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LIABILITY FOR DIRECT ADVERTISING OF DRUGS TO CONSUMERS: AN IDEA WHOSE TIME HAS NOT COME

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It's a puzzlement: If anyone had taken a poll of product liability cognoscenti a decade ago as to whether the learned intermediary rule would survive in the face of the onslaught of massive advertising of drugs in the media, the overwhelming majority would have answered in the negative. The well entrenched doctrine requires that a pharmaceutical manufacturer provide warnings of risks attendant to ingesting a prescription drug to the physician only and *not* to the patient.¹ The principal rationale for the learned intermediary rule is that information concerning risks should be delivered to the physician who is tutored in the science of understanding risk and evaluating risk contextually.² The physician is then charged with the responsibility of picking and choosing among the multitude of risks posed by a drug and then deciding how the risk information is to be communicated to the patient. The basis for the rule is seriously undercut when drugs such as Lipitor, Rogaine, Viagra, and Celebrex are huckstered to the public as if they were M&M candies. If one advertises directly to patients seeking to entice them to urge their physicians to prescribe a drug then one should have a concomitant duty to directly warn the patient of risks associated

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1. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB., § 6(d)(1) (1998) [hereinafter RESTATEMENT]; DAN B. DOBBS, THE LAW OF TORTS § 365 (2000); DAVID G. OWEN, THE LAW OF PRODUCTS LIABILITY § 9.6 (2005).

2. RESTATEMENT, *supra* note 1, at § 6 cmt. b. Other rationales have been used to support the rule. See, e.g., *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245, 1255 (N.J. 1999) (identifying four theoretical bases for the learned intermediary rule: (1) reluctance to interfere with the doctor-patient relationship; (2) physicians are in a superior position to convey information to patients; (3) lack of effective means to communicate directly with patients; and (4) inability of patients to comprehend complex drug warnings).

with their use.³ Pharmaceutical manufacturers should not be able to bypass physicians by marketing directly to consumers and then hide behind the façade of physician expertise to immunize themselves from liability.

When Professor Henderson and I faced this issue in drafting the Products Liability Restatement in 1994, we took the position that for prescription drugs advertised in the media, drug manufacturers forfeited their “learned intermediary” immunity.⁴ Only when the American Law Institute Council cautioned us about taking this position without support in the case law did we then back down. Instead of a firm black letter rule, we drafted language stating the opposing views on the subject and relegated the issue to developing case law.⁵ But, in my heart, I was certain that our evasive language would have a short shelf life. The case law would in quick order vindicate our original position.

The ink was hardly dry on the final version of the Products Liability Restatement when the New Jersey Supreme Court wrote its bombshell decision in *Perez v. Wyeth Laboratories, Inc.*⁶ The Court had read our earlier draft and paid little attention to the fact that we had taken no firm position on the learned intermediary rule.⁷ If the issue was to be left to developing case law, New Jersey would be the first on the bandwagon. Norplant, a contraceptive implant, had been widely marketed in women’s magazines without revealing to potential users a host of side effects that came with its use. The court rehearsed all of the arguments as to why a drug that required a prescription by a physician should have the warning delivered to the physician and not the patient.⁸ And with the ease of a marksman shooting ducks in a pond, it knocked them off one by one. It was a tour-de-force. The learned intermediary rule belonged to history. Like *Henningson*⁹ and *Greenman*,¹⁰ *Perez*

3. See, e.g., Teresa Moran Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 FOOD DRUG COSM. L.J. 829 (1991); Tim S. Hall, Note, *Bypassing the Learned Intermediary: Potential Liability For Failure to Warn in Direct-to-Consumers Prescription Drug Advertising*, 2 CORNELL J.L. & PUB. POL’Y 449 (1993); Bradford B. Lear, Note, *The Learned Intermediary Rule in the Age of Direct Consumer Advertising*, 65 MO. L. REV. 1101 (2000).

