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## Products Liability: The Continued Viability of the Learned Intermediary Rule as it Applies to Product Warnings for Prescription Drugs

Barbara Pope Flannagan  
*University of Richmond*

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## COMMENTS

### PRODUCTS LIABILITY: THE CONTINUED VIABILITY OF THE LEARNED INTERMEDIARY RULE AS IT APPLIES TO PRODUCT WARNINGS FOR PRESCRIPTION DRUGS

Judicial decisions,<sup>1</sup> as well as statutory enactments,<sup>2</sup> have removed many of the traditional stumbling blocks which formerly hampered an injured plaintiff's recovery against the manufacturer of a defective product. Concomitantly, the past few decades have seen a dramatic increase in the number of product liability suits brought by injured consumers directly against manufacturers.<sup>3</sup> These product liability suits have involved

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1. Absent fraud, early nineteenth century consumers had no cause of action against the manufacturer or seller of a defective product under any theory, contract or tort. W. KEETON, PROSSER & KEETON ON TORTS § 95A, at 679 (5th ed. 1984). The Industrial Revolution precipitated the development of recovery under warranty theory. *Id.* at 679-80. Recovery under warranty theories was hampered by privity requirements which limited the class of plaintiffs to "the purchaser or one standing in the shoes of the purchaser as a third party beneficiary." *Id.* at 681.

Under warranty theories of product liability law, the privity requirement was difficult to overcome. See Gilliam, *Products Liability in A Nutshell*, 37 OR. L. REV. 119, 153-55 (1958) (noting that courts have resorted to 28 "legal fictions" to avoid the privity obstacle). Ultimately, the privity requirement under the warranty theory was abrogated in most jurisdictions following the rationale in the leading cases in the area. See *Henningson v. Bloomfield Motors, Inc.*, 32 N.J. 358, 161 A.2d 69 (1960); *Baxter v. Ford Motor Co.*, 179 Wash. 123, 35 P.2d 1090 (1934). See generally RESTATEMENT (SECOND) OF TORTS § 402B (1965).

A recovery under negligence theory for products liability was first recognized in *MacPherson v. Buick Motors Co.*, 217 N.Y. 382, 111 N.E. 1050 (1916). *MacPherson* held that a manufacturer may be held liable in negligence to a third party absent privity of contract if the product "is reasonably certain to place life and limb in peril when negligently made" and "there is added knowledge that the thing will be used by persons other than the purchaser, and used without new tests." *Id.* at \_\_\_\_, 111 N.E. at 1053. American jurisdictions have unanimously accepted the negligence theory of products liability. See W. KEETON, *supra*, § 96, at 683.

Finally, many jurisdictions have judicially adopted strict liability in tort which permits a plaintiff's recovery absent privity of contract or proof of negligence. See Prosser, *The Fall of the Citadel (Strict Liability to the Consumer)*, 50 MINN. L. REV. 791 (1966); see also 1 PROD. LIAB. REP. (CCH) ¶ 4016, at 4026-27 (1984) (table of jurisdictions adopting strict liability). *The Restatement (Second) of Torts* § 402A, detailing the elements of a cause of action under strict liability in tort, has been incorporated into the common law of a majority of states. See *id.* ¶ 4030.

2. See generally 2 PROD. LIAB. REP. (CCH) ¶¶ 90,112-95,270 (1981) (listing state statutes treating products liability).

3. A survey of product liability litigation in eight sample states revealed that the number of appellate cases during the period of January 1971 through September 1976 showed a 71%

the full range of manufactured products and have proceeded under three basic theories of recovery.<sup>4</sup> While no single type of product, either because of its use or purpose, has been immune from products liability suits, some types of products have special relationships between manufacturer and consumer which affect the theory of recovery.

One such type of product is ethical drugs.<sup>5</sup> Ethical drug manufacturers have experienced the same increase in products liability litigation as was felt by other manufacturers;<sup>6</sup> however, a special body of law has emerged with regard to the duty to warn element in such products liability cases.<sup>7</sup> Ethical drug manufacturers will be held to the same degree of care and expertise as other manufacturers,<sup>8</sup> but, because of the unusual relation-

increase over the 1965 through 1970 period. DEPARTMENT OF COMMERCE, FEDERAL TASK FORCE ON PRODUCT LIABILITY FINAL REPORT, ch. 6 at 38 (1978); see also Knepper, *Review of Recent Tort Trends*, 9 J. PROD. LIAB. 89 (1986).

