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REGULATING DIRECT-TO-CONSUMER ADVERTISING WITH TORT LAW: IS THE LAW FINALLY CATCHING UP WITH THE MARKET?

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ABSTRACT

Should direct-to-consumer advertising of prescription drugs impose any tort duty on the drug manufacturer and advertiser to ensure that the advertisements present a fair picture of the risks and benefits of the drug? Until very recently, the answer of American courts has overwhelmingly been "no." However, recently there has been both a rise in concern over the content and effects of direct-to-consumer advertisements and signs of an emerging trend among courts to consider the possibility that a drug company that chooses to bypass traditional avenues of communication of information about prescription drugs should bear responsibility in tort for the content of its direct communications with consumers. This emerging trend has not yet reached critical mass, however, and in at least one case, the pendulum has arguably swung too far in the opposite direction. This Article will discuss recent developments in the litigation surrounding direct-to-consumer advertising, and suggest avenues of development for tort law in this important area.

The American experiment with product-specific, direct-to-consumer advertising of prescription drugs is, as of this writing, approximately twenty years old.[1] Despite two decades of increasing spending on such advertisements,[2] reviews of this practice are decidedly mixed. Few other industrialized nations permit such adver-

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1. *See* Timothy 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, 451-52 (1993).

2. Spending on direct-to-consumer advertising in 2007 was estimated at $4.8 billion, up three-hundred percent from 1997. Stephanie Saul, *For Jarvik Heart Pioneer, Drug Ads Raise Profile and Questions*, N.Y. TIMES, Feb. 7, 2008, at A1; *see also* Steve Lohr, *Publications on Fitness and Health Head to Web*, N.Y. TIMES, Sept. 17, 2007, at

tisement,[3] and there is little data indicating that the practice of advertising prescription drugs directly to consumers improves health outcomes, enhances the physician-patient relationship, or has any positive effect other than improving sales of pharmaceutical products.[4] Indeed, substantial questions remain about whether direct-to-consumer advertisement as currently practiced violates the first principle of medical ethics, *primum non nocere—first, do no harm*.[5] Critics of direct-to-consumer advertising argue that such advertisements do not present a balanced picture of a drug's risks and benefits; that they undermine the physician-patient relationship; and that they inappropriately drive up demand for drugs that provide larger profit margins, not greater therapeutic benefit.[6] Research has shown that advertised drugs are disproportionately newly approved drugs, which may still be under patent protection and thus offer larger profit margins than other drugs in the same therapeutic class.[7]

In spite of these concerns, there has been little effective regulation of the direct-to-consumer advertising market to date. However, two recent developments suggest that the law may be catching up to the regulatory needs of this market. First, in May 2008 Congress took note of the criticisms of direct-to-consumer advertising

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C1 (stating that Internet "advertising for prescription drugs has increased nearly fivefold in the last four years, to $163 million").

3. *See* Alan Cassels, *Canada May Be Forced to Allow Direct to Consumer Advertising*, 332 BRIT. MED. J. 1469 (2006); Rory Watson, *EU Health Ministers Reject Proposal for Limited Direct to Consumer Advertising*, 326 BRIT. MED. J. 1284 (2003); Erin J. Asher, Comment, *Lesson Learned from New Zealand: Pro-Active Industry Shift Towards Self-Regulation of Direct to Consumer Advertising Will Improve Compliance with FDA*, 16 ALB. L.J. SCI. & TECH. 599, 600 (2006).

4. Kate Pickert, *Do Consumers Understand Drug Ads?*, TIME, May 15, 2008, http://www.time.com/health/article/0,8599,1806946,00.html (reporting that every one-thousand dollars invested in direct-to-consumer advertising results in twenty-four new prescriptions for the advertised drug).

5. *See generally* THOMAS L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (5th ed. 2001) (discussing the ethical basis for the traditional medical precept of: "First, Do No Harm").

6. *See, e.g.*, Stephanie Saul & Alex Berenson, *Lipitor Maker Digs in to Fight Generic Rival*, N.Y. TIMES, Nov. 3, 2007, at A1 (describing drug manufacturer Pfizer's increased use of direct-to-consumer advertisements to counter the market effect of FDA approval of a generic competitor to its flagship cholesterol drug Lipitor); Stephanie Saul, *Sleep Drugs Found Only Mildly Effective, but Wildly Popular*, N.Y. TIMES, Oct. 23, 2007, at F4 (describing reports that, despite advertising claims of increased safety, advertised drugs, in fact, had many of the same problems as competing drugs).

7. *See generally* Julie M. Donohue, Marisa Cevasco & Meredith B. Rosenthal, *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 NEW ENG. J. MED. 673 (2007).

with hearings addressing potential problems with three specific television advertisements for prescription drugs and a legislative proposal to restrict direct-to-consumer advertising.[8] Second, in the last two years, two courts have explicitly focused on the direct-to-consumer advertising market by adopting changes to the tort law governing prescription drugs.[9] This Article will discuss these changes, with an emphasis on the regulatory potential of tort law.

In May 2008, Congressman John Dingell, Chair of the House Energy and Commerce Committee, held hearings to explore issues surrounding direct-to-consumer drug advertising, with particular focus on advertisements for three drugs: Lipitor, Vytorin, and Procrit.[10] The first two of these drugs are designed to lower cholesterol levels and thus prevent heart disease, and the latter is designed to combat anemia in connection with chemotherapy.[11]

The Lipitor advertisement featured heart researcher Robert Jarvik as pitchman for the drug.[12] Criticism of this ad campaign focused on the facts that at the time he was recommending Lipitor to potential consumers, Jarvik was not a licensed physician; that he stated in the advertisement that he himself took the drug, which was not accurate at the time the ads aired; and that a scene in the ad that purported to be Jarvik rowing on a lake was staged with a body double.[13]

Congressman Bart Stupak stated at the hearing that while advertisements for Vytorin were generating five-billion dollars in sales in 2007, studies indicating that Vytorin was no more effective than other, less expensive available treatments were not released by the

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8. *See Direct-to-Consumer Advertising: Marketing, Education, or Deception?: Hearing Before Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 110th Cong. (2008) [hereinafter *Direct-to-Consumer Hearings*].