4. RESTATEMENT (THIRD) OF THE LAW: PRODS. LIAB. § 4 cmt. e (Council Draft No. 1A 1994). For a description of the evolution of the Restatement’s rule on learned intermediaries for drugs that are advertised in the media, see Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 161-68 (1997).

5. RESTATEMENT, *supra* note 1, at § 6 cmt. e.

6. 734 A.2d 1245 (N.J. 1999).

7. *Id.* at 1253.

8. *Id.* at 1255-56.

9. *Henningson v. Bloomfield Motors, Inc.*, 161 A.2d 69 (N.J. 1960).

would take its place in products liability history as the case that broke the dam. It would only be a matter of time and it would be all over.

The strange thing is that seven years have passed and nothing has happened. Courts have not signed on to the revolution.¹¹ Simple logic has not triumphed. The question is, why? It does no good to repeat the argument of drug manufacturers that a prescription drug can only reach the hands of patients after the physician has made a decision to prescribe the drug for the specific patient and that the doctor is in the best position to assess the risks and benefits and relay that information to the patient. Advertising seeks to empower patients and to create a demand for a drug that would otherwise not emanate from the physician. Having changed the dynamic as to how drugs are prescribed, the flow of information should change as well.

The few cases that have dealt with liability stemming from drug advertising have not addressed a fundamental policy question: Does direct marketing of drugs to the public serve the commonweal? The medical profession finds media advertisements to be an intrusion into their role in ministering healthcare to patients. They do not take kindly to patients demanding, requesting, or even suggesting certain drug therapies.¹² Pressures to prescribe medication are often hard to resist even when the physician believes that it is not in the patient's best interest to take the drug. On the other hand, one cannot deny that drug advertising has raised the awareness of patients with regard to the availability of drug therapies and to the underlying conditions that need medical attention.¹³ The aggressive marketing of a wide variety of anti-cholesterol drugs has almost certainly encouraged patients to be tested and treated for high cholesterol. And when one drug is not well tolerated, instead of discontinuing taking the drug without informing the physician, patients are more likely to explore alternatives with their

10. *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897 (Cal. 1963).

11. See, e.g., *In re Norplant Contraceptive*, 215 F. Supp. 2d 795 (E.D. Tex. 2002) (granting summary judgment for defendant on claims of failing-to-warn consumers directly for all states, except New Jersey).

12. See Stuart Elliott, *The Media Business: Advertising: A Seminar Examines the Plethora of Prescription Drug Pitches Since Regulations Were Loosened*, N.Y. TIMES, June 15, 1998, at D11 (describing a survey in which 79% of physicians reported that they were concerned that relaxed direct-marketing guidelines would lead to patients demanding unnecessary drug treatments); Melissa Healy, *Wary, and Weary, of Drug Ads: The Messages are Everywhere, but Now Some Lawmakers, Consumers and Physicians are Saying, "Enough"*, L.A. TIMES, June 20, 2005, at F1 (discussing the increase in patients who are "pestering" their physicians for advertised drugs).

13. See Elliott, *supra* note 12 (finding that 65% of doctors surveyed said that the most important aspect of direct-to-consumer advertising was "building awareness of diseases and their symptoms").

physicians. Similarly, male patients suffering from hypertension often do not take drugs designed to reduce their blood pressure. Many patients on anti-hypertension medication manifest a reduction in libido and/or impotence. With the advent of such drugs as Viagra, Levitra, and Cialis, patients are more prone to discuss their sexual problems with their physicians rather than unilaterally stopping to take the medication because of the negative side effects. Furthermore, the fact that there has been a huge amount of advertising of these drugs has encouraged many who could not bring themselves to discuss their sexual problems with their physician to do so for the first time.

