Direct-to-Consumer Advertising of Prescription Drugs: After a Decade of Speculation, Courts Consider Another Exception to the Learned Intermediary Rule

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I. INTRODUCTION

The rising costs of health care have forced changes in institutions that provide health care services to patients. Doctors, hospitals, insurance companies, and drug manufacturers have changed business practices to trim costs and maximize profits. One practice exploited by pharmaceutical companies is the freedom to advertise prescription drug products.[1] Direct-to-consumer advertising can effectively increase product sales by reaching potential consumers through print and broadcast media.[2]

Direct-to-consumer advertising has prompted considerable legal comment regarding the liability of drug manufacturers to the ultimate consumer, the patient.[3] Unlike makers of nonpharmaceutical prod-

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1. Pharmaceutical manufacturers spent an estimated $1 billion on direct-to-consumer advertising in 1997. Kelly N. Reeves, *Open Forum, Direct-to-Consumer Broadcast Advertising: Empowering the Consumer or Manipulating a Vulnerable Population*, 53 FOOD & DRUG L. J., 661, 662 n.11 (1998). In 1998, spending by drug manufacturers on print and broadcast advertising increased to $1.3 billion. Perez v. Wyeth Laboratories, Inc., 734 A.2d 1245, 1252 (N.J. 1999) (quoting Robert Pear, *Drug Companies Getting F.D.A. Reprimands for False or Misleading Advertising*, N.Y. TIMES, Mar. 28, 1999, at 28).

2. *See* Jay P. Speivack, *Direct Ads May Create Liability Dangers*, NAT'L L. J., Mar. 15, 1999, at B7 n.1 (citing David Morrow, *What We've Learned from Those Little Blue Pills*, N.Y. TIMES, Feb. 17, 1999, at G3, (writing that testimonials boosted worldwide sales for Viagra to $788 million)).

3. *See, e.g.*, Michael C. Allen, *Medicine Goes Madison Avenue: An Evaluation of the Effect of Direct-to-Consumer Pharmaceutical Advertising on the Learned Intermediary Doctrine*, 20 CAMPBELL L. REV. 113 (1997); Lars Noah, *Advertising Prescription Drugs to Consumers: Assess-*

ucts, a drug manufacturer does not have a duty to warn a consumer[4] of the risks associated with a drug, rather, it owes a duty to warn the prescribing physician.[5] The physician is recognized as a learned intermediary between the drug manufacturer and the consumer.[6] As a result, the drug manufacturer is shielded from direct liability in failure to warn cases because the physician has the requisite skill to understand the risks described by the drug manufacturer, and the physician knows the health status of the patient far better than the manufacturer does.

Courts are reexamining policies supporting the learned intermediary doctrine in view of direct-to-consumer advertising by pharmaceutical companies. In a recent decision, the New Jersey Supreme Court advocated that when a manufacturer's advertisement misinforms a patient's choice of therapy, the court should recognize an exception to the learned intermediary rule.[7] In a factually similar case, the Fifth Circuit Court of Appeals ruled that it would not abandon the learned intermediary doctrine.[8]

This Comment will explore whether Washington courts should recognize direct-to-consumer advertising as an exception to the learned intermediary rule. With the ultimate goal of advocating the best protection for the consumer, the discussion will suggest that Washington courts should not create an exception. A review of other

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ing the Regulatory and Liability Issues, 32 GA. L. REV. 141 (1997); Reeves, *supra* note 1; Teresa Moran Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 FOOD DRUG COSM. L. J. 829 (1991); Tamar V. Terzian, Note, *Direct-to-Consumer Prescription Drug Advertising*, 25 AM. J. L. & MED. 149 (1999).

4. *Henningsen v. Bloomfield Motors, Inc.*, 161 A.2d 69 (N.J. 1960), is considered the leading case in overturning the established law in torts that direct liability is found only if the parties are in privity with one another. Courts rapidly followed the New Jersey decision, finding that an implied warranty of safety applies to many different products. *See* W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 97, at 690 (5th ed. 1984).

5. *See* Martin v. Ortho Pharmaceutical Corp., 661 N.E.2d 352, 357 (Ill. 1996); Reaves v. Ortho Pharmaceutical Corp., 765 F. Supp. 1287, 1291 (E.D. Mich. 1991); Terhune v. A.H. Robins Co., 90 Wash. 2d 9, 18, 577 P.2d 975, 980 (1978). *See also* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d)(2) (1998).

6. The term "learned intermediary" was first used in *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966). The court distinguished a prescription drug from a normal consumer item. "In such a case the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer." *Id.* If the doctor is warned of side effects, then injury to the patient has an "excellent chance" of being avoided. *Id.*

7. *Perez*, 734 A.2d at 1245. The court stated that in the case of direct-to-consumer advertising of drugs, "patients deprived of reliable medical information [should be allowed] to establish that the misinformation was a substantial factor contributing to their use of a defective pharmaceutical product." *Id.* at 1263.

8. *In re* Norplant Contraceptive Products Liability Litigation, 165 F.3d 374, 379 (5th Cir. 1999) (citing prior Texas case law that "as long as physician-patient relationships exist, the learned intermediary doctrine applies").

exceptions to the learned intermediary rule does not support abandoning the doctrine when a drug company advertises its product directly to consumers. Nevertheless, advertising does affect consumer purchases and does influence consumer choices, and drug companies should accept the responsibility to present balanced information. This responsibility should encompass more than meeting the minimum requirements for balanced advertising presently promulgated by the Food and Drug Administration (FDA).

The following section of this Comment presents a brief background of the learned intermediary doctrine, which provides an exception to the general rule that a product manufacturer is directly liable to a consumer of the product. Section III discusses decisions in which courts have created exceptions to the learned intermediary rule (exceptions to the exception). Next, Section IV presents a brief summary of the Washington court decisions that evaluate whether a pharmaceutical manufacturer should be directly liable to a patient. Section V discusses the role of the FDA and the weight courts give to the defense that drug manufacturers complied with FDA regulations. This section also presents the measures the FDA takes to regulate prescription drug advertising, as well as the challenges to these measures. Finally, Section VI reviews the recent court decision in *Perez v. Wyeth Laboratories*,[9] and the policies discussed therein regarding advertising and the learned intermediary rule. In this last section, the author concludes with a discussion of how health care product advertising impacts consumers.

II. BACKGROUND

A. *Prescription Drugs Are Unavoidably Unsafe Products*

Section 402A of the Restatement (Second) of Torts states that a manufacturer should be held strictly liable if it sells a product that is defective and as such presents an unreasonable danger to the user or consumer.[10] Most states, including Washington, have adopted the rule either by statute or by case law.[11]

Comment k to section 402A suggests that prescription drugs should be considered unavoidably unsafe products because these

9. 734 A.2d 1245 (N.J. 1999).

10. RESTATEMENT (SECOND) OF TORTS § 402A(1) at 347 (1965).

11. *See* Michael J. Wagner & Laura L. Peterson, *The New Restatement (Third) of Torts—Shelter from the Product Liability Storm for Pharmaceutical Companies and Medical Device Manufacturers?*, 53 FOOD & DRUG L.J. 225, 226-27 n.9 (1998). The Washington Supreme Court incorporated section 402A of the Restatement (Second) in its decision in *Terhune*. 90 Wash. 2d at 12, 577 P.2d at 977.

products are "quite incapable of being made safe for their intended and ordinary use."[12] Risks are inherent in taking most, if not all, pharmaceutical drugs. A drug may provide benefit to some people, yet the same drug may not be an appropriate treatment for others. For example, aspirin, a readily available nonprescription drug, is recommended for some patients to reduce the risk of heart attack.[13] Recognition of this property of aspirin, i.e., its effect on blood clotting, justifies its use by a particular population of patients with cardiovascular disease. This same property, however, prompts physicians to recommend another type of pain reliever for post-surgery patients.[14] Because most drugs pose some risk to some patients, drugs are considered unavoidably unsafe. Nevertheless, if a drug is not unreasonably unsafe or defective, then its benefit to many people justifies its sale.[15] The manufacturer should not be held strictly liable because it has supplied the public "with an apparently useful and desirable product, attended with a known but apparently reasonable risk."[16]

Comment k of 402A was reorganized in the Restatement (Third) of Torts: Product Liability.[17] If jurisdictions displace 402A with the rules of the Restatement (Third), courts may change how they determine drug manufacturer liability. In the provision of the Restatement (Third) that describes prescription drug manufacturing, design, and

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12. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). By way of illustration, comment k discusses the rabies vaccine as an example of a pharmaceutical product that can lead to damaging consequences, but rabies itself leads to a "dreadful death." *Id.* The comment continues, "[s]uch a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous." *Id.* The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. *Id.*

13. The American Heart Association recommends aspirin for patients who have experienced a myocardial infarction (heart attack). Aspirin helps prevent blood clots, which lead to strokes and heart attacks. The patient should consult a physician to ensure that he has no other condition that would contraindicate regular intake of aspirin. American Heart Association, *Heart and Stroke A-Z Guide* (last visited June 18, 2000) <http://www.americanheart.org/Heart_and_Stroke_A_Z_guide/aspirin/html>.

14. If a person taking aspirin must undergo even a simple surgical procedure or dental extraction, the surgeon or dentist must be told of the aspirin dosage. The tendency to bleed persists for up to 10 days after aspirin use is stopped. *See id.*

15. *See* RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). In the view of Washington courts, comment k focuses "on the product and its relative value to society." Young v. Key Pharmaceuticals, Inc., 130 Wash. 2d 160, 169, 922 P.2d 59, 64 (1996). Some products are necessary regardless of the risk they pose because the product may be necessary to sustain the life of some individuals. If the drug were not available, the resulting harm would be greater to those individuals than the harm risked by using the drug. *Id.* (quoting Rogers v. Miles Laboratories, Inc., 116 Wash. 2d 195, 204, 802 P.2d 1346, 1351 (1991)).

16. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).

17. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY (1998).

warning defects,[18] a prescription drug is no longer described as an unavoidably unsafe product. Instead, the Restatement (Third) provides

> A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.[19]

Commentators Michael Wagner and Laura Peterson note that the "reasonable health care provider" standard departs from comment k language, and they suggest it is a poorer test for judging the reasonableness of marketing a particular drug or device than a "reasonable manufacturer" standard.[20] Wagner and Peterson contend that requiring a physician to determine whether a product should be on the market is "nonsensical."[21] Consequently, this provision increases the risk that the judiciary will reject the Restatement (Third).[22] In the next few years, pharmaceutical companies and attorneys will closely follow whether, and to what extent, courts will follow the new restatement.