9. *See* Rimbert v. Eli Lilly & Co., 577 F. Supp. 2d 1174 (D.N.M. 2008); State *ex rel.* Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899 (W. Va. 2007).

10. Alison Bass, *A Dose of Honesty in Prescription Drug Ads*, BOSTON GLOBE, June 2, 2008, at A15. Congressional hearings have also been held on the subject of direct-to-consumer advertisements for medical devices. *See* Barry Meier, *Consumer Ads for Medical Devices Subject of Senate Panel*, N.Y. TIMES, Sept. 17, 2008, at C12. Because the regulatory frameworks for medical devices and prescription drugs are different, this Article will focus exclusively on prescription drugs. However, many of the issues raised herein are paralleled in the market for medical devices.

11. Bass, *supra* note 10, at A15.

12. *See* George J. Annas, *Health Care Reform in America: Beyond Ideology*, 5 IND. HEALTH L. REV. 441 (2008).

13. *Direct-to-Consumer Hearings*, *supra* note 8, at 1-2 (statement of Rep. Bart Stupak, Chairman, Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce), *available at* http://energycommerce.house.gov/Subcommittees/OI-Stupak/050808.OI.hrg.DTC.pdf.

manufacturer.[14] Congressman Stupak also alleged that the advertisements for Procrit intimated possible off-label uses of the drug, the advertising of which is "prohibited by the FDA,"[15] but that the Food and Drug Administration (FDA) did not intervene to stop this inappropriate marketing.[16]

In follow-up letters to pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, Congressmen Stupak and Dingell requested that drug manufacturers commit to six specific steps in order to improve the quality of direct-to-consumer advertisements and reduce the instance of deceptive and misleading advertisements. These were: (1) to follow the American Medical Association's (AMA) guidelines regarding the use of health professionals in direct-to-consumer advertisements; (2) to not market directly to consumers until valid data regarding outcomes are available for a drug; (3) to adopt a two-year moratorium on direct-to-consumer advertisements; (4) to not market off-label uses for products in direct-to-consumer advertisements; (5) to provide a toll-free telephone number for reporting adverse effects of medical products[17] in all direct-to-consumer advertisements; and (6) to include any FDA-mandated "black box" warnings in direct-to-consumer advertisements.[18]

FDA oversight of direct-to-consumer advertisements has been inadequate. In fact, despite the substantial increases in the industry's direct marketing budgets, the pace of warning letters sent by the FDA to pharmaceutical manufacturers questioning the content

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14. *Id.* at 2.

15. *Id.*

16. *Id.*

17. The FDA currently maintains such a reporting service called MedWatch. *See* MedWatch, U.S. Food and Drug Administration, http://www.fda.gov/medwatch (last visited Apr. 15, 2009).

18. Letter from Rep. John D. Dingell, Chairman, H. Comm. on Energy & Commerce, and Rep. Bart Stupak, Chairman, H. Subcomm. on Oversight & Investigation, to William C. Weldon, Chairman & CEO, Johnson & Johnson (May 20, 2008), http://energycommerce.house.gov/Press_110/110-ltr.052008.JohnsonandJohnson.pdf.

A "black box" warning is a warning of known, serious risks associated with a drug's use. These warnings are mandated as part of the drug-approval process for serious risks known at the time of approval. *See* Henry Grabowski & Y. Richard Wang, *Do Faster Food and Drug Administration Drug Reviews Adversely Affect Patient Safety?: An Analysis of the 1992 Prescription Drug User Fee Act*, 51 J. L. & ECON. 377, 384 (2008). These warnings can also be added to a drug's required labeling if risks are discovered after the drug is approved. *See* Sandra H. Johnson, *Polluting Medical Judgment?: False Assumptions in the Pursuit of False Claims Regarding Off-Label Prescribing*, 9 MINN. J. L. SCI. & TECH. 61, 79 n.58 (2008) ("Black box warnings are the most severe warnings the FDA can issue for a drug that is to remain on the market despite newly discovered adverse effects.").

of their ads has dropped dramatically in the last decade.[19] Only 21 such letters were sent in 2006, compared with 142 in 1997.[20] While one could argue that this represents a trend towards more appropriate drug advertisement, the problems with current drug advertisements pointed out in the recent congressional hearings suggest otherwise.[21]

Recently proposed legislation would limit the ability of drug manufacturers to advertise directly to consumers within a certain number of years of the approval of a new drug by the FDA.[22] This issue also became a minor point in the Democratic primaries leading up to the 2008 presidential election.[23] The most recent version of this proposal was introduced in the House of Representatives by Representative Rosa DeLauro of Connecticut.[24] This bill would prohibit direct-to-consumer advertising within three years of FDA approval of a new drug.[25] Exceptions would provide for earlier advertising of a drug if it is determined that such advertising "would have an affirmative value to public health."[26] Additionally, an extension of the ban beyond the initial three years would occur "if . . . the drug . . . has significant adverse health effects based on post-approval studies, risk-benefit analyses, adverse event reports, the scientific literature, any clinical or observational studies, or any other appropriate resource."[27] The proposal would also require any direct-to-consumer advertising to contain "a fair balance . . . of the benefits and the risks associated with the drug."[28]

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19. Donahue, Cevasco & Rosenthal, *supra* note 7, at 676-77.

20. *Id.*

21. *See* Letter from Rep. John D. Dingell, Chairman, H. Comm. on Energy & Commerce, & Bart Stupak, Chairman, H. Subcomm. on Oversight & Investigation, to Hon. W.J. Tauzin, President & CEO, Pharm. Research & Mfrs. of Am. (May 20, 2008), http://energycommerce.house.gov/Press_110/110-ltr.052008.PRMA.pdf (stating that the Committee "did not obtain adequate assurances that [drug manufacturers] would reduce misleading and deceptive DTC advertisements").

