁵

The histamine blocker, Claritin, has a home web site with links that define allergies, allow consumers to view their geographic pollen count, and allow consumers to subscribe to a free e-mail group: "pollen alert."¹²⁶ Consumers can join "My Claritin" and create a customized home page for their continued pollen count needs and interests.¹²⁷ The web site also has a link under its "Managing Allergies" tab, which advises consumers about visiting their doctor concerning allergies.¹²⁸ Within this link there are several other links, including pages describing when a patient should go see a doctor, what questions a patient should ask the doctor, and what questions a doctor will ask the visiting patient.¹²⁹ This section also describes what patients should expect from a doctor's appointment concerning allergies.¹³⁰

The Claritin site encourages consumers to return.¹³¹ It teaches consumers by specifically advising what questions to

119. *Id.*

120. *Id.* (advertising on a scrolling marquee, "We'd like to hear from you").

121. *Id.*

122. *Id.*

123. Eli Lilly & Co., *Prozac (Fluoxetine Hydrochloride)*, at <http://www.prozac.com> (last visited Jan. 18, 2001).

124. *Id.*

125. PHARMACOLOGY, *supra* note 92.

126. Clartin Products, *Claritin 10 mg Tablets (Loratadine) For Seasonal Allergy Relief*, at <http://www.claritin.com> (last visited Jan. 18, 2001).

127. *Id.*

128. *Id.*

129. *Id.*

130. *Id.*

131. Clartin Products, *Claritin 10 mg Tablets (Loratadine) For Seasonal Allergy Relief*, at <http://www.claritin.com> (last visited Jan. 18, 2001).

expect during a doctor's visit as well as the type of questions they should pose to determine their allergies.¹³² This site places the drug manufacturer in the role of a teacher and counselor. The manufacturer is directly communicating with the consumer, even explaining the process of how to receive this drug from the doctor. While innocuous on its face, such advertising undercuts a doctor's professional and independent judgment and interferes in the doctor-patient relationship.

When manufacturers use this type of advertising, the overarching premise that a doctor is in a better position than drug manufacturers to warn the end consumer becomes much less convincing.¹³³ If a consumer is in continuous contact with a drug manufacturer, spending hours on an interactive web site sharing testimonials about the drug, and discussing effects of the drug; then the manufacturer, not the doctor, is spending greater time with the consumer, is building a relationship with the consumer,¹³⁴ and is the party giving the consumer advice on his or her condition. Here, the drug manufacturer has advertised itself into the role of the Learned Intermediary, and must accept responsibility of warning the end consumer.

C. Effects of Applying or Revoking the Learned Intermediary Defense

Continuing to apply the Learned Intermediary Doctrine to DTC Internet advertising will have various consequences.¹³⁵ On one hand, drug manufacturers could still market and promote

132. *Id.*

133. See *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1244, 1255 (discussing how the four basic premises of the Learned Intermediary Doctrine are "absent in [DTC] advertising of prescription drugs"). See also *Lars*, *supra* note 11, at 170 (describing how critics of DTC advertising find it "crass, profit-motivated advertising of prescription drugs"). These critics also believe that "[o]nce pharmaceutical manufacturers stoop to direct consumer advertising, the argument goes, they no longer deserve the special treatment that they have enjoyed under tort law." *Id.* See also *Schwartz*, *supra* note 35, at 845 (relating that the prescription drug industry, like any other industry, sells their product and attempts to create a demand). *Schwartz* advocates that when the drug industry engages in advertising directly to consumers it has circumvented the basis of its exception and should be held liable under product liability rules like any other manufacturer. *Id.* at 848; *Hall*, *supra* note 26, at 462 (discussing how DTC advertising is essentially advertising "designed to create a positive image of the product in the mind of the consumer").