B. Duty to Warn

The Restatement (Second) advocates that a manufacturer should be held strictly liable if the manufacturer introduces an unreasonably unsafe product into the stream of commerce.[23] A product may be considered unreasonably unsafe if it is placed in the hands of the ultimate consumer without adequate warning of the dangers involved in the product's use.[24] Under comment k, the seller of prescription drugs is not to be held strictly liable for "unfortunate consequences" attending the use of unavoidably unsafe products provided that the products are "properly prepared and marketed" and that "proper warning is given."[25] To prevent inappropriate administration of a drug, the manufacturer properly warns when it identifies the characteristics of

18. *Id.* § 6 (Liability of Commercial Seller or Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices).

19. *Id.* § 6(c).

20. Wagner & Peterson, *supra* note 11, at 233.

21. *Id.*

22. *Id.*

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

24. *Id.*

25. *Id.* § 402A, cmt. k. Most courts have concluded that a prescription drug is unavoidably unsafe if it meets the requirements of comment k. Allen v. G.D. Searle & Co., 708 F. Supp. 1142, 1149 (D. Or. 1989) (citing Coursen v. A. H. Robins Co., 764 F.2d 1329, 1338 (9th Cir. 1985)).

patient populations that may be adversely affected by the drug and discusses the consequent effects with those particular patients so that harm may be prevented.[26]

In failure to warn cases, the majority of jurisdictions has applied a negligence standard, a position also supported by the Restatement (Third).[27] The reporters for the Restatement (Third) reject the minority view that a company should be strictly liable for injuries caused by a drug it manufactures, and instead focus on the reasonableness of the manufacturer's conduct.[28] A reasonable drug manufacturer is one that knew or should have known about the risks of a prescription drug.[29] To impose liability upon a manufacturer for failing to warn of scientifically unknowable risks is unfair, inefficient, and impossible to insure against.[30]

C. *The Learned Intermediary Rule—An Exception to a Manufacturer's Duty to Warn Consumers*

To establish a claim of negligence, a plaintiff must show that the defendant had a duty to warn, the defendant breached that duty, and the breach was the proximate cause of the plaintiff's injury.[31] Generally, a manufacturer of a product can be held directly liable to a consumer who is injured by the product. In drug liability cases, the learned intermediary rule provides an exception to the duty owed by a drug manufacturer to the consumer of a product, the patient.[32] The manufacturer meets its duty to warn of the dangers associated with a drug when it provides adequate "precautionary information" to the physician prescribing the medication.[33] The physician, in turn, using

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26. The FDA requires that all prescription drug labels have particular content and format. The label must include a description of the drug, as well as information about clinical pharmacology, indications and usage, contraindications, warnings, precautions, adverse reactions, drug abuse and dependence, overdosage, dosage and administration, and method of supply. 21 C.F.R. § 201.57 (2000).

27. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) (1998). *See* Wagner & Peterson, *supra* note 11, at 234-35.

28. *See* Wagner & Peterson, *supra* note 11, at 234-35.

29. *See id.* at 234-35 and cases cited therein. *See also* James A. Henderson & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265, 274 (1990).

30. *See* Henderson & Twerski, *supra* note 29, at 274 and notes therein.

31. *See* KEETON ET AL., *supra* note 4, at 164-65.

32. Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966) (holding that because a prescription drug is not a normal consumer item, the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer).

33. *See, e.g.*, Lacy v. G.D. Searle & Co., 567 A.2d 398, 400 (Del. 1989) ("[I]f the manufacturer of prescription products provides the physician with the legally appropriate information, it has satisfied its duty to warn."); *Terhune*, 90 Wash. 2d at 13, 577 P.2d at 977 (a "well-established rule" is that the duty of a manufacturer to warn of dangers in use of a product is sat-

his or her judgment, has a duty to convey relevant warnings to the patient.[34] The learned intermediary doctrine rests on the assumption that the prescribing physician, not the drug manufacturer, is in the best position to provide warnings to the patient regarding the dangers associated with a particular drug.[35] Distribution of a prescription drug to a patient requires a prescription by a physician because pharmaceuticals are presumed to be unavoidably unsafe.[36] The physician must be informed of the qualities and characteristics of the medication so that he can evaluate the benefits and risks of a particular drug for an individual patient and convey that information as the physician deems appropriate.[37] The learned intermediary rule has been applied in prescription drug cases because (1) courts are reluctant to undermine the physician-patient relationship; (2) physicians, rather than manufacturers, are in a superior position to convey information to the patient; (3) drug manufacturers are unable to communicate with the patient; and (4) the complexity of the subject matter dictates that the physician and not the manufacturer provide the patient with drug information.[38] If the physician was not adequately warned of the risks of the drug and would not have prescribed it if the physician had been warned, the patient who was allegedly injured by a drug may be able to hold the drug manufacturer directly liable.[39]

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isfied when he gives adequate warning to the prescribing physician.). *See also* Noah, *supra* note 3, at 155-56 and notes therein.

34. Martin v. Ortho Pharmaceutical Corp., 661 N.E.2d 352, 354 (Ill. 1996).

35. *See, e.g., Martin*, 661 N.E.2d at 357; *Lacy*, 567 A.2d at 400 (applying the learned intermediary rule because the patient expects the physician to use his or her "informed independent judgment to advise the patient and to prescribe the most appropriate use of the drug or device"); *Terhune*, 90 Wash. 2d at 14, 577 P.2d at 978 (reasoning that if the product is properly labeled with necessary instructions and warnings, the physician will exercise informed judgment in the best interest of the patient).

36. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). *See, e.g., Young*, 130 Wash. 2d at 170, 922 P.2d at 64; Grundberg v. Upjohn Co., 813 P.2d 89, 95 (Utah 1991). Prescription drugs pose some risk of side effects in certain persons because drugs are chemical compounds that are designed to interact with chemical and physiological processes of the human body. *Id.*

37. *Terhune*, 90 Wash. 2d at 14, 577 P.2d at 978. ("[T]he manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient."). *See also* Reaves v. Ortho Pharmaceutical Corp., 765 F. Supp. 1287, 1289 (E.D. Mich. 1991) (stating that the physician has a "duty to be informed of the characteristics of prescription drugs and to exercise independent professional judgment in determining the appropriateness of a specific drug considering the susceptibilities of the patient."). *Cf.* Ferrara v. Berlex Laboratories, Inc., 732 F. Supp. 552, 555 (E.D. Pa. 1990) (ruling that the drug manufacturer was not strictly liable when the physician admitted to negligently prescribing a decongestant and antidepressant for a patient and the physician had forgotten warnings regarding the dangerous effects of simultaneously administering both medicines).

38. *See* Noah, *supra* note 3, at 157-59.

39. McEwan v. Ortho Pharmaceutical Corp., 528 P.2d 522, 538 (Or. 1974) (holding that

Even though it is unknown whether courts and legislators will adopt its revisions, the Restatement (Third) reflects the current, vigorous debate regarding liability of drug manufacturers for alleged warning defects. The Restatement (Third) adopts the rule that a prescription drug is "not reasonably safe due to adequate instructions or warnings if reasonable instructions or warnings" are not provided to the prescribing "health care providers."[40] In comment b of the Restatement (Third), the reporters express that in certain limited therapeutic relationships the physician has a "much-diminished" role as an evaluator and decision maker.[41] In those circumstances, it may be appropriate to impose on the manufacturer the duty to warn the patient directly.[42] Liability will then depend upon whether the manufacturer knew or had reason to know that healthcare providers were not in a position to reduce the risks of harm in accordance with the instructions or warnings.[43]

III. EXCEPTIONS TO THE LEARNED INTERMEDIARY RULE

Although Washington courts have not recognized an exception to the learned intermediary rule in a drug product liability action, other jurisdictions have recognized exceptions to the learned intermediary rule and have held that drug manufacturers can be directly liable to a consumer. This section will explore whether historical exceptions to the rule reveal a basis for an additional exception related to direct-to-consumer advertising. One historical exception is the absence of a physician to counsel, and a second occurs when a drug manufacturer is required to provide the patient with product information.

A. Absence of Physician to Counsel

In *Davis v. Wyeth Laboratories*,[44] the Ninth Circuit recognized an exception to the learned intermediary rule because a physician was not

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manufacturers were negligent in failing to warn physicians in light of the manufacturers' knowledge of the inherent dangers in using contraceptives). *See also Allen*, 708 F. Supp. at 1148 (denying summary judgment in favor of drug manufacturer in view of plaintiffs' contention that the manufacturer did not appropriately change warnings provided to physicians regarding the Cu-7 IUD). *See generally* Noah, *supra* note 3, at 160 and notes therein.

40. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d)(1) (1998). The reasonable health care provider standard also generates controversy because it was created without apparent precedent in case law. Wagner & Peterson, supra note 11, at 230 n.27 (citing Jeffrey D. Winchester, *Section 8(c) of the Proposed Restatement (Third) of Torts: Is It Really What the Doctor Ordered?*, 82 CORNELL L. REV. 644, 665-69 (1997)).

41. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) cmt. b (1998).

42. *Id.*

43. *Id.* § 6(d)(2).

44. 399 F.2d 121 (9th Cir. 1968).

available to counsel a patient who received a polio vaccination in a mass vaccination setting. The appellant, Mr. Davis, received the Type III Sabin oral polio vaccine and, within 30 days, he exhibited symptoms of polio and ultimately was paralyzed from the waist down.[45] At the vaccination clinic, the only information presented regarding the vaccine was in posters that did not disclose any risks.[46] At the time of the vaccination, the manufacturer, Wyeth Laboratories, was aware of the risk to adults, albeit a small risk, of contracting poliomyelitis from the vaccine; it was also aware that the Surgeon General recommended that vaccination be provided to adults only with "the full recognition of its very small risk."[47] The court found that the manufacturer had a responsibility to warn against the risks.[48] Because Wyeth Laboratories knew that physicians were not present at the clinic and that no information was provided to adults that would assist them in choosing whether or not to have the vaccination, the court held that Wyeth had failed to warn Mr. Davis and was liable for his injury.[49]

The Fifth Circuit followed *Davis* in a case involving an infant injured by a polio vaccine that was administered at a clinic without an attending physician.[50] The defendant, Wyeth, argued that the circumstances were significantly different than those in *Davis*: the infant's parents requested the vaccine; a public health nurse administered the vaccine; Wyeth had a passive role in this immunization program; and, unlike in *Davis*, Wyeth had no knowledge that the vaccine would not be administered as a prescription drug.[51] The court did not find that these grounds justified a result different from *Davis*.[52] Wyeth knew or had reason to know that the clinics dispensed the vaccine without consultation with medical personnel; therefore, Wyeth had a duty to warn users.[53]

The court also was not persuaded by Wyeth's argument that because the infant's mother had signed a release form purportedly releasing the state from liability, she assumed the risk that her daugh-

45. *Id.* at 122.
46. *Id.* at 125.
47. *Id.* at 124.
48. *Id.* at 130.
49. *Id.* at 131. "[The vaccine] was dispensed to all comers at mass clinics without an individualized balancing by a physician of the risks involved . . . . Here [Wyeth] knew that warnings were not reaching the consumer." *Id.*
50. Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1270 (5th Cir. 1974).
51. *Id.* at 1277.
52. *Id.*
53. *Id.*

ter might contract polio.[54] This argument raises a fundamental doctrinal problem in failure to warn cases, that is, whether a warning to the user would in fact have altered his or her decision to use the product.[55] This issue is also evident in cases where some courts recognize a second exception to the learned intermediary rule: when a patient is provided with written information about a drug.