22. *See* Responsibility in Drug and Device Advertising Act of 2008, H.R. 6151, 110th Cong. (2008).

23. *See Edwards Unveils Plan to Control Drug Advertising*, REUTERS, Oct. 28, 2007, http://www.reuters.com/article/latestCrisis/idUSN28439707.

24. *See* Responsibility in Drug and Device Advertising Act of 2008. Previous legislative proposals have suggested a two-year moratorium. They have also attempted to use the tax system to disincentivize direct-to-consumer advertisements by denying deductions for advertisements that fail to present the risks of the drug or occur within two years of the drug's approval. *See* Fair Balance Prescription Drug Advertisement Act of 2007, H.R. 2823, 110th Cong. (2007).

25. *See* Responsibility in Drug and Device Advertising Act § 2(a)(2).

26. *Id.*

27. *Id.*

28. *Id.*

For those who believe that the costs of direct-to-consumer advertising outweigh the benefits, the current state of affairs seems grim. Spending on this advertising, while still dwarfed by expenditures on other forms of drug promotion, is rising rapidly, and, according to recent research, is effective in promoting—perhaps overpromoting—use of the advertised drugs.[29] The drugs chosen for direct-to-consumer advertisements seem to be chosen not according to the likely benefit to the potential patients, but according to the need to promote newly approved drugs, which may themselves have unknown or unclear risk profiles compared to others on the market.[30] Despite these factors, there has been significantly less enforcement of such advertising by the regulatory agencies in the past decade.[31] Additionally, proposals for more strict regulation, such as bans on advertisements during the first years of a drug's approval,[32] are of questionable constitutionality.[33] What, if anything, can be done to minimize future abuses of American drug manufacturers' privilege to communicate directly with potential consumers of their drugs?

This Article argues that the answer is found in the application of tort law to direct-to-consumer advertising. However, in order to achieve meaningful regulation of direct-to-consumer advertising through tort law, the courts must be convinced to substantially alter the application of the so-called "learned intermediary rule,"[34] which, as currently applied by the majority of courts, prevents virtually all failure-to-warn suits by consumers against pharmaceutical manufacturers. This Article will briefly discuss the learned intermediary rule in the context of pharmaceutical failure-to-warn liability, and will set forth a proposed change to the application of the rule that would enable consumers of prescription drugs to hold drug

29. *See supra* note 4 and accompanying text.

30. *See supra* text accompanying note 7.

31. *See supra* notes 19-20 and accompanying text.

32. *See supra* notes 24-28 and accompanying text.

33. Substantial questions exist as to whether any ban on direct-to-consumer advertisements would be enforceable given current commercial speech doctrine under the First Amendment. *See, e.g.*, Miriam Shuchman, *Drug Risks and Free Speech—Can Congress Ban Consumer Drug Ads?*, 356 NEW ENG. J. MED. 2236 (2007).

34. The learned intermediary rule allows manufacturers to rely on the skill and expertise of an intermediary to furnish appropriate warnings to the consumer of the product. In the case of prescription drugs, "[t]he obligation of a manufacturer to warn about risks attendant to the use of drugs and medical devices that may be sold only pursuant to a health care provider's prescription traditionally has required warnings directed to health care providers and not to patients." RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. b (1997).

manufacturers liable for deceptive advertising in appropriate circumstances.

The current regulatory system is ineffective to ensure a safe and efficient flow of information about drugs to the potential consumers of those drugs. Policymakers face two fundamental options if the status quo is inadequate: either ban the practice of direct-to-consumer advertising altogether or further regulate the practice. A total ban on direct-to-consumer advertising is suboptimal for two reasons. First, as several commentators have suggested, the First Amendment may operate to protect the type of speech in which pharmaceutical manufacturers are engaged.[35] Second, a ban ignores the substantial potential benefits of an increased flow of information to consumers of prescription drugs.[36] For these reasons, improved regulation of direct-to-consumer advertisement is a superior alternative to an outright ban on the practice.

However, the remaining question is how to implement effective regulation. The most recent legislative proposal has been for a temporal ban on direct-to-consumer advertisement. This proposal would ban direct advertisement of a prescription drug within two years of FDA approval.[37] It has the benefit of addressing the perverse incentive in the direct-to-consumer advertising market regarding which drugs get advertised. Generally, the tendency has been for advertisements to disproportionately feature drugs that either generate higher revenue for the manufacturer—drugs that have been recently approved are more likely to enjoy patent protection, and correspondingly higher profit margins[38]—or drugs that

35. Shuchman, *supra* note 33, at 2238.

36. *See* Jaclyn Carole Hill, *The Learned Intermediary Doctrine and Beyond: Exploring Direct-to-Consumer Drug Advertising in the New Millennium*, 72 DEF. COUNS. J. 362, 376 (2005) ("[T]he public should ultimately realize that the greater good of the community is served by allowing for the advertisement of prescription drugs."); *see also* Jennifer Girod, Note, *The Learned Intermediary Doctrine: An Efficient Protection for Patients Past and Present*, 40 IND. L. REV. 397 (2007); Corey Schaecher, Comment, *Ask Your Doctor if This Product is Right for You*, 26 ST. LOUIS U. PUB. L. REV. 421 (2007).

37. *See supra* notes 24-28 and accompanying text.