4. A cause of action may be asserted under one or more of three basic theories: negligence, strict liability in tort, and warranty. W. KEETON, *supra* note 1, § 98, at 694. It is generally agreed that regardless of the theory the plaintiff must prove: (1) the product was defective; (2) the defect existed at the time the product left the defendant's hands; (3) the defect caused the harm; (4) this harm is appropriately assignable to the identified defect. A. WEINSTEIN, A. TWERSKI, H. PIEHLER & W. DONOHER, *PRODUCTS LIABILITY AND THE REASONABLY SAFE PRODUCT* 17 (1978). In a product liability action based on negligence, the plaintiff must also establish that the manufacturer's conduct was unreasonable. *Id.*; see also *Stone v. Smith, Klein & French Laboratories*, 731 F.2d 1578 (11th Cir. 1984) ("§ 402A does no more than codify the principles of negligence"); *Werner v. The Upjohn Co.*, 628 F.2d 848, 858 (4th Cir. 1980) (finding the issue under either theory is essentially: "was the warning adequate?"), *cert. denied*, 449 U.S. 1080 (1981). See generally Wrubel, *Liability for Failure to Warn or Instruct*, *PRODUCT LIABILITY OF MANUFACTURERS—PREVENTION AND DEFENSE* (1985); Wall, *Strict Liability and Negligence: The Distinguishable Twins of Products Liability*, 8 J. PROD. LIAB. 319 (1985).

5. The term "ethical drug" is frequently used in judicial opinions to denote products which by law, 21 U.S.C. § 353 (b)(1) (1982), may be dispensed only by a doctor or by a doctor's prescription as opposed to products which may be purchased over-the-counter. See, e.g., *Stanback v. Parke, Davis & Co.*, 657 F.2d 642, 644 (4th Cir. 1981).

6. Drug product liability and malpractice actions filed annually tripled between 1976 and 1982. 7 *LAWYERS' MEDICAL CYCLOPEDIA, DRUGS IN LITIGATION* (2d ed. 1982), reprinted in 1 *DIXON, DRUG PRODUCT LIABILITY* § 1.01 n.1 (1985).

7. See generally Dillard & Hart, *Product Liability: Direction for Use and the Duty to Warn*, 41 VA. L. REV. 145 (1955); Keeton, *Products Liability—Drugs and Cosmetics*, 25 *VAND. L. REV.* 131 (1972); Rheingold, *Products Liability—The Ethical Drug Manufacturers' Liability*, 18 *RUTGERS L. REV.* 947 (1964); Note, *The Liability of Pharmaceutical Manufacturers for Unforeseen Adverse Drug Reactions*, 48 *FORDHAM L. REV.* 735 (1980).

8. Ethical drug manufacturers must exercise the reasonable care, skill, and knowledge of experts in the field of pharmacology. *Wooderson v. Ortho Pharmaceutical Co.*, 235 Kan. 387, —, 681 P.2d 1038, 1051 (1984). It is the manufacturer's duty to disclose to the medical profession any risk or contraindications associated with the use of his drug. *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1231 (4th Cir. 1984). The manufacturer has an ongoing duty to revise and update prescription information and to notify the medical profession of subsequent discoveries. *Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87, 91 (2d Cir. 1980). Drug information is disseminated through package labels and inserts, "Dear Doctor" letters, sales representatives, and advertising. Britain, *Product Honesty is the Best Policy: A Com-*

ship between the manufacturer and the consumer of ethical drugs, a vast majority of states hold that the drug manufacturer must warn only the physician who prescribes the drug and not the patient who ultimately consumes the drug.<sup>9</sup> The jurisdictions adopting this so-called "learned intermediary rule" recognize that the physician prescribing the drug stands between the manufacturer and the consumer as the proper conduit for information regarding risks associated with the drug's use.<sup>10</sup> Therefore, the manufacturer is exculpated from liability for what would otherwise be a breach of the duty to warn the consumer if an adequate warning as to the risks attendant with the drug's use was furnished to the physician/learned intermediary.<sup>11</sup>

The subject of much litigation in drug products liability cases has been the issue of whom an ethical drug manufacturer must warn regarding the risks associated with use of a prescription drug.<sup>12</sup> This comment will focus on the question of whom the drug manufacturer must warn. It examines several recent court decisions which cast doubt on the continued validity of the learned intermediary rule and the potential impact of these decisions on the duty to warn element in a drug products liability case. This comment will conclude that, whenever possible, the law should require that the manufacturer warn the consumer or affected party directly. However, it is also noted that the learned intermediary rule should continue to be a valid defense in the following situations: (1) where the adverse effects of an ethical drug involve medical complexities which cannot be translated into ordinary language; and (2) where warning the consumer of the drug's adverse effects would amount to a meaningless gesture on

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*parison of Doctors' and Manufacturers' Duty to Disclose Drug Risks and the Importance of Consumer Expectations in Determining Product Defect*, 79 Nw. U.L. Rev. 342, 385 (1984).