B. Manufacturers Required to Provide Patient with Product Information

For particular pharmaceutical drugs, the FDA requires that package inserts containing product information be provided to patients.[56] The requirement is imposed when the FDA believes that a patient should be informed of the risks, as well as the benefits, of a particular drug. For example, manufacturers of birth control pills must provide a package insert that informs the user of potential adverse effects.[57] The FDA promulgated these regulations because healthy women electing to take oral contraceptives have alternative methods of treatment available to them, and because oral contraceptives have a relatively high incidence of serious illnesses associated with their use.[58] The FDA also found a patient may not remember everything mentioned to her in conversation with her physician, and therefore, in order to make an informed decision, she should have written available information for future reference.[59]

The intent of the FDA regulation is not to displace the primary relationship between the physician and the patient: the physician has the "primary responsibility" to caution and warn.[60] A majority of

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54. *Id.* at 1278.

55. *See* Henderson & Twerski, *supra* note 29, at 305. In order to prove direct liability of a manufacturer, a plaintiff would not only have to prove that she would have read, understood, and remembered the warning but also that she would have altered her conduct to avoid injury. Henderson and Twerski contend that the plaintiff can offer "little more than self-serving testimony and anecdotal evidence" to establish proximate cause. *Id.*

56. *See* Patient Package Inserts for Oral Contraceptives, 21 C.F.R. § 310.501 (2000); Patient Package Inserts for Estrogens, 21 C.F.R. § 310.515 (2000). *See also Lacy*, 567 A.2d at 401 (noting that at the time of litigation, federal regulation required manufacturers of IUDs to provide direct warning to consumer); Edwards v. Basel Pharmaceuticals, 933 P.2d 298 (Okla. 1997) (product inserts required for nicotine patches).

57. 21 C.F.R. § 310.501(c)(7)-(10) (2000). An adverse effect is defined as any medical condition that worsens or appears after a patient begins to take the drug. 21 C.F.R. § 130.45(a) (2000). Post-marketing reporting of adverse drug experiences is required of drug manufacturers. 21 C.F.R. § 314.80 (2000).

58. *See* MacDonald v. Ortho Pharmaceutical Corp., 475 N.E.2d 65, 69-70 (Mass. 1985) (citing 43 Fed. Reg. 4,215 (1978)).

59. *See id.* (citing 35 Fed. Reg. 9,002 (1970)).

60. *See, e.g.*, MacPherson v. Searle & Co., 775 F. Supp. 417, 425-26 (D.D.C. 1991) (citing the FDA Commissioner's comments regarding package insert requirements for oral contraceptives (43 Fed. Reg. 4,215 (1978)).

jurisdictions has retained the learned intermediary rule in cases involving injury from birth control pill use.[61]

A minority of jurisdictions, rejecting the doctrine, has ruled that when written information is provided to the patient as required by federal regulations,[62] the drug manufacturer can be found directly liable to the patient if the information did not provide adequate warning.[63] In *MacDonald v. Ortho*,[64] the court found that birth control pills had peculiar characteristics that warranted imposing on the manufacturer a common law duty to warn users directly of associated risks.[65] In *Odgers v. Ortho Pharmaceutical Corp.*,[66] the court followed *MacDonald*, finding the holding a "more reasoned rule of law."[67] The learned intermediary rule was rejected because "the healthy, young consumer of oral contraceptives is usually actively involved in the decision to use 'the pill,' as opposed to other available birth control products," relegating the physician to a relatively passive role.[68] Both courts reasoned that the physician is also less involved because the patient renews the prescription yearly, and the renewal can be accomplished with a phone call instead of an office visit.[69]

One policy argument supporting the learned intermediary rule is that a physician should shield a patient from the knowledge of potential risks if those risks induce fear rather than inform.[70] The potential detrimental consequence is that the patient would refuse what the physician considers necessary treatment.[71] In *Odgers*, however, the

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61. *See, e.g., Martin*, 661 N.E.2d at 352; *MacPherson*, 775 F. Supp. at 417; *Reaves*, 765 F. Supp. at 1287 (repudiating the holdings in Odgers v. Ortho Pharmaceutical Corp., 609 F. Supp. 867 (D.C. Mich. 1985), and Stephens v. G.D. Searle & Co., 602 F. Supp. 379 (E.D. Mich. 1985)).

62. *See* 21 C.F.R. § 310.501 (2000).

63. *See MacDonald*, 475 N.E.2d at 65; *Odgers*, 609 F. Supp. at 867; *Stephens*, 602 F. Supp. at 379. *See also* Edwards v. Basel Pharmaceuticals, 116 F.3d 1341 (10th Cir. 1997). Basel claimed that it met the FDA requirements regulating the product insert it provided to patients about the drug Halbitrol, a nicotine patch, and therefore met its duty to warn. The Tenth Circuit Court reversed a district court grant of summary judgment in favor of the manufacturer after the Oklahoma Supreme Court ruled in *Edwards v. Basel Pharmaceuticals*, 933 P.2d 298, 303 (Okla. 1997), that if a drug manufacturer is required by the FDA to provide package inserts to the patient, an exception to the learned intermediary rule applies.

64. *MacDonald*, 475 N.E.2d at 65.

65. *Id.* at 69.

66. *Odgers*, 609 F. Supp. at 867.

67. *Id.* at 879.

68. *MacDonald*, 475 N.E.2d at 69.

69. *Id.*; *Odgers*, 609 F. Supp. at 878.

70. *Odgers*, 609 F. Supp. at 874 (citing P. Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947 (1964)).

71. *Id.* at 878. *See also* Schwarz, *supra* note 3, at 830 n.9 (citing William J. Curran, *Package Inserts for Patients: Informed Consent in the 1980s*, 305 NEW ENG. J. MED. 1564 (1981), in which the author argued that because patients lacked expertise necessary to assess warnings about side

court maintained that informed choice was more critical.[72] Because a woman choosing birth control pills as a contraceptive method has several alternatives, the additional information ensures that she will make an informed choice.[73]

Many of the policy arguments supporting the exception to the learned intermediary rule seem counterintuitive. The relationship between a woman and her physician develops early in life because women seek and need medical advice about birth control, pregnancy, and cancer prevention.[74] Health care programs advocate that all women see a gynecologist or general practitioner once a year.[75] In *Reaves v. Ortho Pharmaceutical Corp.*,[76] a physician testified that before a doctor prescribes birth control pills, "standard practice" dictates that a physician interview a patient about herself and her family's medical history and conduct a complete physical examination.[77] The witness characterized the physician's role as active rather than passive, with both the physician and patient sharing in the decision-making regarding which contraceptive method is appropriate for the patient.[78] Testimony was also offered that "most practitioners" prescribe birth control pills for three to six months initially so that the patient and physician can evaluate whether the woman has suffered any side effects.[79]

The argument that physicians do not act as learned intermediaries because they have a passive role in prescribing other birth control methods also fails. In *Hill v. Searle Laboratories*,[80] the court found an exception to the learned intermediary rule when the patient had an intrauterine device (IUD) inserted under "clinic-type conditions," limiting the physician-patient contact.[81] However, a physician must skillfully insert an IUD, which can be painful and have complications,

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effects, they might be frightened and not take needed medications).

72. *Odgers*, 609 F. Supp. at 878.

73. *Id.*

74. The American College of Obstetricians and Gynecologists recommends that women have an annual pelvic exam beginning in their early to middle 20s. Mayo Clinic Family Health 2.0, (IVI Publishing, Minneapolis, Minn. 1996) (CD Rom on file with the author).

75. *See id.*

76. *Reaves*, 765 F. Supp. at 1287.

77. *Id.* at 1290. The witness for the defendant was the Chairperson of Obstetrics and Gynecology at Detroit Henry Ford Hospital and a clinical professor at the University of Michigan Medical School. *Id.*

78. *Id.*

79. *Id.* A faculty member at a school of pharmacy testified that many prescriptions are offered for three to six months, and therefore, the same practice with birth control pills is not unusual. *Id.* at n.2.

80. 884 F.2d 1064 (8th Cir. 1989).

81. *Id.* at 1071 (finding an exception to the learned intermediary rule in part because the physician-patient contact is limited in "clinic-type conditions").

requiring a physician to actively participate in a patient's care.[82] Most importantly, for birth control methods as well as for other drugs, if a drug has serious adverse effects, the physician's role is more important, not less.[83]

Cases involving injury from birth control pills also raise the issue of whether an adequately warned patient would heed the warning if it were properly given. In *MacDonald*,[84] the court found that the product information describing the risks associated with birth control pills was inadequate.[85] Essentially, the decision turned on the lack of a word in the pamphlet—stroke.[86] The manufacturer warned users of birth control pills that "[the] most serious known side effect is abnormal blood clotting which can be fatal."[87] The pamphlet listed numerous symptoms, including weakness and numbness of an arm or leg, and stated that a woman experiencing any of the symptoms should call her doctor immediately and stop taking the pill.[88] The plaintiff in *MacDonald* purportedly experienced two episodes of numbness in her hand, which she did not report to her doctor.[89] Ortho argued that this evidence supported the belief that MacDonald would not have heeded the warning even if the pamphlet warned patients against the possibility of "stroke" rather than blood clotting.[90] The court, however, did not consider this evidence because it raised the issue of comparative negligence, which was not raised in the court below.[91]

Holding a drug company liable because the patient did not understand, or arguably chose to ignore, the warning illustrates that the standard a drug company needs to meet to fulfill its duty to warn

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82. *See Lacy*, 567 A.2d at 401 (finding the rationale supporting the learned intermediary rule in IUD contraception cases is stronger than in cases involving birth control pills because the patient must "rely on her physician's expertise whenever an IUD is used").