134. See *Perez*, 734 A.2d at 1252 (discussing how DTC advertising places information directly before the consumer).

135. See *Lars*, *supra* note 11, at 152 ("argu[ing] that DTC promotion is of educational value and will improve the physician-patient relationship, increase patient compliance with drug therapy and physician visits and lower drug prices."); *Perez*, 734 A.2d at 1259 (discussing various effects of their holding of a rebuttable presumption that if the manufacturers duty to warn the end consumer is met, the manufacturers complied with FDA guidelines).

knowledge about their products,¹³⁶ developing the Internet as a reliable medium¹³⁷ for consumers to acquire information.¹³⁸ Unfortunately, on the other hand it allows mammoth drug manufacturers, playing on an uneven field, to take advantage of the uneducated consumer.¹³⁹ Drug manufacturers are “not educating people about medicine they take—which is what needs to be done—they’re (referring to drug manufacturers) trying to increase demand.”¹⁴⁰ Applying the Learned Intermediary Doctrine allows drug manufacturers to artificially create demand,¹⁴¹ while escaping liability.¹⁴² This is poignantly evident when companies use cost-effective web sites to advertise. Drug manufacturers can reach and interact with millions of consumers from one web site. The result is that manufacturers are not being held liable for their products, while their profits increase and the price of drugs decrease in the market. This forces the few injured consumers to bear the cost for the entire market.

Disposing of the Learned Intermediary Defense would also have many effects on the involved parties.¹⁴³ Prescription drug

136. See, e.g., *Perez*, 734 A.2d at 1263 (stating that pharmaceutical companies have a right to communicate with the public); *Tamar v. Terzian, Direct-to-Consumer Prescription Drug Advertising*, 25 AM. J.L. & MED. 149, 157 (1999) (describing the marketing expectations of the pharmaceutical drug industry).

137. See Chester Chuang, *Is There a Doctor in the House? Using Failure-to-Warn Liability to Enhance the Safety of Online Prescribing*, 75 N.Y.U. L. REV. 1452, 1478 (2000) (expanding upon how the application of the Learned Intermediary rule would enhance online doctor-patient relationships, which would encourage the development of the Internet as a reliable source for prescription drugs); *Perez*, 734 A.2d at 1254-59 (explaining why DTC advertising undercuts the basic premise for the Learned Intermediary Doctrine).

138. See Reeves, *supra* note 33, at 669-70 (discussing the FDA’s initiatives to inform consumers about prescription drugs).

139. See J. Howard Beales III & William C. MacLeod, *Assessment of Pharmaceutical Advertisements: A Critical Analysis of the Criticism*, 50 FOOD & DRUG L.J. 415, 415-16 (discussing opponents of drug advertising who criticize that this type of advertising relies upon “questionable research,” obscures unfavorable evidence, fails to “provide adequate information” to consumers and exaggerates the benefits of one product over another).

140. See *Perez*, 734 A.2d at 1252-53 (discussing how DTC advertising only contains general warnings about each pharmaceutical drug’s effect); Jon D. Hanson & Douglas A. Kysar, *Taking Behavioralism Seriously: Some Evidence of Market Manipulation*, 112 HARV. L. REV. 1420, 1456 (1999) (discussing how direct-to-consumer advertisements do not inform a patient sufficiently about the inherent risks of using a specific prescription drug).

141. Miner, *supra* note 7, at 1.

142. See cases cited *supra* note 9.

143. Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 MICH. J.L. REFORM 461, 466-67 (1997) (listing how too much liability could decrease research and development, force actors to leave the market, create shortages and higher costs).

manufacturers would be subject to liability in failure to warn cases, equalizing the burden of the drug manufacturers' failure to warn across all its consumers, but increasing drug cost.¹⁴⁴ These higher costs could translate into less advertising,¹⁴⁵ but the threat of liability will likely yield more cautious advertising, and a better-warned Juliet.¹⁴⁶

This may create a disincentive for doctors to warn their patients.¹⁴⁷ However, revoking the Learned Intermediary Defense will provide plaintiff-consumers a source of redress if indeed the drug manufacturer causes serious injury about which the manufacturer failed to warn consumers.

III. "SOME SHALL BE PARDON'D AND SOME PUNISHED"¹⁴⁸ A SLIDING COMPROMISE

Choosing between polar opposites regarding the use of Internet advertising and the availability of the Learned Intermediary Defense is not an appropriate solution to these problems.¹⁴⁹ A better approach to DTC Internet advertising and the Learned Intermediary Doctrine allows patient choice. The following approach also allows manufacturers to advertise, while still allowing patients redress when drug manufacturers' approach to the interactivity of the Internet have gone beyond the logical bounds of their defense.¹⁵⁰

If courts decide along bifurcated lines concerning DTC advertising¹⁵¹ and the Learned Intermediary Doctrine, there will

144. See Lars, *supra* note 11, at 152 (discussing how DTC advertising is "misleading by failing to adequately communicate the risk information, and that such promotion will damage the physician-patient relationship, increase drug prices, increase liability actions, and lead to over-medication and drug abuse").