38. *See, e.g.*, Jessie Cheng, Note, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471, 1472 (2008) ("In the prescription drug market, a patent holder—usually the brand name drug manufacturer that developed the pioneer drug, like Eli Lilly—has time-limited, exclusive rights to market its patented drug, allowing it to realize hefty profits. Upon the patent's expiration . . . market competition replaces the previously lawful monopoly: Manufacturers of generic drugs (generic manufacturers) enter the market, and the incumbent brand name manufacturer may face a steep drop in profits and market share." (footnotes omitted)).

are attempting to tap into new markets for which no competing treatments exist.[39]

Two main critiques of direct-to-consumer advertising arise from these practices. The first critique is that direct-to-consumer advertisements tend to overmedicalize conditions previously considered within the range of "normal" human experience.[40] This increases drug sales, but also has the effect of driving up the cost of health care and diverting health care resources from more serious health issues. The second critique stems from the fact that new drugs often have incomplete safety data despite their FDA approval. Thus, direct advertisement may lead to overuse of these products by misrepresenting the risk-benefit calculation versus other treatment options in the marketplace.[41]

Given these perverse incentives, the proposal to temporally restrict direct-to-consumer advertisements has some appeal. However, this proposal has not yet been successful in Congress, and there are commentators who argue that such restrictions would run afoul of the constitutional protection given to commercial speech.[42] Even if such legislative proposals were adopted and found to be constitutional in inevitable court challenges, such a ban would not address remaining issues such as off-label promotions and general overpromotion of the benefits versus harms of a drug. Moreover,

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39. For example, the diagnosis of "restless leg syndrome" has been challenged as being driven in part by drug companies' desire to promote pharmaceutical treatment for this condition. *See, e.g.*, Steven Woloshin & Lisa M. Schwartz, *Giving Legs to Restless Legs: A Case Study of How the Media Helps Make People Sick*, 3 PLoS MED. 452 (2006), http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0030170.

40. *See generally id.* and other "disease-mongering" articles in that symposium.

41. An example of this phenomenon is the marketing and subsequent withdrawal from market of the pain drug Vioxx, which was widely prescribed despite, as later data showed, its greater risk of cardiac side effects and lack of greater efficacy than other pain drugs then on the market. The marketing withdrawal and litigation surrounding Vioxx has been widely discussed. *See, e.g.*, David R. Culp & Isobel M. Berry, *Merck and the Vioxx Debacle: Deadly Loyalty*, 22 ST. JOHN'S J. LEGAL COMMENT. 1 (2007); Richard A. Epstein, *Regulatory Paternalism in the Market for Drugs: Lessons from Vioxx and Celebrex*, 5 YALE J. HEALTH POL'Y L. & ETHICS 741 (2005); Margaret Gilhooley, *Vioxx's History and the Need for Better Procedures and Better Testing*, 37 SETON HALL L. REV. 941 (2007); Ronald M. Green, *Direct-to-Consumer Advertising and Pharmaceutical Ethics: The Case of Vioxx*, 35 HOFSTRA L. REV. 749 (2006); Jennifer Wolsing, *The Vioxx Litigation: Disincentivizing Patient Safety Through Misdirected Tort Rules*, 75 DEF. COUNS. J. 209 (2008).

42. *See, e.g.*, Lars Noah, *The Little Agency That Could (Act with Indifference to Constitutional and Statutory Strictures)*, 93 CORNELL L. REV. 901 (2008); Mark I. Schwartz, *To Ban or Not to Ban—That is the Question: The Constitutionality of a Moratorium on Consumer Drug Advertising*, 63 FOOD & DRUG L.J. 1 (2008).

in the absence of a private enforcement mechanism, it is by no means clear that the FDA has either the resources or the inclination to adequately police any new restrictions on direct-to-consumer advertisements.

I have in the past proposed, and continue to advocate for, a solution that requires no legislative action and thus bypasses the current legislative gridlock on this issue.[43] I propose that common law tort doctrine embrace its regulatory potential in the context of direct-to-consumer advertisements. To date, the majority of courts addressing the issue have been unwilling to impose tort liability for harms arising from direct-to-consumer advertisements, due in large part to a historic failure to adapt common law doctrine to the needs of the current marketplace for pharmaceutical products.[44] However, in 2007 and 2008, gaps have appeared in the wall of protection surrounding drug manufacturers.

The most important legal doctrine governing liability of prescription drug manufacturers to the ultimate users of their products is the learned intermediary rule.[45] Products liability law generally holds the manufacturer of a defective product liable to an end user harmed through the use of the product.[46] In the prescription drug context, the defective nature of the product is generally not a manufacturing defect, but rather a lack of an appropriate warning about the relative risks and benefits of the product.[47] By their very nature, prescription drugs can present a danger of harm to the user even when used properly.[48] As inherently dangerous products, prescription drugs do not generate liability for harms caused by the proper use of the product, so long as they are accompanied by adequate warnings and instructions.[49] The provision of such warnings

43. *See* Timothy S. Hall, *Reimagining the Learned Intermediary Rule for the New Pharmaceutical Marketplace*, 35 SETON HALL L. REV. 193 (2004).

44. *See generally id.* (providing a complete account of changes in the pharmaceutical marketplace, including, but not limited to, the rise of direct-to-consumer advertising and the implications for tort law).

45. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. b (1997); *see supra* note 34 and accompanying text.

46. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 1 ("One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect.").

47. *Id.* § 6(b)(3) cmt. a ("Until recently, courts refused to impose liability based on defective designs of drugs . . . sold only by prescription.").

48. *Id.* § 6(b)(3) cmt. b; RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1984).

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

and instructions shifts the risk from the manufacturer of the product to the user who freely chose to use the product.[50]

In the vast majority of non-pharmaceutical settings, manufacturers must deliver warnings and instructions to the end user of a product in order to be legally protected.[51] However, because prescription drugs are not ordinarily available directly to patients, but are only available through the intervention of a licensed physician as a gatekeeper, courts have traditionally held that the necessary warnings must be given to the prescribing physician and not to the end user of the drug.[52] Therefore, the provision of adequate warnings to the physician is a defense to a products liability claim brought against the manufacturer by a patient harmed by the drug.[53] This is the learned intermediary rule, and it acknowledges that, unlike most other products, the decision whether to use a prescription drug is not made solely by the patient, but rather is made in conjunction with and after consultation with a physician upon whose education and training a patient relies to make a decision when selecting an appropriate drug.[54] Because pharmacology is such a complex field, the patient is not considered capable of understanding the drug's warnings and instructions or making rational decisions based on the benefits and risks of the drug without the intervention of a physician.[55]

The learned intermediary rule makes sense for a certain vision of the physician-patient relationship.[56] However, as described in more detail elsewhere,[57] the modern doctor-patient relationship often deviates from that ideal in what should be legally significant ways. Except to a very limited extent, the law has not recognized these changes in the health care marketplace. These changes include, in addition to the proliferation of direct-to-consumer adver-

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50. As one recent commentator put it, provision of effective warnings "recast[ ] the user as the least-cost-avoider of injury." *See* Victor E. Schwartz & Christopher E. Appel, *Effective Communication of Warnings in the Workplace: Avoiding Injuries in Working with Industrial Materials*, 73 MO. L. REV. 1 (2008).

51. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(c) cmt. i ("[D]epending on the circumstances, Subsection c may require that instructions and warning be given *not only to purchasers, users and consumers*, but also to others who a reasonable seller should know will be in a position to reduce or avoid the risk of harm." (emphasis added)).

52. *Id.* § 6.

53. *Id.*

54. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1984).

55. Hall, *supra* note 43, at 202-03.

56. *Id.* at 195-96.

57. *Id.*

tising over the last twenty years, the following: (1) increased emphasis on the patient as ultimate decision-maker in the health care context, as opposed to more traditionally authoritative models of the physician-patient relationship;[58] (2) massive investment by the pharmaceutical industry in research and development of new drug therapies;[59] (3) an increased emphasis within the pharmaceutical industry on so-called "lifestyle" drugs;[60] and (4) increased availability of prescription drugs through nontraditional and often illegal outlets, including Internet pharmacies and importation from other countries.[61] Although all of these changes suggest that the learned intermediary rule has been outstripped by market developments, this Article focuses on the effect of direct-to-consumer advertisements.

The law permits drug companies to communicate directly with patients, thus generating demand for the advertised drugs, but it insulates them from liability to those same patients based upon those communications. Therefore, the law currently sets up a significant market distortion that overincentivizes expenditure on direct-to-consumer advertisements.

In 1999, just as the pharmaceutical industry's investments in direct-to-consumer advertisements were skyrocketing,[62] one court took note of the effect of direct-to-consumer advertising on the physician-patient relationship and the learned intermediary rule. In *Perez v. Wyeth Laboratories Inc.*, the Supreme Court of New Jersey held that direct advertisement of Norplant, an implantable long-term contraceptive drug, prevented the application of the learned intermediary rule to the plaintiff's claim as a matter of New Jersey law.[63] In limiting the application of the learned intermediary rule, the court relied explicitly on the intentional act of the drug manu-

58. *Id.* at 226-28.

59. *Id.* at 228.

60. *Id.* at 229-30. The term "lifestyle drug" refers to therapies developed or marketed for cosmetic or functional enhancement rather than for the treatment of a disease as that term is traditionally interpreted. *See generally* Kim H. Finley, Comment, *Life, Liberty, and the Pursuit of Viagra?: Demand for "Lifestyle" Drugs Raises Legal and Public Policy Issues*, 28 CAP. U. L. REV. 837 (2000). Classes of drugs deemed "lifestyle drugs" by the Medicaid program "include weight loss, weight gain, infertility, drugs for cosmetic purposes or hair growth, drugs for symptomatic relief of coughs and colds, smoking cessation products, and vitamins and minerals." Joshua Parsons Cohen et al., *Role of Budget Impact in Drug Reimbursement Decisions*, 33 J. HEALTH POL. POL'Y & L. 225, 233 (2008) (citation omitted).

61. Hall, *supra* note 43, at 230-31.

62. *See supra* notes 1-2 and accompanying text.

63. Perez v. Wyeth Laboratories Inc., 734 A.2d 1245, 1256 (N.J. 1999).

facturer in "seek[ing] to influence a patient's choice" through "direct claims to consumers for the efficacy of its product" as a justification for imposition of a duty to warn the drug consumer of the risks attendant upon use of the drug, rather than merely warning the prescribing physician.[64]

After *Perez*, commentators opined that other courts would follow the lead of New Jersey in limiting the protection of the learned intermediary rule for drug manufacturers who engage in direct-to-consumer marketing.[65] However, for almost a decade after the *Perez* case, despite invitations by litigants to extend *Perez* to other jurisdictions, no other court chose to follow *Perez*'s lead. That state of affairs may now be changing.

In the past two years, two more courts have explicitly declined to extend the protection of the learned intermediary rule to prescription drug manufacturers, citing, *inter alia*, the prevalence of direct-to-consumer advertising to justify their holdings. First, in the case of *Johnson & Johnson Corp. v. Karl*,[66] the Supreme Court of Appeals of West Virginia, after a thorough discussion of the direct-to-consumer advertising market[67] and an analysis of the adoption of the learned intermediary rule in other American jurisdictions,[68] concluded that the "justifications for the learned intermediary doctrine [are] largely outdated and unpersuasive."[69] It declined to adopt the rule as part of the common law of tort in West Virginia.[70]

In *Karl*, the plaintiff's decedent was prescribed Propulsid, a drug manufactured by Janssen Pharmaceutica, Inc.[71] Unfortunately, she died three days after taking the drug.[72] Plaintiff sued both the prescribing physician and the drug manufacturer under products liability and medical negligence theories of liability.[73] Janssen moved for summary judgment on the grounds of the learned intermediary doctrine, but the trial court denied this motion because the learned intermediary rule had not been explicitly

64. *Id.* at 1247.
65. *Id.*
66. Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899 (W. Va. 2007).
67. *Id.* at 907-09.
68. *Id.* at 903-05.
69. *Id.* at 906.
70. *Id.* at 901.
71. *Id.*
72. *Id.*
73. *Id.*

adopted by the West Virginia's highest court.[74] The lower court also denied a motion *in limine* to exclude certain evidence relating to the question of whether the manufacturer had a duty to directly warn the consumer of the drug's dangers.[75] Janssen appealed both of these rulings to West Virginia's Supreme Court by filing a petition for a writ of prohibition,[76] which the court denied.[77]