83. *See Reaves*, 765 F. Supp. at 1291. In *In re Norplant*, the court bluntly commented on the decision in *Edwards v. Basel Pharmaceuticals*, 933 P.2d 298 (Okla. 1997): "[w]hy the learned intermediary doctrine should somehow be less applicable when the severity of the side effects encourages the FDA to promote additional labeling escapes us." 165 F.3d at 379.

84. *MacDonald*, 475 N.E.2d at 65.

85. *Id.* at 71-72.

86. *Id.* at 67, n.4.

87. *Id.* at 67. A stroke occurs when a blood vessel that brings oxygen and nutrients to the brain bursts or is clogged by a blood clot or some other particle. Strokes are categorized into four main types, two caused by blood clots and two caused by hemorrhage, a rupturing of a blood vessel. Strokes caused by blood clots or other particles are far more common, accounting for about 70–80% of all strokes. American Heart Association, *Heart and Stroke A-Z Guide*, (last visited June 18, 2000) <http://www.americanheart.org/Heart_and_Stroke_A_Z_Guide/stroke.html>.

88. *MacDonald*, 475 N.E.2d at 67 n.4.

89. *Id.* at 72.

90. *Id. See* Henderson & Twerski, *supra* note 55, regarding the difficulty of proving that a plaintiff would have heeded a warning if given.

91. *MacDonald*, 475 N.E.2d at 72.

is difficult and perhaps unrealistic. While providing information about the risks of birth control pills directly to the consumer is valuable and important, the decision in *MacDonald* illustrates the unfair consequences of this requirement when a drug manufacturer believes it has presented the risks in lay language.[92]

A number of courts hearing similar cases have retained the learned intermediary rule and held for the drug manufacturer.[93] In *MacPherson v. Searle*,[94] a case in which a woman suffered a loss of vision as a result of using oral contraceptives, the plaintiff contended that the learned intermediary rule should not be applied and that the manufacturer was directly liable because it failed to supply an adequate warning. A pamphlet provided to the patient stated that blood clots "occur rarely in the blood vessels of the eye, resulting in blindness or impairment of vision in that eye."[95] The package insert also cautioned the user regarding "[d]isorders of vision."[96] Mrs. MacPherson acknowledged that she read the package insert, but "as a lay person reading the risks and adverse reaction section, . . . [she] did not realize that permanent loss of eyesight was a risk associated with birth control pills."[97] The court ruled that the warning was sufficient and the learned intermediary rule applied.[98] Even if the manufacturer had a duty to warn the patient directly, the court stated it likely would have found that the plain language of the package insert supplied adequate information.[99]

The *MacDonald* court appeared to focus on the role of physicians and drug manufacturers in prescription drug liability cases, but it actually may have been struggling with the unarticulated and underlying issue of the "balancing process . . . between the need for adequate recovery and viable enterprises."[100] In *Reyes v. Wyeth Laboratories*,[101] the court stated that a drug manufacturer is in a better

92. In *MacDonald*, the dissent argued that while the majority found it unnecessary to decide whether Ortho complied with the FDA's required language, "I do not believe that any rational trier of fact could have concluded that Ortho failed to comply with the regulation." *Id.* at 75.

93. *See Odgers*, 609 F. Supp. at 874 n.15; *MacPherson*, 775 F. Supp. at 425 (citing the dissent in *MacDonald* and listing fourteen court decisions that adhered to the learned intermediary rule).

94. 775 F. Supp. 417 (D.D.C. 1991).

95. *Id.* at 419-20.

96. *Id.* at 420 and 425.

97. *Id.* at 420.

98. *Id.* at 425.

99. *See id.*

100. *Reyes*, 498 F.2d at 1294 (citing Helene Curtis Industries, Inc. v. Pruitt, 385 F.2d 841, 862 (5th Cir. 1967)).

101. *Reyes*, 498 F.2d at 1264.

position to pay for injuries resulting from use when the risk "was foreseeable statistically, although unknowable individually."[102] Rather than the costs falling on the injured, the costs could be borne by the manufacturer as a foreseeable cost of doing business; this extra monetary burden would be "passed on to the public in the form of price increases to customers."[103] The court's task is to determine whether a person's injury occurred because of statistical probability, or because the physician or manufacturer failed to warn the injured plaintiff.

IV. WASHINGTON CASE LAW

Washington courts have decided few cases in which injured plaintiffs have directly sued pharmaceutical drug manufacturers.[104] The courts follow comment k of Section 402A of the Second Restatement, which defines pharmaceutical drugs as unavoidably unsafe products. In *Terhune v. A.H. Robins Co.*,[105] Washington adopted the learned intermediary rule and the courts have not since recognized any exceptions.

In *Terhune*, the plaintiff was injured by the Dalkon Shield, an IUD, when it perforated her uterus. She sued the manufacturer claiming that the company did not adequately warn her of the risks of using the device. The court concluded that the manufacturer was not liable because it had a duty to warn her physician; it did not have a duty to warn the patient directly.[106] The physician was aware of the risk but chose not to inform the patient, a choice, the court stated, that resulted from "an exercise of judgment on the physician's part."[107]

In contrast to the court in *MacDonald*,[108] the *Terhune* court emphasized the physician's responsibility to advise the patient of the advantages and disadvantages of various choices of therapy, even though the patient made the final choice.[109] Medical care decisions other than birth control selection can also present a variety of treatment choices, and a physician can encourage the patient to choose a

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102. *Id.* at 1294.

103. *See id.*

104. Cases decided by the Washington Supreme Court include *Young*, 130 Wash. 2d 160, 922 P.2d 59 (1996); *Washington State Physicians Ins. Exchange and Ass'n v. Fisons Corp.*, 122 Wash. 2d 299, 858 P.2d 1054 (1993); *Rogers v. Miles Laboratories, Inc.*, 116 Wash. 2d 195, 802 P.2d 1346 (1991); *McKee v. American Home Products*, 113 Wash. 2d 701, 782 P.2d 1045 (1989); *Terhune*, 90 Wash. 2d 9, 577 P.2d 975 (1978).

105. 90 Wash. 2d at 9, 577 P.2d at 975.

106. *Id.* at 17, 577 P.2d at 979.

107. *Id.* at 16, 577 P.2d at 979.

108. 475 N.E.2d 65.

109. *Terhune*, 90 Wash. 2d at 15, 577 P.2d at 978.

particular course for herself.[110] In any situation, "the patient is expected to look to the physician for guidance" regarding treatment and not to the manufacturer of products that might be prescribed.[111] The *Terhune* court found that the manufacturer has a duty to warn the physician and, if it performs this duty, even if the physician decides to withhold the information from the patient, the manufacturer should not be held accountable for an injury to the patient.[112] If the manufacturer has warned the physician of the danger attendant to the use of a product, the manufacturer need not inform the patient as well.[113]

Mrs. Terhune testified that she had reviewed a pamphlet published by the manufacturer and that the pamphlet did not mention any risk of uterine perforation. At the time of litigation, IUD manufacturers were not required to supply patients with product inserts.[114] Arguably, the pamphlet promoted the product without presenting the risks.[115] Even so, the court found that the physician decided whether to give Mrs. Terhune the pamphlet and whether to warn her of the risk of perforation.[116] Whether Mrs. Terhune would have chosen to use a Dalkon Shield if she had been informed of the risk is a matter of speculation. The case does illustrate the importance of balancing the presentation of benefits and risks in drug information provided to patients.

Washington courts consistently have found that only physicians play the key role of learned intermediaries. In *McKee v. American Home Products Corp.*,[117] the Washington Supreme Court refused to extend the duty to warn to pharmacists. The court held that pharma-

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110. *Id.*

111. *Id.*

112. *Id.* at 16-17, 577 P.2d at 979.

113. *Id.*

114. In 1977, the FDA required that a package insert be made available to patients interested in using an IUD as a contraceptive. The FDA required that the pamphlet list adverse reactions and risks. Spychala v. G.D. Searle & Co., 705 F. Supp. 1024, 1027-28 (D.N.J. 1988) (citing 21 C.F.R. § 310.502(b)(2)).

115. The risk of uterine perforation was purportedly minimal. *Terhune*, 90 Wash. 2d at 17, 577 P.2d at 979. A.H. Robins did, however, eventually withdraw the Dalkon Shield from the market in 1974 because of the number of women who reported injury and disease related to its insertion. Bankruptcy proceedings for A.H. Robins concluded in 1989 with the creation of the Dalkon Shield Claimants Trust. *See In re* A.H. Robins, Co., 42 F.3d 870 (4th Cir. 1994). This Comment focuses on the learned intermediary rule litigation and does not address the merits of the design defect litigation. For an account of this civil litigation, bankruptcy proceeding, and products liability litigation, see RICHARD B. SOBOL, BENDING THE LAW: THE STORY OF THE DALKON SHIELD BANKRUPTCY (1991).

116. *Terhune*, 90 Wash. 2d at 15-16, 577 P.2d at 979.