The duty to warn element, however, does not shield the ethical drug manufacturer from liability for negligence in the manufacturing of his product. Thus if a drug causes injury because of contamination or because of defective packaging, the manufacturer will be liable to the consumer for any injury that results from such defects. Likewise, if a drug could be produced without the use of an injurious ingredient, the manufacturer would be liable.

9. See *infra* notes 32-34 and accompanying text.

10. The ethical drug manufacturer's duty is to warn the physician who acts as a learned intermediary between the manufacturer and the consumer. Safe and effective use of ethical drugs requires medical expertise and detailed warnings which, if given directly to the patient, might "mislead patients" or interfere with the physician/patient relationship. See *infra* notes 35-42 and accompanying text.

11. The learned intermediary rule emphasizes the role of the physician in prescribing any drug. In making a medical judgment as to the appropriate course of treatment in an individual case, the physician's knowledge of the patient is balanced against the risk and benefits of the drug. The physician acts as a learned intermediary between the manufacturer and the consumer to insure that the patient makes an "informed decision" regarding his treatment. See generally 1 DIXON, DRUG PRODUCT LIABILITY § 1.05 (1)-(2), (5) (1985). See *infra* notes 35-42 and accompanying text.

12. See *infra* note 32.

the part of the manufacturer. Overall, the continued validity of the learned intermediary rule must be determined on a case-by-case basis in light of the merits of the individual claim.

## I. MODERN DRUG MANUFACTURER'S DUTY TO WARN

### A. *The Emergence of the Learned Intermediary Rule*

#### 1. The Ethical Drug Dilemma

Discoveries and developments in the field of ethical drugs have been a source of immeasurable benefit to mankind,<sup>13</sup> but with these benefits have come a grave potential for danger.<sup>14</sup> Some ethical drugs, while extremely beneficial to one patient under one set of circumstances, may, in another patient and under a different set of circumstances, be harmful or fatal. Other ethical drugs have serious adverse side effects but, because of their therapeutic and preventive characteristics, are still prescribed. Still other drugs are experimental. In any case, the ethical drug may be "unavoidably unsafe"<sup>15</sup> for some patients under some circumstances, and therefore an appropriate warning must be given to the consumer.<sup>16</sup> In the *Restatement (Second) of Torts*, Dean Prosser summarized the situation as follows:

Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. 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. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation

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13. Antibiotics used to treat infection in man are excellent examples of these new drugs. Penicillin, the first of such drugs, was discovered in London in 1928 by Alexander Fleming. A vaccine for polio, a crippler of man since ancient times, is another example of the wonders of modern drugs. Research led to Dr. Jonas Salk's development of the first polio vaccine in the early 1950's.

14. Vaccines are good examples of drugs which are highly beneficial to the vast majority of the population but which have a potential for serious harm to some individuals. *See, e.g., Conafay v. Wyeth Laboratories, Inc.*, No. 83-0637, slip op. (D.D.C. Mar. 19, 1985) (diphtheria and tetanus toxoids and pertussis vaccine causing neurological problems in child); *Carmen v. Eli Lilly & Co.*, 109 Ind. App. 76, 32 N.E.2d 729 (1941) (rabies vaccine causing death of patient).

15. RESTATEMENT (SECOND) OF TORTS § 402A comment k (1965). Unavoidably unsafe products are those "which in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." *Id.*

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

calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.<sup>17</sup>

The dilemma recognized by Dean Prosser and others was how to reap the benefits of these potentially advantageous and "reasonably safe" drugs while at the same time protecting the consumer from unknown risks. The dilemma was increased because drug manufacturers would not produce and market such drugs for fear of the potential liability nor were they in a position to warn the consumer about the potential risks under the myriad of circumstances which might arise.<sup>18</sup>