In denying the writ of prohibition and allowing the lower court's orders to stand, the West Virginia court relied on two main arguments. First, the court articulated a different calculation as to how many jurisdictions have in fact adopted the learned intermediary rule. Unlike the court in *In re Norplant*, which calculated that the doctrine has been adopted in forty-eight states,[78] or the court in *Larkin v. Pfizer, Inc.*, which concluded that thirty-four states have adopted the rule,[79] the *Karl* court, using a somewhat more restrictive methodology, concluded that only twenty-two states have definitively adopted the rule—twenty-one by judicial adoption and one by statute.[80] The *Karl* court reached this result by looking only to binding pronouncements by the highest court in each state, and did not include lower court decisions as the other opinions had.[81] Thus, the *Karl* court viewed the learned intermediary rule as a doctrine on which the states are split roughly down the middle, rather than the virtual unanimity that prevails in other courts' views.

Second, the *Karl* court gave special consideration to changes in the pharmaceutical marketplace and the physician-patient relationship since the rule was first articulated and widely adopted. The court concluded that two changes in particular merit rejection of the rule: "the initiation and intense proliferation of direct-to-consumer advertising, along with its impact on the physician-patient relationship, and the development of the internet as a common method of dispensing and obtaining prescription drug information."[82] The court noted that these "[s]ignificant changes in the

74. *Id.* In the past, several federal courts had predicted that West Virginia would, in fact, adopt the learned intermediary rule, should the question be presented.

75. *Id.*

76. *Id.*

77. *Id.*

78. *In re* Norplant Contraceptive Prods. Liab. Litig., 215 F. Supp. 2d 795, 806 (E.D. Tex. 2002).

79. Larkin v. Pfizer, Inc., 153 S.W.3d 758, 768 (Ky. 2004).

80. *Karl*, 647 S.E.2d at 903-04. The one state adopting the rule by statute is North Carolina. *See* N.C. GEN. STAT. § 99B-5(c) (2007).

81. *Karl*, 647 S.E.2d at 903-04.

82. *Id.* at 907.

drug industry have post-dated the adoption of the learned intermediary doctrine"[83] and specifically noted that "[s]ince the 1997 proliferation of [direct-to-consumer] advertising, only four high courts have adopted the learned intermediary doctrine."[84] Furthermore, those four courts failed to give "thorough consideration to . . . direct-to-consumer advertising"[85] when deciding to adopt the rule.

Interestingly, there is no mention in the *Karl* opinion of a claim by the plaintiff that the decedent saw, relied upon, or was unduly influenced by direct-to-consumer advertising. Although the attorney for the plaintiff argued in the brief that the existence of direct-to-consumer advertising for Propulsid should justify an exception to the learned intermediary rule,[86] the brief contains no allegation that the decedent relied on, or even saw, that advertising in the course of being prescribed and taking the medication that allegedly caused her death.

After *Karl*, one other court has expressly declined to adopt the learned intermediary rule, although in a different context and for different reasons. In *Rimbert v. Eli Lilly & Co.*,[87] the Federal District Court for the District of New Mexico refused to certify the question of whether New Mexico would adopt the learned intermediary rule as a matter of state tort law, and instead predicted that the Supreme Court of New Mexico would not adopt the rule. Although the *Rimbert* case does not include claims relating to direct-to-consumer advertising, the court discussed the *Karl* opinion in reaching its decision.[88] The *Rimbert* court relied more strongly on its interpretation of the New Mexico courts' strict liability jurisprudence, concluding that "the learned-intermediary doctrine . . . is fundamentally inconsistent with New Mexico's strict-liability jurisprudence."[89] The *Rimbert* court reasoned that since the learned intermediary rule insulates the drug manufacturer from liability, it necessarily shifts that liability onto the physician, undermining the goal of strict liability, which is "to ensure that the risk of loss for

83. *Id.*

84. *Id.* at 908-09.

85. *Id.* at 909; *see also* Vitanza v. Upjohn Co., 778 A.2d 829 (Conn. 2001); McCombs v. Synthes, 587 S.E.2d 594 (Ga. 2003); Larkin v. Pfizer, Inc., 153 S.W.3d 758 (Ky. 2004); Freeman v. Hoffman-La Roche, Inc., 618 N.W.2d 827 (Neb. 2000).

86. Brief of Respondent at 26-27, Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899 (W. Va. 2006) (No. 33211).

87. Rimbert v. Eli Lilly & Co., 577 F. Supp. 2d 1174 (D.N.M. 2008).

88. *Id.* at 1193-94.

89. *Id.* at 1215.

injury resulting from defective products is borne by the suppliers."[90]

Despite the *Karl* and *Rimbert* opinions, not all recent learned intermediary rule decisions have taken the side of restricting the application of the rule. In 2004, the Supreme Court of Kentucky, in *Larkin v. Pfizer, Inc.*, adopted the rule for the Commonwealth of Kentucky.[91] The court did so over the dissent of Justice Wintersheimer, who urged the court to take more account of changes in the medical marketplace, such as the rise of direct-to-consumer advertising.[92] Similarly, in *Porter v. Eli Lilly & Co.*,[93] the District Court for the Northern District of Georgia rejected a plaintiff's claim that Georgia courts would "reject the learned intermediary doctrine and require direct warnings to consumers" based on its reading of recent Georgia jurisprudence in this area.[94]

Some recent learned intermediary rule cases are more ambiguous. The United States District Court for the District of South Dakota denied a plaintiff's motion to compel discovery related to direct-to-consumer advertising in a drug-related product liability action. In *Schilf v. Eli Lilly & Co.*,[95] the court used two avenues of reasoning to reject a tort plaintiff's request for information on the defendant's direct marketing practices as part of its discovery. First, the court accepted the defendant's arguments that the state of South Dakota had already adopted the learned intermediary doctrine, so this evidence would not be relevant to a claim or defense in the case.[96] Second, the court noted that "[p]laintiffs are not factually positioned to persuasively argue that Lilly's direct marketing efforts rendered the prescribing doctor less important in choosing [the drug for plaintiff] to use, i.e. that the learned intermediary was not the person who selected" the treatment.[97]

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90. *Id.* at 1215, 1217 ("Allowing drug manufacturers to shift the burden of defective product to physicians would undermine the Supreme Court of New Mexico's conclusion that the burden should be on the manufacturer . . . ."). It is a weakness of the district court's reasoning that none of the cases on which it relies for its view of New Mexico's strict liability jurisprudence are pharmaceutical liability cases.