117. 113 Wash. 2d 701, 782 P.2d 1045. McKee also named her physician and the drug manufacturer as defendants. The Washington Supreme Court only heard the plaintiff's appeal from a summary judgment motion granted to the defendant pharmacists.

cists, like manufacturers, do not have sufficient medical education or knowledge of the patient's medical history to justify imposing upon them a duty to intrude into the physician-patient relationship.[118] The plaintiff, McKee, sought damages for physical and psychological injuries allegedly sustained as a result of an addiction to an amphetamine prescribed for weight loss.[119] Warnings accompanying the drug stated that the drug should be prescribed for only a few weeks because patients become tolerant to its anorectic effect and might become addicted and suffer adverse effects.[120] The pharmacists refilled McKee's prescription for over ten years. The court held that the pharmacist had a duty to accurately fill a prescription but did not have a duty to question a judgment made by the physician or to warn consumers.[121] Seemingly taken aback by the majority decision, Justice Dore, writing for the dissent,[122] wrote that the pharmacists have a duty of care as health care providers.[123] The dissent argued that knowing this drug should only be prescribed for a few weeks fit within the majority's definition of "obvious lethal dosages, inadequacies in the instructions" or "*known* contraindications" that require "corrective measures."[124]

The decisions in *Terhune* and *McKee* suggest that Washington courts view the physician's knowledge of any dangers to patients who take a particular drug as central to the physician's role as learned intermediary. In *Young v. Key Pharmaceuticals*, the Washington Supreme Court addressed the issue of when a drug company should warn a physician.[125] A young boy treated for asthma with the prescription drug theophylline suffered brain damage resulting from seizures allegedly caused by toxic levels of the drug in his bloodstream.[126] The boy had been suffering flu-like symptoms and a fever at the time. The plaintiff claimed that Key had not warned physicians about the effects of viral infection on a patient's ability to metabolize theophylline.[127] Concurrent with the time of the plaintiff's injury, another drug manufacturer had published an advertisement in a medical journal stating that high fever and certain viral illnesses could decrease elimination of

118. *McKee*, 113 Wash. 2d at 711, 782 P.2d at 1051.
119. *Id.* at 704, 782 P.2d at 1047.
120. *Id.* at 722, 782 P.2d at 1056.
121. *Id.* at 720, 782 P.2d at 1055-56.
122. Justice Dore wrote the dissent with Justices Utter and Brachtenbach and Justice Pro Tem Pearson concurring.
123. *McKee*, 113 Wash. 2d at 723, 782 P.2d at 1057 (Dore, J., dissenting).
124. *Id.* at 734, 782 P.2d at 1063.
125. 130 Wash. 2d 160, 922 P.2d 59 (1996).
126. *Id.* at 162, 922 P.2d at 60.
127. *Id.*

the drug. Because the plaintiff did not present sufficient evidence that Key knew or should have known that children with fevers were at greater risk,[128] the supreme court reversed the decision of the appellate court and affirmed the jury verdict at trial that Key was not negligent.[129]

Nothing in *Young* or in other cases indicates that Washington courts will depart from the learned intermediary rule, so long as drug manufacturers adequately warn physicians of risks associated with the drug. Although not raised in *Young*, an issue presented by the facts in that case is why one drug company chose to issue a warning about theophylline and another did not.[130] Key contended that the relationship between the fevers or viral illnesses and theophylline was "not yet clinically reliable."[131] The other manufacturer may have had more data on which to base its decision, or it may have acted more cautiously on the basis of its internal policy. Another question is whether the FDA was involved in the decision-making of either manufacturer.

V. FDA REGULATIONS

A. Compliance—Minimum Requirement, Rebuttable Presumption, or Evidence to Be Considered?

In determining whether a manufacturer has met its duty in failure to warn cases, courts have considered the weight that should be given to a drug manufacturer's defense that it complied with pertinent FDA regulations. According to a minority, compliance creates a rebuttable presumption that the manufacturer has met its duty to warn.[132] The majority of courts, including courts that have decided to displace the learned intermediary rule or to create an exception to it, as well as those that have retained the rule, holds that compliance with FDA regulations is not dispositive.[133]

The majority view is that a manufacturer's compliance with FDA regulations shows only that the manufacturer has met minimum safety requirements.[134] Courts support this view with the comments

128. *Id.* at 174-75, 922 P.2d at 66-67.

129. *Id.* at 179, 922 P.2d at 68-69.

130. The evidence regarding the other manufacturer's advertisement was not admitted because it lacked the proper foundation. This evidence would be relevant to prove negligence only if it indicated the industry standard. *Id.* at 174-75, 922 P.2d at 66-67.

131. *Id.* at 165, 922 P.2d at 62.

132. *See Perez*, 734 A.2d at 1245.

133. *See Martin*, 661 N.E.2d at 243-44 and citations therein.

134. *See, e.g., Allen*, 708 F. Supp. at 1152 (stating regulations established by the FDA are

of the FDA Commissioner, who stated that whether a manufacturer is liable depends "upon the facts surrounding the manufacture, sale, and use of the drug product, and on the nature of the injury."[135] Furthermore, laws governing drug product liability "can be adjusted by state courts and Legislatures in light of the facts presented by patient labeling."[136] Whether a manufacturer knew or should have known that a drug presented greater dangers than those indicated in its required warning is a decision for the courts.[137] State courts provide protection for plaintiffs because plaintiffs cannot contest the adequacy of the warnings by bringing suit against the FDA. Under the Federal Drug and Cosmetics Act, consumers do not have a private right of action.[138]

Not all courts are convinced that the FDA has adequate staffing, expertise, or databases to warrant substituting FDA compliance for judicial scrutiny.[139] Even when a drug manufacturer adheres to all FDA regulations, all the risks related to the administration of a particular drug may not come to the attention of the agency until more consumers have used the drug. A drug company may perform the clinical studies necessary to assess a drug's safety and then, after the drug is marketed and more widely distributed, find that it presents additional risks. Not until the drug is sold and more people begin to use it do the more rare, unexpected adverse events become apparent. *Young* raised the issue of when a manufacturer should warn physicians of an unexpected adverse effect of a drug.[140] The defendant argued that a manufacturer's knowledge of adverse effects caused by its product is not imputed when a competitor chooses to inform the medical community about a serious adverse effect associated with a similar product.[141]

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minimum standards and do not conflict with state laws that set higher standards for due care and safety); *Spychala*, 705 F. Supp. at 1030 ("[W]hile FDA regulation of prescription drugs may establish minimum standards for product design and warning labels, compliance does not necessarily absolve a manufacturer of tort liability."); *Odgers*, 609 F. Supp. at 877-78 ("FDA's regulation of oral contraceptives was not intended in any way to preclude imposition of tort liability for failure to warn."); *MacDonald*, 475 N.E.2d at 70-71 ("Compliance with FDA requirements, though admissible to demonstrate lack of negligence, is not conclusive on this issue."); *McEwan*, 528 P.2d at 534 (holding warnings may be found inadequate even though all government regulations and requirements were satisfactorily met).

135. *Spychala*, 705 F. Supp. at 1031; (quoting 43 Fed. Reg. 4214 (1978)); *Odgers*, 609 F. Supp. at 877; *MacDonald*, 475 N.E.2d at 70.

136. 43 Fed. Reg. 4214 (1978).

137. *See McEwan*, 528 P.2d at 534.

138. *See Martin*, 661 N.E.2d at 356.

139. *See* Grundberg v. Upjohn Co., 813 P.2d 89, 100 (Utah, 1991) (Stewart, J., dissenting) (citing Toner v. Lederle Laboratories, 732 P.2d 297, 313 (Idaho 1987)).

140. *Young*, 130 Wash. 2d at 160, 922 P.2d at 59.

141. *Id.* at 174-75, 922 P.2d at 67-68.

While drug manufacturers are required by the FDA to report all unexpected and serious adverse events,[142] the FDA may or may not respond to the manufacturer in a timely manner. In *Grundberg v. Upjohn Co.*,[143] the dissent contended that the FDA has made critical errors in judging some products to be safe.[144] Drugs that purportedly met the FDA requirements were found later to pose significant risks.[145] Delay in identifying the risks leads to delay in warning physicians about the potential adverse effects of a drug upon certain patients.[146]

A minority of courts has found that when a pharmaceutical company adheres to FDA regulations, the company presumptively meets its duty to warn. In *Perez v. Wyeth Laboratories*,[147] the court asserted that if Wyeth, the manufacturer of Norplant, complied with the FDA guidelines regarding advertising, labeling, and warning, then it presumptively met its duty to warn.[148] The court reasoned that by applying the rebuttable presumption, the manufacturer's duty to both physicians and the public was "harmonized" with the public's interest in being informed about available therapies.[149] The court's ultimate rationale was that without this presumption, drug manufacturers would be considered guarantors of patient safety and sued for injuries that were not scientifically verifiable.[150] The consequence that concerned the *Perez* court and commentators is that over-deterrence will

142. 21 C.F.R. § 314.80 (2000). Post-marketing reporting of adverse drug experiences requires that the manufacturer report unexpected adverse events within 15 days after the manufacturer is notified that such an event occurred. § 314.80(c)(l)(i). A seller or distributor of the drug is required to keep these records for a minimum of ten years. § 314.80(i).

143. 813 P.2d 89 (1991). The issue before the court was whether a drug manufacturer should be held to strict liability when the plaintiff's claim is based on a design defect. The court ruled a drug that has been approved by the FDA for sale has passed through "the extensive regulatory system" and should be immune from strict liability. *Id.* at 99. While the court accepted adherence to regulations as a defense to allegations of design defect, it ruled that a company may still be liable for a failure to warn. *Id.* at 97. The data that provide the basis for the label of a drug are the same data that show that the drug can safely be given to patients. The court's willingness to accept compliance as support for drug design, but not adequate warning, seems inconsistent.

144. *Id.* at 100.

145. *See id.* The dissent stated "[n]umerous congressional investigations have demonstrated that the FDA has often approved drugs in complete ignorance of critical information relating to the hazards of such drugs which was contained either in its own files or in the published medical literature, or both." *Id.*

146. *See id.* at 100-02.

147. 734 A.2d 1245 (1999).

148. *Id.* at 1259.

149. *Id.*

150. *Id.*

impede the research and development of new products.[151] This argument, however, remains theoretical.[152]

The majority viewpoint, that meeting FDA requirements is a minimum standard, will result in a more consistent application of the law and arguably provide better protection to the consumer. The FDA, like other regulatory agencies, can change policies as political realities change. Even though federal agencies may sometimes be slow to change policies (the FDA is one of the most notorious in this regard[153]), agency rules can be challenged in court. The FDA also establishes policies on pharmaceutical drug advertising; thus, the agency and those it impacts should consider what role the FDA should play in regulating information content provided from drug companies to consumers and physicians.

B. FDA Regulation of Drug Manufacturer Print and Broadcast Advertising

The FDA has regulated drug product advertising since 1963. The early statutes did not contain language defining the audience for these advertisements, but at that time Congress was concerned with regulating advertisements directed to health care professionals.[154] In the mid-1980s, drug companies began to advertise directly to consumers, prompting the FDA to request a voluntary moratorium on direct-to-consumer advertising in order to allow it to review the practice.[155] In 1985, the moratorium was withdrawn,[156] and drug companies have steadily increased direct-to-consumer advertising.[157]

The FDA has defined three categories of direct-to-consumer promotion. One category consists of "product-claim" advertisements, which contain safety and efficacy claims about a particular drug.[158]

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151. *See id. See also* Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, U. MICH. J. L. REFORM 461, 466-67 (1997).

152. In *Grundberg*, the dissent contended that increasing profitability would result in making more unnecessarily dangerous drugs available. "Furthermore, not a shred of evidence has been presented to this Court that indicates that liability under the tort system has deterred pharmaceutical companies from introducing new drugs." 813 P.2d at 102-03.