## 2. The Physician Solution?

As early as 1941, the courts were faced with issues regarding the manufacturer's duty to warn the ultimate consumer of a drug obtained through a physician.<sup>19</sup> The court in *Carmen v. Eli Lilly & Co.*<sup>20</sup> determined that the manufacturer was not liable because the facts established that the physician and the patient had been fairly and adequately warned regarding the potential side effects of a rabies vaccine.<sup>21</sup> In 1948, the court in *Marcus v. Specific Pharmaceuticals, Inc.*<sup>22</sup> granted the defendant drug manufacturer's motion to dismiss and held that a drug manufacturer could not be found negligent for failure to warn the ultimate consumer of a product which was available only by a physician's prescription.<sup>23</sup>

The problem with the rule articulated in *Marcus* was that, at this early juncture, the loosely defined term "prescription drug" included many

17. RESTATEMENT (SECOND) OF TORTS § 402A comment k (1965).

18. *Conafay*, No. 83-0637. The court noted the following:

One reason courts are reluctant to apply the general requirements for strict liability in cases involving drugs is that the imposition of such a standard would chill if not smother the research, development, production and marketing of new prescription or experimental drugs necessary to alleviate or cure ills to which persons are subject.

*Id.* at 5.

19. *See, e.g., Carmen*, 109 Ind. App. 76, 32 N.E.2d 729.

20. *Id.* In a wrongful death action against the manufacturer of rabies vaccine, the plaintiff alleged the manufacturer was negligent for failing to provide a warning of possible side effects to either the decedent or his physician. The court noted that the facts established that the decedent and his physician were fairly and adequately warned. It was unnecessary, therefore, for the court to consider the manufacturer's assertion that their pamphlet "should be construed to be for the information of doctors only and not for the information of laymen." *Id.* at \_\_\_, 32 N.E.2d at 732-33.

21. *Id.*

22. 191 Misc. 285, 77 N.Y.S.2d 508 (1948).

23. The court granted defendant manufacturer's motion to dismiss because the manufacturer had made no representation to plaintiff. *Id.* at \_\_\_, 77 N.Y.S.2d at 509. In dictum, the court noted that if false representations were made to the physician, then a claim of misrepresentation to the physician for the benefit of the consumer might properly be made. *Id.*

drugs which are now sold over-the-counter. The practice of defining prescriptions to include such "safe drugs," which were in actuality not administered under the supervision of a physician, placed an unrealistic burden on the physician and unjustly exculpated the drug manufacturer from its duty to warn. This definitional problem was alleviated in 1951 when federal legislation was passed. The Federal Food, Drug, and Cosmetic Act,<sup>24</sup> for the first time, established federal criteria for classifying products as prescription drugs.<sup>25</sup> The purpose of the amendment was twofold: (1) to protect the public from abuses in the sale of potent prescription drugs; and (2) to relieve retail pharmacists and the public from burdensome and unnecessary restrictions on the dispensing of drugs that are safe for use without the supervision of a physician.<sup>26</sup>

The first case to articulate the modern learned intermediary rule was *Sterling Drug, Inc. v. Cornish*.<sup>27</sup> The modern rule states that the ethical drug manufacturer has a duty to adequately warn only the medical profession of the risks associated with the use of a prescription drug.<sup>28</sup> A warning to the physician is adequate if it clearly discloses any risk or contraindications the manufacturer knows or should know are associated

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24. 21 U.S.C. §§ 301-392 (1982).

25. *Id.* § 353 (b); see Rachanow, *The Switch of Drugs from Prescription to Over-the-Counter Status*, 39 FOOD DRUG COSM. L.J. 201, 201 (1984). As originally enacted, the law contained no guidelines for distinguishing prescription and nonprescription drugs, and the FDA for years issued administrative regulations attempting to differentiate drugs. *Id.*

The statute now provides that a prescription drug is one which is "habit forming . . . or . . . because of its toxicity or other potentiality for harmful effect . . . is not safe for use except under the supervision of a practitioner licensed by law . . . or . . . is limited by an approval application." 21 U.S.C. § 353 (b)(1)(A)-(C) (1982). For a brief but fascinating overview of the development of drug regulation in this country, see Janssen, *Outline of the History of U.S. Drug Regulation and Labeling*, 36 FOOD DRUG COSM. L.J. 420 (1981).