145. See, e.g., Lars, *supra* note 11, at 169 (describing how manufacturers may react to further liability if the duty to warn is expanded by "conveying far less rather than more information to patients").

146. See *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1244, 1262 (elaborating that the court holds a patient's interest for accurate and reliable information to supercede a manufacturer's interest in being shielded from liability in failure to warn cases).

147. See Lars, *supra* note 11, at 179 (expounding that "such a solution may work to undermine effective dissemination of risk information to patients because the one party best situated to convey such technical information in understandable terms will face reduced incentives to do so if the manufacturers also must provide warnings").

148. Shakespeare, *supra* note 1, at 1099.

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

150. See *id.* (discussing generally a centrist approach with other forms of advertising).

151. The first case that directly correlated the revocation of the Learned Intermediary defense with DTC in the prescription drug setting was *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245 (N.J. 1999). There, the court held that if prescription drug manufacturers advertise directly to consumers they can no

be consequences on both ends of the spectrum which will be unsatisfactory to both consumers and drug manufacturers.¹⁵² If courts continue to apply the Learned Intermediary Doctrine to DTC advertising, although increasing patient choice,¹⁵³ this defense will allow drug manufacturers the opportunity to take advantage of uneducated consumers.¹⁵⁴ If the Learned Intermediary Doctrine is not used as a defense to liability, drug manufacturers may choose to decrease advertising because of the risk of liability, thus decreasing both consumer access to information about prescription drugs¹⁵⁵ and patient choice, which will inflate the price of drugs.¹⁵⁶ Instead of either of these choices the courts should take a more centrist approach: measuring the interactivity of each web site to determine if it undercuts the doctor-patient relationship.

The middle-of-the-road approach suggested herein adopts a test that courts have been administering recently to determine whether a long-arm statute's jurisdiction extends over Internet companies accessed by consumers in the forum.¹⁵⁷ As the U.S. Supreme Court foresaw in *Burger King Corp. v. Rudzewicz*, "modern commercial life" will reach a point where the defendant's presence in the forum will be obviated.¹⁵⁸ With modern communications, an advertiser and manufacturer do not have to be in the forum to reach the end consumer. Some companies have subjected themselves to specific jurisdiction in the states in which they advertised depending upon the interactivity level of their web site.¹⁵⁹ The same should apply to prescription drug web sites. To

longer use the Learned Intermediary Defense. *Id.* at 1251.

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

153. *Reeves*, *supra* note 33, at 675-76.

154. *Beales*, *supra* note 139, at 415-16.

155. *Lars*, *supra* note 11, at 141.

156. *Id.*

157. *E.g.*, *Caulder v. Jones*, 465 U.S. 783 (1984); *Panavision Int'l L.P. v. Toeppen*, 141 F.3d 1316 (9th Cir. 1998); *LFG, LLC, v. Zapata Corp.*, 78 F. Supp. 2d 731 (N.D. Ill. 1999); *Pheasant Run, Inc. v. Moyse*, No. 98 C 4202, 1999 WL 58562, at *6 (N.D. Ill. Feb. 3, 1999); *Scherr v. Abrahams*, No. 97 C 5453, 1998 WL 299678, at *6 (N.D. Ill. May 29, 1998); *Vitullo v. Velocity Powerboats, Inc.* No. 97 C 8745, 1998 WL 246152, at *7 (N.D. Ill. Apr. 27, 1998); *Zippo Mfg. Co. v. Zippo Dot Com, Inc.*, 952 F. Supp. 1119 (W.D. Pa. 1997).

158. *See generally Burger King v. Rudzewicz*, 471 U.S. 462, 476 (1985); *Caulder*, 465 U.S. at 785 (1984); *Pheasant Run, Inc.* 1999 WL 58562, at *6; *Vitullo*, 1999 WL 246152, at *7; *Scherr*, 1998 WL 299678, at *4-*6; *LFG*, 78 F. Supp. 2d at 734-38; *Zippo Mfg. Co.*, 952 F. Supp. at 1121.

159. *See LFG*, 78 F. Supp. 2d at 736 (characterizing a "portal" web site as interactive when it provided access to "internet search engines, e-mail accounts, discussion groups, web sites categorized by topic, and directories, among other things"); *Pheasant Run, Inc.*, 1999 WL 58562, at *2-3 (characterizing plaintiff's one paragraph internet advertisement, which did contain plaintiff's telephone number but did not allow for electronic

the extent that the manufacturer interacts with the end consumer, the manufacturer should no longer be able to consistently use the Learned Intermediary Doctrine as a defense.