153. *See* Robert W. Hamilton, *Procedures for the Adoption of Rules of General Applicability: The Need for Procedural Innovation in Administrative Rulemaking*, 60 CAL. L. REV. 1276, 1287-88 (1972) (noting that more than 7,700 pages of transcript were generated regarding the question of whether peanut butter should consist of 90% peanuts or 87.5% peanuts).

154. For a brief historical perspective, see Noah, *supra* note 3, at 142-43 and Reeves, *supra* note 1, at 663. Prescription drug advertisement regulations are codified at 21 C.F.R. § 202.1 (2000).

155. Direct-to-Consumer Promotion, 60 Fed. Reg. 42,581 (1995).

156. *Id.*

157. *See supra* note 1.

158. Direct-to-Consumer Promotion, 60 Fed. Reg. at 42,582.

The second category includes "help-seeking" advertisements, which provide information about a disease or condition and recommend that the consumer consult a health care provider.[159] Generally, mention or discussion of particular drugs or treatments is excluded. The third, "reminders," contain limited information about a particular drug and do not include "representations or suggestions" about the drug.[160]

Regulations governing the content of print and broadcast advertisements necessarily differ because of the differences in each type of media. For print media, a brief summary must present a description of side effects, contraindications, and effectiveness,[161] as well as all risk-related information that is required for a product's package labeling.[162] Drug manufacturers could not practically meet these requirements in television commercials and in other broadcast media. Therefore, in 1997, the FDA modified the brief summary requirements, adding the requirement for an "adequate provision" and a "major statement."[163] The content of a major statement must include the major risks associated with the drug and must be presented either in the audio portion or in both the audio and visual portion of the broadcast advertisement.[164] In conjunction with presentation of risk information in the major statement, the "adequate provision" requirement is fulfilled when the company disseminates the approved drug package label.[165] Because the labeling may be too complex for consumers without medical training to understand, the guidelines encourage manufacturers to provide "consumer-friendly information that is consistent with approved product labeling."[166]

Advertisements are reviewed within the FDA by the Division of Drug Marketing, Advertising, and Communications (DDMAC).[167]

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159. *Id.*

160. *Id.*

161. 21 C.F.R. § 202.1(e)(1) (2000).

162. *See supra* note 26. Labeling is a term of art and includes written, printed, or graphic information "(1) upon any [drug or device] or any of its containers or wrappers, or (2) accompanying such [drug or device]." 21 U.S.C. § 321(k) & (m) (1999).

163. Draft Guidance for Industry; Consumer-Directed Broadcast Advertisements, 62 Fed. Reg. 43,171 (1997). The Draft Guidance can be accessed at <http://www.fda.gov/cder/guidance/index.htm.> The regulations specifically addressed advertising of prescription drugs through broadcast media, which included radio, television, or telephone communication systems. *See* Allen, *supra* note 3, at 123-24.

164. Draft Guidance for Industry, 62 Fed. Reg. at 43,172.

165. *Id.* The FDA encourages drug companies to include the FDA-approved patient labeling as part of the full prescribing information. The Draft Guidance noted that the FDA would solicit feedback as to whether consumers took advantage of the availability of these product inserts. 62 Fed. Reg. at 43,173.

166. Draft Guidance for Industry, 62 Fed. Reg. at 43,172.

167. Communications through Internet websites generally must meet the more extensive requirements governing print media. Even though DDMAC has sent a few warning letters to

The Division does not require pre-screening of advertisements prior to airing; therefore, DDMAC responds to ads already viewed by the public.[168] If an advertisement does not present a summary of risks, or if the presentation is not equal in display to the description of the potential benefit of the drug, DDMAC considers the advertisement misleading and it will send a "notice of violation" letter or, for more flagrant conduct, a warning letter, to the offending manufacturer.[169] In the letter, DDMAC will describe the violation and what remedial action is expected to correct the presentation. DDMAC posts the letters on its website, which is accessible to the public.[170]

Television advertisements for prescription drugs, because of their brevity and minimal content, would likely not be considered, and should not be considered, a warning of the risks to consumers if they take the drugs. However, lack of adequate information in the label and in consumer pamphlets given to the patients could provide the basis of a lawsuit for failure to warn. At this time, drug companies are asked to provide this information as a service; however, the guideline does not have the weight of law behind it. Advocates for control of drug manufacturer advertising can comment to the FDA that the dissemination of information should move beyond a recommendation to a requirement.[171]

C. *Future Challenge to FDA's Power to Regulate Drug Manufacturer Advertising*

Reliance on the FDA to monitor prescription drug commercials and to force drug companies to comply with the guidance may be misplaced. Drug companies are expected to increase the advertising of

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drug manufacturers, it has not actively monitored pharmaceutical company websites. The FDA has not commented whether the agency has adequate resources for monitoring websites or whether it has the authority to do so. The Federal Trade Commission may be the appropriate agency for regulating website content. *See generally* Kristen Green, Comment, *Marketing Health Care Products on the Internet: A Proposal for Updated Federal Regulations*, 24 AM. J.L. & MED. 365 (1998); Marilyn A. Moberg et al., *Surfing the Net in Shallow Waters: Product Liability Concerns and Advertising on the Internet*, 53 FOOD DRUG L.J. 213 (1998).

168. *See* Direct-to-Consumer Promotion, 61 Fed. Reg. 24,314, 24,315 (2000). *See also* Terzian, *supra* note 3, at 153; Reeves, *supra* note 1, at 666 and notes therein.

169. Reeves, *supra* note 1, at 666 and notes therein. An advertiser is prohibited from presenting false or misleading statements. 21 U.S.C. § 352(n) (1999).

170. The DDMAC home page can be accessed at <http://www.fda.gov.cder.ddmac>. The warning letters can be accessed through the home page or at <http://www.fda.gov./cder/warn/index.htm>. Even though a manufacturer's nonconformity with a guidance principle does not have the same legal consequence as a violation of a regulation, the warning letters have impact. A broadcast company removed advertisements for Claritin when the manufacturer, Schering-Plough, received a warning letter from DDMAC. *See* Terzian, *supra* note 3, at 153-54.

171. *See* Schwartz, *supra* note 3, at 847.

their products on television.[172] The increase will require DDMAC to expend more resources to monitor the increase in the number of commercials. In times of limited resources, surveillance may be minimal because the FDA must maintain its primary mission to evaluate the safety and efficacy of new drugs.[173]

In addition, the FDA may soon face a constitutional challenge of its power to regulate advertisements. The Washington Legal Foundation (WLF),[174] a free market-oriented public interest law and policy center, is considering whether to challenge FDA guidelines on the grounds that they violate a drug company's rights of commercial free speech.[175] The issue is whether the FDA's restrictions on truthful, nonmisleading speech present an undue burden on constitutionally protected speech.[176]

The WLF recently challenged certain FDA requirements imposed on manufacturers that promote off-label use of their products.[177] An off-label use is one not specifically defined on the drug's label.[178] Physicians are free to prescribe a drug for an off-label use, such as prescribing a different dose or a different dosing schedule or prescribing a drug for a disease not named on the label but related to the medical condition indicated on the label (thus, varying the patient population treated).[179] While off-label use by physicians is considered a common practice, particularly in oncology[180] and pediatrics,[181] and in

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172. *See supra* note 1.

173. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301; 21 U.S.C. 355(a), (b), and (j) (1994).

174. The Washington Legal Foundation (WLF) advocates "free enterprise and economic growth, a balanced and reasonable judiciary, limited and accountable government, due process rights for the victims of violent crime, and the effective administration of justice." Capital Research Center, *Guide to Nonprofit Advocacy and Policy Groups* (last visited June 18, 2000) <http://www.capitalresearch.org/advocacy%20guide/Groups/wlf.html>. The WLF Internet homepage can be accessed at www.wlf.org.

175. *DTC Ads Could Be WLF's Next Constitutional Challenge*, THE PINK SHEET, FDA/F-D-C REPORTS, INC., Oct. 18, 1999, at 27.

176. *Id.* (quoting Sandra Dennis, attorney for Morgan, Lewis & Bockius).

177. Washington Legal Foundation v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998) *appeal dismissed, vacated in part sub nom.* Washington Legal Foundation v. Henney, 202 F.3d 331 (D.C. Cir. 2000); Washington Legal Foundation v. Henney, 56 F. Supp. 2d 81 (D.D.C. 1999) *appeal dismissed, vacated in part* 202 F.3d 331.

178. *See supra* notes 26 and 163.

179. A drug manufacturer designs its clinical studies to investigate the treatment of a particular disease or condition in a particular, well-defined patient population. The results of the studies, in turn, define what the drug company can claim in its label as a use for the drug. *See* 21 C.F.R. 201.56 (2000).

180. *See Washington Legal Foundation*, 13 F. Supp. 2d at 56 (citing Off-Label Drugs, Reimbursement Policies Constrain Physicians in Their Choice of Cancer Therapies, GAO/PEMD-91-14 at 4 (Sept. 1991)).

181. *See id.* (citing Deposition of William K. Hubbard, Associate Commissioner for Policy

some circumstances constitutes the standard of medical care, in other instances, such use has been harmful.[182] In an attempt to ensure that public health is protected, the FDA promulgated guidelines limiting the distribution of "enduring materials" (journal article reprints and text books)[183] by a manufacturer and defining the permissible involvement of drug companies in continuing medical education (CME) seminars.[184] The District Court for the District of Columbia ruled that these regulations violate commercial free speech.[185] In a subsequent opinion, the court held that the entire Food and Drug Administration Modernization Act (FDAMA), which incorporated the above guidance plus additional restrictions, also violated constitutionally protected commercial speech rights.[186]

The FDA filed an expedited appeal with the Disrict of Columbia Circuit Court of Appeals. The FDA was expected to argue that no other alternatives adequately address the government's substantial interest in regulating off-label use.[187] The court expected to hear "a difficult constitutional question of considerable practical importance," but instead saw the dispute disappear "before [its] eyes."[188] At oral argument, the government stated that neither FDAMA nor the CME Guidance independently authorized the FDA to prohibit or sanction speech.[189] Instead, the FDA created a safe harbor for manufacturers, ensuring that the FDA would not use FDAMA to independently challenge the content of information about off-label use.[190] In other words, the government agreed with the WLF that FDAMA did not provide the FDA with authority to regulate a manufacturer's speech.[191]

Coordination, at 59-61 (Mar. 21, 1996)).

182. *See id.* at 56-57. In the 1980s, physicians prescribed two antiarrythmic drugs to treat minor disturbances in patients who recently had heart attacks. Taking these drugs in combination increased their risk of dying by two-and-one-half times. *Id.* at 56.