26. S. REP. NO. 946, 82d Cong., 1st Sess., reprinted in 1951 U.S. CODE CONG. & AD. NEWS 2454.

27. 370 F.2d 82 (8th Cir. 1966) (affirming trial court's decision that under Missouri law the drug manufacturer had a duty to warn the purchaser's doctor of known, rare side effects). In the case of prescription drugs, the purchaser's physician was a learned intermediary between the drug manufacturer and consumer who, if properly warned of potential adverse reactions, might have averted the injury. *Id.* at 85. The manufacturer who fails to adequately warn the physician is negligent and is liable to the consumer. *Id.* However, if the physician is warned about the drug's dangers, the drug manufacturer has no duty to warn the general public. *Id.* The rule expressed in *Sterling Drug* was actually not new. Earlier decisions found that manufacturers of drugs available only by prescription had no duty to warn the general public. See, e.g., *Stottlemire v. Cawood*, 213 F. Supp. 897, 899 (D.D.C. 1963); *Magee v. Wyeth Laboratories, Inc.*, 214 Cal. App. 2d 340, —, 29 Cal. Rptr. 322, 328 (1963); *Parker v. State*, 201 Misc. 416, —, 105 N.Y.S.2d 735, 741 (1951), *aff'd*, 280 A.D. 157, 112 N.Y.S.2d 695 (1952).

28. *Stanback v. Parke, Davis & Co.*, 657 F.2d 642 (4th Cir. 1981); *accord Reyes v. Wyeth Laboratories, Inc.*, 498 F.2d 1264 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974); *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968); *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966); *McKee v. Moore*, 648 P.2d 21 (Okla. 1982); *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375, 528 P.2d 522 (1974).

with the use of the ethical drug.<sup>29</sup> This duty to warn is continuous, and the manufacturer must notify the medical profession of adverse effects subsequently discovered.<sup>30</sup> Further, the ethical drug manufacturer is directly liable to a consumer for a breach of its duty to adequately warn the medical profession.<sup>31</sup>

The vast majority of jurisdictions which have considered whether the ethical drug manufacturer has a duty to warn the user have adopted the learned intermediary rule.<sup>32</sup> Some jurisdictions have extended the learned

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29. See *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1231 (4th Cir. 1984); *Stanback*, 502 F. Supp. at 770; *Seley v. G.D. Searle & Co.*, 67 Ohio St. 2d 192, \_\_\_, 423 N.E.2d 831, 836 (1981); *McKee*, 648 P.2d at 24. The critical questions facing a court construing the adequacy of the warning given by the drug manufacturer to the physician are whether the manufacturer's written warnings were adequate in view of the medical and scientific knowledge available at the time the drug was prescribed by a physician. See *Chambers v. G.D. Searle & Co.*, 441 F. Supp. 377 (D. Md. 1975), *aff'd*, 567 F.2d 269 (4th Cir. 1977). There is a split of authority as to whether the adequacy of the warning is a question of fact to be decided by the jury or whether it is a question of law. Compare *Baker v. St. Agnes Hosp.*, 70 A.D. 400, 421 N.Y.S.2d 81 (1980) (reversal of decision upholding adequacy of warning as a matter of law finding that it is a matter for jury) with *Pierluisi v. E.R. Squibb & Sons, Inc.*, 440 F. Supp. 692, 694 (D.P.R. 1977) (A warning by a manufacturer is deemed sufficient as a matter of law if it is "sufficient to appraise [sic] a general practitioner as well as the 'unusually sophisticated medical man' of the dangerous propensities of the drug.")

30. *Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87, 91 (2d Cir. 1980), *rev'd*, 637 F.2d 87 (2d Cir. 1980); *accord Stanback*, 502 F. Supp. at 770; *McEwen*, 270 Or. at \_\_\_, 528 P.2d at 528. Ethical drug manufacturers advise the medical profession of drug side effects through package labels and inserts, "Dear Doctor" letters, sales representatives, and advertising. Britain, *supra* note 9, at 385.

31. *Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919, 923 (8th Cir. 1970); *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375, \_\_\_, 528 P.2d 522, 529 (1974).