91. Larkin v. Pfizer, Inc., 153 S.W.3d 758, 770 (Ky. 2004).

92. *Id.* at 770-71 (Wintersheimer, J., dissenting).

93. Porter v. Eli Lilly & Co., No. 1:06-CV-1297-JOF, 2008 WL 544739 (N.D. Ga. 2008).

94. *Id.* at *8-9.

95. Schilf v. Eli Lilly & Co., No. CIV 07-4015, 2008 WL 4442557 (D.S.D. 2008).

96. *Id.* at *1.

97. *Id.* Although the thesis of this Article is that courts should consider direct-to-consumer advertising relevant to the learned intermediary rule, if the *Schilf* court is correct that the plaintiff's "use of Cymbalta was not directly or indirectly related to

In *Mendez Montes de Oca v. Adventis Pharma*, the District Court for the District of Puerto Rico considered the learned intermediary rule in the context of the plaintiff's allegations regarding direct-to-consumer advertising.[98] The court held that the learned intermediary rule barred plaintiff's claim that defendant's synthetic insulin caused the decedent's cancer and subsequent death.[99] However, a close reading of this case calls into question exactly what the court intended to hold with regard to direct-to-consumer advertising and the learned intermediary rule. While the court stated that no case since *Perez* had applied a direct-to-consumer exception to the rule,[100] the court also stated that "plaintiffs have failed to explain why the circumstances surrounding this particular product should trump the reasons for the rule."[101] Thus, it is a reasonable reading of the case that, although the court may be amenable to articulating a direct-to-consumer advertising exception in an appropriate case, the plaintiff in *Mendez* simply failed to make an adequate showing to justify such a departure from traditional doctrine.[102] This is buttressed by the court's conclusion that mere allegations "that defendant conducted direct to consumer advertising. . . . without more, is not sufficient to defeat defendant's learned intermediary defense."[103]

There has been more doctrinal movement in the last two years on this issue than in the previous six post-*Perez* years. While the ultimate doctrinal outcome is still in doubt, the courts should continue this trend, as a matter of common law tort doctrine, to modify the learned intermediary rule to allow the tort system to perform its traditional regulatory function in the context of prescription drug advertising. However, the courts should not, as West Virginia has done, throw out the baby with the bathwater. The *Karl* court, while it should be commended for its detailed attention to the changes in the health care marketplace over the last decade, went too far. It went even further than the New Jersey court in *Perez*, which was

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Lilly's direct marketing efforts," then the substantive outcome of this motion seems correct. *Id.*

98. Mendez Montes de Oca v. Adventis Pharma, 579 F. Supp. 2d 222 (D.P.R. 2008).

99. *Id.* at 223.

100. *Id.* at 228-29. The court did not cite or discuss *Karl*.

101. *Id.* at 229.

102. *Id.* at 230 ("Even assuming . . . the direct to consumer advertising exception, the record in this case is devoid of any evidence intimating that decedent even saw informational material regarding [the drug] prior to his visit" to his physician.).

103. *Id.*

the first to articulate the relationship between direct-to-consumer advertising and the learned intermediary rule. *Perez* held, in pertinent part, that

> when mass marketing of prescription drugs seeks to influence a patient's choice of drug, a pharmaceutical manufacturer that makes direct claims to consumers for the efficacy of its products should not be *unqualifiedly* relieved of a duty to provide proper warnings of the dangers or side effects of the product.[104]

This is a more nuanced approach to direct-to-consumer advertising than the *Karl* court's wholesale rejection of the learned intermediary doctrine. It recognizes that the existence of direct-to-consumer advertising in a particular case should be grounds for an exception to the learned intermediary rule, not grounds for rejection of the rule altogether. In that respect, the courts in *Schilf* and *Mendez*, while they did not ultimately adopt a direct-to-consumer advertising exception, seem to be on the right track in what they implicitly require of plaintiffs to justify future adoption of such an exception.

As I have previously argued, the courts should alter the application of the learned intermediary rule to parallel the related but distinct "sophisticated user doctrine."[105] Like the learned intermediary rule, the sophisticated user doctrine is applied in situations where warnings are given to an entity other than the end user of a product.[106] Unlike the learned intermediary rule, however, the sophisticated user doctrine explicitly allows the court to analyze whether, in the context of a particular case, the decision to rely solely on a third-party intermediary to convey warnings to the end user was justifiable, thus shielding the defendant manufacturer from liability to the end user.[107]

The main difficulty with the traditional application of the learned intermediary rule to cases involving direct-to-consumer advertising is that the rule does not permit an individualized determination of whether the so-called intermediary is actually performing the purported function that the law ascribed to her.[108] The classic formulation of the learned intermediary rule explicitly forecloses, in

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104. Perez v. Wyeth Laboratories. Inc., 734 A.2d 1245, 1247 (N.J. 1999) (emphasis added).

105. Hall, *supra* note 43, at 239-44.

106. *Id.* at 242.

107. *Id.* at 242-44.