183. Advertising and Promotion; Guidance, 61 Fed. Reg. 52,800 (1996) (codified at 21 U.S.C. 360aaa-1 (1999)).

184. Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,093 (1997).

185. *Washington Legal Foundation*, 13 F. Supp. 2d at 56.

186. *Washington Legal Foundation*, 56 F. Supp. 2d at 87.

187. *See WLF Ruling Offers No Viable Alternatives for Encouraging sNDAs—FDA Appeal*, THE PINK SHEET, FDA/F-D-C REPORTS, INC., Oct. 18, 1999, at 28.

188. Washington Legal Foundation v. Henney, 202 F.3d 331, 335 (D.C. Cir. 2000).

189. *Id.* at 335. The court noted that both parties' briefs "were quite confusing" regarding the meaning of FDAMA and the CME Guidance. The FDA was asked to clarify its position at oral argument because, at times, the FDA's brief shared the WLF's assessment that the FDA had legal authorization to restrict a drug manufacturer's speech, but more frequently the government asserted that compliance provided nothing more than a safe harbor. *Id.*

190. *Id.*

191. *Id.* at 336. The FDA does retain the prerogative to use as evidence questionable pro-

If the FDA had not changed its stance and the court had decided the constitutional issue in favor of WLF's position, the consequences might have been more far-reaching than regulation of off-label use.[192] Possibly, the FDA's power to regulate all drug labeling could have been restricted.[193] The impact of such decisions on advertising might also have limited the power of DDMAC, which protects against "potentially misleading" speech.[194]

Court challenges to the FDA's authority and the cumbersome process of working through government bureaucracy potentially hamper the effectiveness of DDMAC to regulate prescription drug advertising.[195] The FDA's mission to protect the health of citizens, as well as the importance of getting safety information to consumers, would likely ensure that risk information would not be removed from advertisements. Nevertheless, if requirements for drug manufacturer advertising become less stringent, defendant drug companies will have little trouble showing compliance.

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motional conduct related to a CME Guidance or FDAMA in a misbranding or "intended use" enforcement action. *Id.*

192. One of the present consequences is that the position of the FDA is unclear, leaving drug companies unsure of what can and cannot be said. One commentator believes that

> [t]he decision returns an issue with significant First Amendment implications to the caverns of informal, ad hoc FDA enforcement. By forcing potential speakers to guess at future agency actions and motives, the decision threatens to 'chill' speech that modern courts have striven mightily to protect.

Glenn C. Smith, *Faint-Hearted 'Off-Label' Ruling*, NATL. L. J., Mar. 20, 2000, at A21.

193. *See FDA Bites Its "Free Speech" Bullet in Appeal of WLF Defeat*, DICKINSON'S FDA REVIEW, Aug. 1999, at 2. Former FDA counsel Peter Barton Hutt and William W. Vodra and American University law professor Lewis Grossman commented that the decisions of the court in *WLF v. Friedman*, *WLF v. Henney*, and in *Pearson v. Shalala*, 164 F.3d 650 (D.D.C. 1999) (holding that FDA requirement that health claims be omitted from dietary supplement labels violates constitutional free speech rights) would restrict labeling information about the effectiveness of the drug. Vodra suggested that the "decisions could return FDA to pre-1962 days before there was a drug-efficacy requirement." *Id.*

194. *See id.* at 3. At present DDMAC does not undertake a constitutional analysis of advertisement content to determine if the advertisement is misleading speech. 21 C.F.R. § 202.1(e)(5) and (e)(6) provide extensive criteria to determine what is false, lacking in fair balance, or misleading.

195. Rather than pursue action through DDMAC, the drug company Zeneca lodged its marketing complaints against Eli Lilly by filing a law suit, alleging Lanham Act violations. Commenting on Zeneca's choice, attorney William Vodra observed that Zeneca obtained information to support its claims through the legal process of discovery in less time than would be required by DDMAC. *Do Firms Need Courts to Protect Them from DDMAC Ineptness?*, DICKINSON'S FDA REVIEW, Aug. 1999, at 5.

VI. ADVERTISING—ITS IMPACT

A. Advertising and the Learned Intermediary Rule

Advertising of prescription drugs has changed the relationship among patients, physicians, and pharmaceutical companies. Some commentators and courts advocate that allowing a drug company to communicate directly to the consumer requires the company to provide warnings directly to the patient and, if the warnings are inadequate, be directly liable to the consumer.[196] Advocates of an exception to the learned intermediary rule believe that health care providers should no longer shield manufacturers from direct liability.[197] Others maintain that direct-to-consumer advertising should not create an exception to the learned intermediary rule because health care providers are still required to write prescriptions.[198] Two recent court decisions reflect these two opposing views.

1. *In re Norplant* and *Perez v. Wyeth Laboratories*

In *In re Norplant*,[199] the court emphasized that the rationale for the learned intermediary rule was to shield drug manufacturers from liability when a properly trained physician prescribes a drug.[200] In this way, the drug manufacturer is encouraged to make prescription drugs available despite their potentially harmful side effects.[201] In contrast, in *Perez v. Wyeth Laboratories*,[202] the court maintained that the patient's interest in reliable information should predominate a policy interest in insulating manufacturers from liability.[203]

Both lawsuits were brought by women claiming they were injured by the contraceptive Norplant, which is sold by Wyeth Laboratories, a subsidiary of American Home Products.[204] In *In re Nor-*

196. *See, e.g.*, Schwartz, *supra* note 3, at 845 (stating that the same legal principles that apply to other product sellers should apply to drug manufacturers who advertise); Garside v. Osco Drug, Inc., 764 F. Supp. 208, 211 n.4 (D. Mass. 1991), *rev'd on other grounds*, 976 F.2d 77, 80 (1st Cir. 1992) (noting that the decision may have been different if the manufacturer had directly advertised to consumers); Doe v. Alpha Therapeutic Corp., 3 S.W.3d 404, 419 (Mo. Ct. App. 1999), (stating without citation to any authority that advertising of a drug product provides an exception to the learned intermediary rule).

197. Schwartz, *supra* note 3, at 842-45.

198. *See generally* Noah, *supra* note 3; Allen, *supra* note 3.

199. 165 F.3d 374 (1999).

200. *Id.* at 379.

201. *Id.*

202. 734 A.2d at 1245.

203. *Id.* at 1262.

204. In *In re Norplant*, five recipients of Norplant brought the first of three bellwether suits, asserting that Wyeth violated the Texas Deceptive Trade Practices Act. 165 F.3d at 377. In *Perez*, which also had five plaintiffs, the plaintiffs sought a determination of whether the

plant, the plaintiffs argued that the learned intermediary rule should not apply because Wyeth aggressively marketed Norplant.[205] However, the plaintiffs did not present any evidence that their decision to use Norplant was influenced by advertisements. The Fifth Circuit stated that even if evidence of such influence had been heard, as long as a physician-patient relationship existed, the court would apply the learned intermediary rule.[206] Thus, the court found that because Norplant is a prescription drug and because minor outpatient surgery is required for implantation, the physician actively participated in the patients' health care decision.[207]

In *Perez*, the New Jersey court maintained that the way of doing business in the pharmaceutical industry has changed; therefore, the underlying policies of the learned intermediary rule require reexamination.[208] The court summarized its view by asserting that a drug company should not be relieved of a duty to provide proper warnings of the dangers or side effects of a drug when it undertakes mass marketing of the drug in order to influence a patient's choice, and when it makes direct claims to consumers about the efficacy of its product.[209]

The *Perez* court declared that the policies supporting the learned intermediary doctrine were less meaningful when drug manufacturers advertised directly to the consumer.[210] The court asserted that the only policy that could justifiably support the rule was the need for a physician to interpret complex medical information.[211] The court and commentators suggest that advertising significantly disrupts the physician-patient relationship by allowing manufacturers to communicate directly with the consumer through print and broadcast advertising.[212] The question becomes whether advertising disrupts the relationship to such an extent that the physician's role in the patient's care has been abrogated.

2. Advertising and the Patient-Physician Relationship

Advocates for creating an exception to the learned intermediary rule contend that by advertising, a manufacturer affects the patient-

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learned intermediary doctrine applied. The New Jersey Supreme Court did not decide Wyeth's liability for plaintiffs' alleged injuries. 734 A.2d at 1248.

205. *In re Norplant*, 165 F.3d at 379.

206. *Id.*

207. *Id.*

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

209. *Id.*

210. *Id.* at 1255-56. The court listed the policies as set out in Noah, *supra* note 3, at 157-59.

211. *Perez*, 734 A.2d at 1256.

212. *Id.* at 1255-57.

doctor relationship because it influences the patient to ask for, and perhaps demand, a particular product.[213] In *Perez*, the court raised an additional concern: that in the changing health care environment, physicians have less time to spend with patients and, as a result, will acquiesce more readily to patient demands.[214] Because physicians are "inundated with information about various prescription drug products," their role may be limited when prescribing drugs.[215]

Even though direct-to-consumer advertising has interjected drug manufacturers into the physician-patient relationship, physicians cannot abdicate their role as healers. A physician has ethical and legal obligations to provide the best care for his or her patients' health needs. Bowing to a patient's insistence on a particular treatment can ultimately lead to undesirable consequences. For example, physicians often succumb to the demands of patients and parents of ill children to prescribe antibiotics for the common cold.[216] The over-prescription of antibiotics has led, in part, to the emergence of bacteria resistant to more common antibiotics, leaving physicians with fewer choices for treatment.[217] Patients should be their own best advocates for their health care, but a physician should remain one of the best resources to help evaluate information.

A correlation between direct-to-consumer advertising and disruption of the patient-doctor relationship has not been established. However, if courts acquiesce to this unsubstantiated influence, the result is destruction, not disruption, of the patient-doctor relationship. Such reasoning becomes an excuse to hold manufacturers directly liable for injuries associated with prescription drugs, ultimately removing the physician's obligation to decide whether to prescribe a drug

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213. *See, e.g.*, Schwartz, *supra* note 3, at 843-44.

214. *Perez*, 734 A.2d at 1255 (citing Sheryl Gay Stolberg, *Faulty Warning Labels Add to Risk in Prescription Drugs*, N.Y. TIMES, June 4, 1999, at A27). The court quoted the article: "In a 1997 survey of 1,000 patients, the F.D.A. found that only one-third had received information from their doctors about the dangerous side effects of drugs they were taking." *Id.*

215. Hill v. Searle Laboratories, 884 F.2d 1064, 1071 (8th Cir. 1989).

216. *See, e.g.*, D.B. Jernigan et al., *Minimizing the Impact of Drug-Resistant Streptococcus Pneumoniae (DSRP)*, 275 J. AMER. MED. ASSOC. 206 (1996); A.C. Nyquist et al., *Antibiotic Prescribing for Children with Colds, Upper Respiratory Tract Infections, and Bronchitis*, 279 J. AMER. MED. ASSOC. 875 (1998).