The sliding-scale test used by courts to determine the interactivity of web sites was introduced in an opinion by the Western District of Pennsylvania in *Zippo Mfg. Co. v. Zippo Dot Com, Inc.*¹⁶⁰ Within this sliding-scale test, the court characterized three levels of interactivity of a defendant company's web site.¹⁶¹ The first level of web site interactivity is informational and passive. Information is accessible to users, but is only posted on the web site.¹⁶² The second level allows the user to exchange information with the host of the web site.¹⁶³ Courts retain jurisdiction over web sites within this level depending upon the "level of interactivity and commercial nature" of the site.¹⁶⁴ The third and highest level is a web site that allows the user to transact business with the manufacturer.¹⁶⁵

A. The Passive Web Site

At the bottom of this "interactive" technology scale is the passive web site.¹⁶⁶ Manufacturers are simply switching mediums and placing print advertising on the Internet, and in essence their interaction with the end consumer is minimal.¹⁶⁷ Courts reason that there must be "something more" than simply placing information on an Internet site to be considered an interactive web site.¹⁶⁸ In the setting of the Learned Intermediary Doctrine,

communication as a passive web site); *Scherr*, 1998 WL 299678, at *5 (characterizing a free internet informational electronic mini-journal as having a low interactivity rate, even though visitors exchanged their e-mail addresses with the company); *Vitullo*, 1998 WL 246152, at *6 (characterizing a web site containing the capacity for customers to e-mail the retailer with its "contact us" button as an interactive web site); *Zippo Mfg. Co.*, 952 F. Supp. at 1125-26 (holding that a web site was interactive and not passive because the company had not simply posted information on the web site). See also *CoolSavings.com, Inc. v. IQ Commerce Corp.*, 53 F. Supp. 2d 1000, 1001-03 (N.D. Ill. 1999) (characterizing a web site with a "clip" and "pop up" coupon as interactive).

160. See *Zippo Mfg. Co.*, 952 F. Supp. at 1124 (setting out the specific personal jurisdiction test for web sites that are based upon the interactivity, or the level of exchanged information that occurs on web sites). This jurisdiction test is a sliding-scale test which includes three categories: passive, intermediate, and transactional. *Id.*

161. *Id.*

162. *Id.*

163. *Id.*

164. *Id.*

165. *Zippo Mfg. Co.*, 952 F. Supp. at 1123-24.

166. See *Vitullo*, 1998 WL 246152, at *5 (characterizing passive web sites as sites that simply place information on the web).

167. *Id.*

168. *Id.* at *5. See *Pheasant Run, Inc.*, 1999 WL 58562, at *2-3 (holding that a one paragraph advertisement on the Internet, that did not enable the user to

prescription drug manufacturers' web sites that are passive should still be able to use the Learned Intermediary Defense. While these web sites do reach the end consumers, the sites do not interact with the end consumer, instead contacting the user only minimally through their advertising. Thus, such web sites do not undercut the premise upon which the Learned Intermediary Doctrine is based.

B. The Intermediary Web Site

The intermediate category of interactivity is where most web sites fall.¹⁶⁹ Courts characterize these web sites as interactive and commercial.¹⁷⁰ Within this category there is a range of web sites.¹⁷¹ For example, when a manufacturer gives consumers access to a web site designed for interaction, the success of which depends upon interaction, the courts consider these web sites interactive enough to warrant minimum contacts.¹⁷² Some of these sites are called "portal" web sites and give consumers access to search engines, e-mail accounts, discussion groups, web sites categorized by topic, and directories that create a communal feeling.¹⁷³ Courts refer to this concept as an "Internet neighborhood," promoting long

contact the defendant directly, was a passive site). For further delineation between the levels of interactivity see *Scherr*, 1998 WL 299678, at *5 (discussing the interactivity level of a web site, where the user had direct contact with the host, as a web site that fell within the second category: intermediate).

169. *Zippo Mfg. Co.*, 952 F. Supp. at 1124.

170. *Vitullo*, 1998 WL 246152, at *5.