108. *Id.* at 225.

exchange for judicial efficiency and ease of operation,[109] an inquiry into the role of non-intermediary sources of information, including express attempts by the manufacturer to bypass the role of the intermediary and provide information directly to the potential consumer.[110]

Direct-to-consumer advertising is by definition advertising; in other words, it is not designed solely to convey information but to persuade. The effectiveness of this persuasion is evident by the return on investment of the manufacturers' direct advertising expenditures.[111] If the practice of communicating directly with consumers was not efficient, profit-maximizing manufacturers would not engage in it. This is not to say that all direct-to-consumer advertising oversteps appropriate boundaries. Yet, the continuing concern by Congress and consumer advocates over the content of many such ads,[112] combined with demonstrably lax exercise of extant regulatory authority by the FDA,[113] shows that additional oversight is needed.

A tort regime that allows courts to inquire whether the marketing practices of drug manufacturers in fact undermine the role of the physician as gatekeeper to prescription drugs would at least in part cure the market distortions introduced and perpetuated by the current tort system. It would reintroduce a disincentive to oversell the potential benefits of advertised drugs. The learned intermediary rule should be revised to permit plaintiffs to prove that, in the factual context of any given case, a manufacturer's marketing practices unduly influenced the decision to seek and use a drug, thus resulting in harm. This will help ensure that the cost of harms are borne by the party bearing responsibility for that harm, while preserving the concept of the physician as the primary, and most desirable, source for information about prescription drugs and other treatment options.

First, the law should recognize that drug companies owe drug consumers a duty to present an accurate and balanced picture of the risks and benefits associated with a drug once the companies

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109. Girod, *supra* note 36, at 399-406.

110. Hall, *supra* note 43, at 245-48.

111. *See supra* note 4 and accompanying text. It has been suggested that a two-year moratorium on direct-to-consumer advertisements could cost the drug industry ten billion dollars in sales. *See* Aaron Smith, *Banning Drug Ads Could Cost $10B*, CNN MONEY.COM, Aug. 1, 2005, http://money.cnn.com/2005/08/01/news/fortune500/directconsumer/index.htm.

112. *See supra* notes 10-16 and accompanying text.

113. *See supra* notes 19-20 and accompanying text.

make the choice to step beyond the traditional bounds of the physician-patient relationship and communicate directly with the consumer via direct-to-consumer advertisements. Second, the law should recognize that this duty is breached when a company's direct marketing practices overemphasize benefit over risk or engage in other forms of overpromotion of the advertised drug. Third, such overpromotion should be acknowledged to cause legally cognizable damages when it can be shown that, but for the overpromotional activities of the manufacturer, the patient would not have used the drug. This proof could take the form of a showing that the patient was induced to obtain the drug outside normal physician-patient channels, such as through an Internet pharmacy that requires no meaningful physician interaction to generate a prescription; that the patient acted against medical advice in taking the drug; or that the patient engaged in doctor-shopping to obtain the drug in response to the manufacturer's promotional message. In any case, the mere presence of a licensed physician in the chain of distribution should no longer in and of itself dispose of the plaintiff's claim.

This revision of the learned intermediary rule would not constitute a radical expansion of tort law or require a wholesale rejection of the learned intermediary rule in the vast majority of cases. It would merely bring the law governing the duty to warn, in the pharmaceutical context, in line with the duty to warn in other areas where a third-party intermediary is in a position to convey warnings to the ultimate users of a product.[114] The drug manufacturer would benefit from a presumption that the traditional doctor-patient relationship ensures that the consumption of dangerous drugs is undertaken only after an educated, informed consideration of risks and benefits.[115] However, unlike the current rule, that presumption should no longer be irrebuttable.

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114. *See, e.g.*, Timothy S. Hall, *Reimagining the Learned Intermediary Rule for the New Pharmaceutical Marketplace*, 35 SETON HALL L. REV. 193, 221-23 (2004) (describing the "sophisticated user doctrine" under which warnings to third parties are, under certain circumstances, sufficient to discharge the duty to warn); 3 AMERICAN LAW OF PRODUCTS LIABILITY §33:16, at 30 (3d rev. ed. 2006) (A "supplier's duty to warn is discharged by providing information to third parties whom it can reasonably expect will communicate the information to the ultimate users.").

115. *See, e.g.*, *In re* Norplant Contraceptive Prods. Liab. Litig., 165 F.3d 374, 379 (5th Cir. 1999). In that case the court, while adopting the learned intermediary rule to shield the manufacturer from liability, stated that even if the learned intermediary doctrine did not apply in cases involving direct-to-consumer advertising, no liability would attach if the plaintiff were not in fact exposed to, or did not rely on, the marketing claims of the manufacturer.

CONCLUSION

Many of the characteristics of the current market for direct-to-consumer advertisements are the result of an unequal set of incentives for drug manufacturers. Virtually all of the market incentives are pro-advertisement, and there is a notable lack of incentives either to advertise with the best interest of patients in mind, or to be conservative in avoiding deceptive or misleading advertisements. Recent developments show that voluntary advertising guidelines are not effective in preventing deceptive or misleading advertising practices. Further, under the failure-to-warn tort doctrine, as currently interpreted and applied, tort law is unable to act as an effective deterrent against irresponsible behavior.

In the past two years, courts have shown a new willingness to consider claims that direct-to-consumer advertising undermines the rationale for the learned intermediary rule.[116] State courts presented with the learned intermediary rule as a doctrine of first impression should follow the lead of the Supreme Court of Appeals of West Virginia in *Karl* and carefully consider whether the extent of direct-to-consumer advertising justifies amendment, if not abrogation, of the rule in the context of claims in which plaintiffs claim reliance on overreaching advertisement and overpromotion.[117] Federal courts applying state law should be reticent to assume that state courts would not take notice of the dramatically changed marketplace for information about prescription drugs in considering the contours of the learned intermediary rule. Finally, even in states where the learned intermediary doctrine has been adopted, plaintiffs' lawyers should make good faith arguments for the modification of this doctrine in light of the increasing prevalence of, and issues surrounding, direct-to-consumer advertising. In this way, hopefully the common law will evolve an approach to pharmaceutical products liability litigation that reflects the complexity of the pharmaceutical marketplace.

116. *See supra* notes 62-89 and accompanying text.

117. *See generally* Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899 (W. Va. 2007).