217. *See* Nyquist et al. and Jernigan et al., *supra* note 217. *See also* L.F. McCaig and J.M. Hughes, *Trends in Antimicrobial Drug Prescribing Among Office-Based Physicians in the United States*, 279 J. AMER. MED. ASSOC. 214 (1998). The common cold, caused by viruses, is not affected by antibacterial agents. Exposure of a person's normal bacterial flora to antibiotics contributes to increasing resistance of potential pathogens to commonly used antibiotics. Treating diseases caused by bacteria that have become resistant to antibiotics requires that patients use more expensive and potentially more toxic agents. The ultimate concern is that the antibiotics currently available will be ineffective in the future.

and to choose which drug to prescribe. The central role of the physician in a patient's care cannot be forgotten or minimized.

Critics of the learned intermediary rule who advocate a manufacturer's direct liability to the patient do not maintain that a drug manufacturer does not have a duty to warn the physician.[218] The complexity of the material describing the risks and benefits of a particular drug becomes the most important rationale for retaining the learned intermediary rule. The physician is the learned intermediary because the physician has training, experience, and knowledge of the patient, all of which are required for optimal care.[219] In *Perez*, the court ultimately concluded, "neither the physician nor the manufacturer should be entirely relieved of their respective duties to warn."[220] In this scenario, a plaintiff would bring both the physician and manufacturer into court, and the jury would determine the contribution of each to the proximate cause of harm.[221]

The *Perez* court may be correct in its assessment of a jury's ability to analyze different defendants' relative contribution to a plaintiff's harm, but the role of direct-to-consumer advertising in liability should be viewed skeptically. The goal of advertising is to sell a product,[222] and this goal is not different when the product is a prescription drug. Advertisements, even if balanced, do not constitute warnings. Therefore, if a duty to warn was created merely by advertising, drug manufacturers would need to develop additional means to fulfill that duty. For example, the FDA could expand its requirement that manufacturers provide understandable written information to patients who are prescribed products that are advertised.[223] Drug companies may protest these additional costs; however, additional advertising may result in increased sales. To determine whether a drug manufacturer proximately caused an injury claimed by the plaintiff, the court would first examine whether the advertisement presented a balance of risks and benefits. The next question would be whether written product

218. *See generally* Noah, *supra* note 3, at 157-59.

219. *See* citations, *supra* note 37.

220. *Perez*, 734 A.2d at 1262-63.

221. The *Perez* court believed that this was a workable system. The pharmaceutical manufacturer could seek contribution, indemnity, or exoneration if the physician was negligent. " In our experience, jurors are extremely skilled at sorting out the justly and legally responsible parties." *Id.* at 1263. (citing Estate of Chin v. St. Barnabas Med'l Ctr., 734 A.2d 778 (N.J. 1999)).

222. *See* Jon D. Hansen & Douglas A. Kysar, *Taking Behavioralism Seriously: Some Evidence of Market Manipulation*, 112 HARV. L. REV. 1420, 1427 (1999). "[M]anufacturers have every incentive to utilize cognitive biases to lower consumer appreciation of product risks. Such manipulation . . . is simply another form of cost externalization, a practice that manufacturers naturally pursue in an effort to avoid costs and increase profit margins." *Id.*

223. Schwartz, *supra* note 3, at 847.

information was provided to the patient. Ultimately, the adequacy of the product insert would be decided. The majority of courts, however, has not found that providing a patient with a product insert creates an exception to the learned intermediary rule.[224] The minority decisions have been disfavored, and an advertising exception may not be recognized in those jurisdictions either.[225] If an extensive written description of the risks and benefits of a drug is not accepted by courts as adequate warning, a 30-60 second television spot, even if balanced, certainly should not be either.

B. *Marketing Truths*

The practice of medicine in the United States is less paternalistic than in the past because patient involvement in health care decisions has increased.[226] Patients have greater access to information, particularly through the Internet, and also have more choices in the type of health care sought, as alternative medicine becomes more acceptable to insurance carriers in addition to traditional Western practice. Direct-to-consumer advertising can be another source of information for consumers who want to become advocates for their own health care. Advertising, however, does influence consumers and cannot simply be dismissed.[227]

Because health is critically important to consumers and their families, the information in and presentation of health care product advertisements has greater significance for consumers than the contents of advertisements for hair care products or athletic shoes. Commentators Jon Hansen and Douglas Kysar argue that consumers are susceptible to manufacturer manipulation, which likely results in the purchase of too many risky products.[228] They support their con-

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224. *See, e.g. Martin*, 661 N.E.2d at 356; *MacPherson*, 775 F. Supp. at 425-26; *Lacy*, 567 A.2d at 401-02.

225. *See, e.g., Martin*, 661 N.E.2d at 243. The *Reaves* court disfavored the decisions in *Stephens* and *Odgers*, cases where courts refused to apply the learned intermediary doctrine when the drug was an oral contraceptive. *Reaves*, 765 F. Supp. at 1290. In *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 80 (1st Cir. 1992), the court cited *MacDonald* as authority for the general applicability of the learned intermediary rule even though the *MacDonald* court created an exception to the rule. The holding of *MacDonald* was not discussed in *Martin*; therefore, whether the court was minimizing the *MacDonald* decision as one that held an exception to the learned intermediary rule is not known.

226. *See Perez*, 734 A.2d at 1255.

227. *See* Hanson & Kysar, *supra* note 233, at 1429. Hanson and Kysar write that a "multitude of nonrational factors influence individual decisionmaking, [and] consumers cannot be expected to engage in efficient product purchasing analyses—regardless whether manufacturers are required to supply product warnings." *Id.* at 1425. Pharmaceutical drug advertising, particularly advertising directed to physicians, is briefly discussed. *Id.* at 1455-59.

228. *Id.* at 1425. Hanson and Kysar argue their review of behavioral research and evidence

clusion with an analysis of the influence that cigarette advertisements have on consumers.[229] Through advertisements, tobacco companies convinced the public that filter and low tar cigarettes were less harmful than other cigarettes.[230] Scientific analysis does not support that contention.[231]

Drug manufacturers that have advertised on television have reported an increase in sales.[232] Whether patients requesting the drugs are newly identified as having a particular condition that is treatable with the medication or whether the sales represent patients who have requested a switch in medications is not known. An important difference between the sale of cigarettes and the sale of pharmaceutical products is that cigarette smokers can directly purchase any cigarette they choose. Consumers targeted by pharmaceutical advertisements need to have a physician prescribe the advertised drug.

Physicians complain that advertisements influence patients, who, in turn, pressure physicians to prescribe the advertised drugs.[233] An often cited reference in the Annals of Internal Medicine stated that a significant number of physicians do not support pharmaceutical advertising.[234] At the same time, physicians themselves accept perks and give-away items from drug companies.[235] Possibly, the physicians who responded to the Annals of Internal Medicine poll do not represent the same population of doctors who accept gratuities from drug companies. The impact of televised drug advertising on physicians' work, as well as on their attitudes about its benefits and drawbacks, would be useful information for this debate.

VII. CONCLUSION

Neither case law precedent nor policy arguments support the argument that direct-to-consumer advertising should create an exception to the learned intermediary rule in drug liability actions; Washington courts should not recognize this exception. Historical

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of market manipulation vindicates early advocates of product liability because manufacturers exert "undue influence" over consumers. *Id.* at 1428.

229. *Id.* at 1467-1551.

230. *Id.* at 1473-75.

231. *Id.* at 1475.

232. *See supra* note 1.

233. *See* Terzian, *supra* note 3, at 157-58 and citations therein.

234. Martin S. Wilkes et al., *Pharmaceutical Advertisements in Leading Medical Journals: Expert's Assessments*, 116 ANNALS INTERNAL MED. 912 (1992). The scientific validity of this survey has been questioned, but it has been widely reported in the popular press as well as in law review articles. *See* Reeves, *supra* note 1, at 668.

235. *See generally* Susan Heilbronner Fisher, Note, *The Economic Wisdom of Regulating Pharmaceutical "Freebies,"* 1991 DUKE L.J. 206 (1991).

exceptions to the learned intermediary rule do not provide sound legal precedent for creating another exception based on direct-to-consumer advertising. While some of the policy reasons for the rule are no longer as valid as they were twenty years ago, an exception to the rule would undermine the most critical policies. The importance of a patient's interaction with a physician would be minimized if a drug company were held directly liable when it advertises to consumers. A physician has the skill, knowledge, experience, and ethical commitment to provide the best care for patients.

The fundamental policies underlying tort law are to compensate the injured individual and to deter the negligent party from not fulfilling its duty of care.[236] At first glance, making a drug manufacturer directly liable to an injured user of the drug would promote compensation. Manufacturers could spread the cost of injury among those who use the products. Pharmaceutical companies would argue, however, that subjecting them to direct liability would increase the costs of business so significantly that research and development of new therapeutics would suffer, resulting in fewer available treatments.[237] Another potential negative consequence to the patient is that drug manufacturers may have less incentive to inform the physician of all benefit and risk data, preventing the physician from providing necessary information about a drug to the patient.

The physician's skill and experience contribute far more to reducing injury than holding drug manufacturers directly liable for "misleading" advertisements ever could. Advertisements are manipulative; they are intended to be. Asking the courts to pretend otherwise serves neither the patient nor the manufacturer. If consumers, physicians, and the legal system believe that advertising by pharmaceutical manufacturers creates additional risks for patients and burdens physicians, the FDA guideline describing "help-seeking" advertisements or "reminder" advertisements can supplant the "product claim" ads.[238] While many of us might find advertisement of health care products unseemly, that does not justify further confusing tort law in product failure to warn cases by creating another exception to the learned intermediary rule.

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236. *See* KEETON ET AL., *supra* note 4, at 25.

237. *See* Allen, *supra* note 3, at 130-31. Allen discusses the near-crisis in the childhood vaccine market. Because of potential litigation, the number of drug companies manufacturing the diphtheria-tetanus-pertussis (DPT) vaccine decreased from eight manufacturers to two. Without federal government intervention to create a pool of money to provide for injured vaccinees, all companies might have ceased vaccine production.

238. *See* Advertising and Promotion, 60 Fed. Reg. at 42,582 (2000).