171. *Pheasant Run, Inc.*, 1999 WL 58562, at *6. Web sites can differ dramatically within this category. A company may have one e-mail address on its page precluding it from falling in the passive category, but in intent, the web page is more passive than it is interactive. *Id.* The Northern District of Illinois held that a defendant's web site was interactive because the inclusion of e-mail addresses facilitated conversations between the defendant and its potential customers. *Id.* Similarly in *International Star Registry of Ill. v. Bowman-Haight Ventures, Inc.*, No. 98 C 6823, 1999 WL 300285, at *6 (N.D. Ill. May 6, 1999), the court held that a web site inviting potential customers to make inquiries via e-mail made it more interactive. Zapata's web site was also characterized as interactive because it was a portal web site and had a contact button for help and to join their mailing list. *LFG, LLC v. Zapata Corp.*, 78 F. Supp. 2d 731, 736-37.

172. See *LFG*, 78 F. Supp. 2d at 736 (holding that an interactive "portal" site was designed for user interaction and the success of the web site depended upon the number of users, thus characterizing this site as highly interactive). A portal web site is, as the court defined it, a "super web site" providing a "variety of services, aiming to be 'one-stop shops' for internet needs." *Id.* at 736. This type of web site usually "offer[s] access to internet search engines, e-mail accounts, discussion groups, web sites categorized by topic, and directories, among other things—all free to the user." *Id.* These web sites "generate their income by selling [Internet] advertising space." *Id.*

173. *Id.*

visits by users and ensuring that visitors will return.¹⁷⁴ Courts also consider “contact us” buttons as highly interactive.¹⁷⁵ The purpose of this web site feature is to contact and interact with consumers for the direct purpose of financial gain.¹⁷⁶ Such web sites are interacting, discussing, and creating a community or neighborhood for consumers and encouraging them to return. Manufacturers of pharmaceutical products who use this form of DTC advertising are undercutting the doctor-patient relationship, which is the very relationship to which they appeal when asserting the defense of a Learned Intermediary. Thus, the Learned Intermediary Doctrine should not apply to manufacturers using highly interactive intermediate web sites.

C. The Transactional Web Site

While transactional web sites that sell pharmaceutical drugs do exist, such sites are not the focus of this Comment.¹⁷⁷ Obviously, if a manufacturer is bypassing the Learned Intermediary altogether, and completely undercutting the doctor-patient relationship,¹⁷⁸ if not obliterating it, the manufacturer should not be allowed to use the Learned Intermediary Doctrine.

The use of this sliding-scale may decrease some advertising, but, because of Internet profitability, will likely change the advertising from a consumer and manufacturer interaction-based advertising to a primarily informative type of advertising.

CONCLUSION

Using this sliding-scale, while complicated, will lead to a more equitable use of the Learned Intermediary Doctrine. Those pharmaceutical companies that are interacting with the consumer

174. *Id.* at 737.

175. *Id.*

176. *LFG*, 78 F. Supp. 2d at 736-37 (describing an interactive web site designed for user interaction and the company’s purposes for developing these web sites).

177. See generally Chester Chuang, *Is There a Doctor in the House? Using Failure-to-Warn Liability to Enhance the Safety of Online Prescribing*, 75 N.Y.U. L. REV. 1452 (2000), for further discussion on the Learned Intermediary Doctrine and transactional web sites that sell pharmaceutical drugs.

178. See *Reyes v. Wyeth Labs., Inc.*, 498 F.2d 1264, 1276-77 (holding that when a drug manufacturer knew or had reason to know that the prescription drug would not be administered by a physician it had a duty to warn the end consumer); *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1244, 1255 (listing a premise for the doctrine as the “complexity of the subject” and discussing the “doctor knows best” of need for the patient’s informed consent); *Allen v. G.D. Searle*, 708 F. Supp. 1142, 1147-48 (discussing the birth control/contraceptive exception to the rule); Hall, *supra* note 26, at 462-64 (describing the exceptions to the Learned Intermediary Doctrine); Schwartz, *supra* note 35, at 832-33 (discussing the two exceptions to the Learned Intermediary Rule).

and undercutting the doctor-patient relationship will not be able to use the doctrine. However, those that do not undercut the basic premises of the Learned Intermediary Doctrine will continue to have the ability to utilize this defense. Within these bounds the consumers will continue to have choices and will continue to have access to information, but will not be lured into a neighborhood of advertising that undercuts the foundations of the doctor-patient relationship.