What does this debate about the net worth to society of drug advertising have to do with whether drug companies should be required to warn directly to the public when the drugs are advertised in the media? In my opinion, once one chooses a side on either side of the question, the issue of the learned intermediary rule resolves itself. If one believes that media advertisement of prescription drugs is a bad idea, one will have little sympathy for providing drug companies with an immunity from liability because they adequately warned physicians. If, however, media advertisements are viewed as social good, then courts will have to grapple with the problem that there are real limitations on the ability of pharmaceutical manufacturers to warn patients about risks attached to taking a drug.

The problem is elementary. It is far easier to describe the benefits of a drug than it is to portray its risks. Think about the drugs you have seen advertised. The first page is what I call the "smiley" page. A patient suffering from arthritis, impotence, or depression is pictured as happy once the yoke of disease has been lifted from his shoulder. Drug benefits are targeted to specific conditions and the alleviation of an undesirable condition is a story simply told.¹⁴ Negative drug side effects are far more nuanced and infinitely more difficult to communicate. Look at a typical package insert often set forth on the reverse side of the smiley page. Frequency, severity, and short and long-term implications to the patient must be dealt with for scores of possible side effects. The fact that the manufacturer gave some warning on the "unhappy" page will be of small solace to the pharmaceutical manufacturer. Indeed having recognized the risk, the claim will be that the warning was not

14. Accurate portrayal of benefits can be nuanced as well. For example, how efficacious is a drug; what percentage of patients are helped by a drug; are there other substitutes that are less costly; are all questions that go to the benefit side of the equation.

adequate.¹⁵ Plaintiffs will argue that the warning should have been more direct, bolder, and more threatening. That risks and warnings must be hierarchical may be unconvincing to a jury and the adequacy of warning is almost always a jury issue.

Furthermore, it is no easy matter to communicate risk in context. Is the risk of any given side effect equivalent to the frequency of being killed in an airplane crash or crossing the street in a crowded urban environment? Or is it like the risk of being injured when speeding 30 miles per hour over the limit? The only certain refuge from uncertain or perhaps limitless liability for failure to warn is the learned intermediary rule. Of all theories of product liability, failure-to-warn has the least rigor and is thus not subject to significant judicial control over unwarranted jury discretion.¹⁶ Without the learned intermediary rule, direct advertising failure-to-warn cases are likely to constitute an expansive and expensive category of liability.

I do not choose sides on the fundamental question as to whether the world is a better place because of direct consumer marketing of prescription drugs. I admit to considerable ambivalence on this issue. But for the first time I see the issue of direct warning in a different light. We simply cannot have our cake and eat it too. Contrary to my original thinking, it cannot glibly be said, "If you can successfully market a drug, you can adequately warn against its side effects." The two are very different enterprises.

Drug manufacturers have done much better in recent years in communicating to consumers about drug side effects. One need only to peruse drug advertisements to see that common side effects are being warned against. That they are now more prominent and easier to understand is probably due to the threat of product liability litigation. Nonetheless, there is just no way that drug side effects can be as effectively communicated as drug benefits.¹⁷ Therein lies the dilemma.

15. Richard E. Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?*, 37 WAKE FOREST L. REV. 97, 137 (2002) ("It is difficult to see how drug manufacturers can provide consumers with complete and understandable information about product related risks through direct communication."); Noah, *supra* note 4, at 174 ("Once the duty to warn expands, risk information contained in the advertisements would not satisfy a drug manufacturer's duty to warn patients directly.").

16. See James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265 (1990).

17. Pharmaceutical manufacturers of prescription drugs may be able to comply with the FDA requirement that print media advertisements present a "fair balance" of a drug's benefits and detriments, see 21 C.F.R. § 2021(e)(5)(ii), (6)(i)-(v), but still be open to liability because a jury would find that the warning was not strong enough and thus inadequate under classic product liability failure-to-warn doctrine. See Ausness, *supra* note 15, at 137.

Ultimately, the learned intermediary defense will stand or fall based on whether we view drug advertisements as an important public good or as an avaricious over-reaching by the pharmaceutical manufacturers to force unwanted and unnecessary drugs on the American public.