32. See *Stanback*, 657 F.2d 642 (applying Va. law) (polio vaccine); *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 656 (1st Cir. 1981) (applying N.H. law) (oral contraceptive); *Timm v. The Upjohn Co.*, 624 F.2d 536, 538 (5th Cir. 1980), *cert. denied*, 449 U.S. 1112 (1981) (applying La. law) (antibiotic cleocin); *Givens v. Lederle*, 556 F.2d 1341, 1345 (5th Cir. 1977) (applying Fla. law) (oral polio vaccine); *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 142 (3d Cir. 1973) (applying Pa. law) (chloroquine phosphate); *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 426 (2d Cir. 1969) (applying Conn. law) (chloroquine drug); *Fellows v. USV Pharmaceutical Corp.*, 502 F. Supp. 297, 299 (D. Md. 1980) (doriden); *Lindsay*, 481 F. Supp. at 322, 347, 352 (oral contraceptive); *Goodson v. Searle Laboratories*, 471 F. Supp. 546, 548 (D. Conn. 1978) (oral contraceptive); *Dunkin v. Syntex Laboratories, Inc.*, 443 F. Supp. 121, 123 (W.D. Tenn. 1977) (oral contraceptive); *Chambers*, 441 F. Supp. at 381 (oral contraceptive); *Pierluisi*, 440 F. Supp. at 694 (Kenalog 40); *Yarrow v. Sterling Drug, Inc.*, 263 F. Supp. 159, 162 (D.S.D. 1967), *aff'd*, 408 F.2d 978 (8th Cir. 1969) (chloroquine phosphate); *Dyer v. Best Pharmacal*, 118 Ariz. 465, \_\_\_, 577 P.2d 1084, 1087 (Ariz. Ct. App. 1978) (anorexiant drug); *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 989, 95 Cal. Rptr. 381, 400 (1971) (hormones); *Mahr v. G.D. Searle & Co.*, 72 Ill. App. 3d 540, \_\_\_, 390 N.E.2d 1214, 1229 (1979) (oral contraceptive); *Ortho Pharmaceutical Corp. v. Chapman*, 180 Ind. App. 33, \_\_\_, 388 N.E.2d 541, 548 (1979) (oral contraceptive); *Wooderson v. Ortho Pharmaceutical Corp.*, 235 Kan. 387, 681 P.2d 1038, *cert. denied*, 105 S. Ct. 365 (1984) (oral contraceptive); *Mulder v. Parke, Davis & Co.*, 288 Minn. 332, \_\_\_, 181 N.W.2d 882, 885 (1970) (antibiotic chloromycetin); *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143, 146 (Mo. 1967) (chloroquine phosphate); *Johnson v. The Upjohn Co.*, 442 S.W.2d 93, 95 (Mo. Ct. App. 1969) (antibiot-



intermediary rule to include medical devices, such as cardiac pacemakers, which are available only through the services of a physician.<sup>33</sup> Moreover, the manufacturer's duty to warn the physician of the contraindications has been interpreted to encompass all physicians who may be involved with the patient in the "decision-making capacity."<sup>34</sup>

### B. *The Rationale for the Learned Intermediary Rule*

The reason most often cited by courts for adopting the learned intermediary rule is that expressed by Justice Wisdom in *Reyes v. Wyeth Laboratories*:<sup>35</sup>

We cannot quarrel with the general proposition that where *prescription* drugs are concerned, the manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use. This special standard for prescription drugs is an understandable exception to the Restatement's general rule that one who markets goods must warn foreseeable users of dangers inherent in his products. Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.<sup>36</sup>

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ics); *Hines v. St. Joseph's Hosp.*, 86 N.M. 763, \_\_\_, 527 P.2d 1075, 1077 (1974) (blood); *Cunningham v. Charles Pfizer & Co.*, 532 P.2d 1377, 1381 (Okla. 1974) (oral polio vaccine); *Incollingo v. Ewing*, 444 Pa. 263, 288, 282 A.2d 206, 220 (1971) (antibiotic); *Gravis v. Parke, Davis & Co.*, 502 S.W.2d 863, 870 (Tex. Civ. App. 1973) (drugs used to make anesthetic); *Terhune v. A.H. Robins Co.*, 90 Wash. 2d 9, \_\_\_, 577 P.2d 975, 979 (1978) (intrauterine contraceptive device).

33. *See, e.g.*, *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1232 (4th Cir. 1984) (applying S.C. law) (holding manufacturer of cardiac pacemaker had no duty to warn consumer directly); *McKee*, 648 P.2d at 24 (holding manufacturer of intrauterine contraceptive device had duty to warn prescribing physician); *Terhune*, 90 Wash. 2d at \_\_\_, 577 P.2d at 979 (manufacturer of intrauterine contraceptive device fulfills its duty if it warns physician).

34. *McEwen*, 270 Or. at \_\_\_, 528 P.2d at 529. In *McEwen*, the court reasoned that "if the prescribing physician is entitled to make an informed choice in deciding whether the patient should begin taking a prescription drug, it follows that a treating physician should have the same information in making his decision as to whether the patient should stop taking that drug." *Id.*; *see also Lindsay*, 637 F.2d at 91.

35. 498 F.2d 1264 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974).

36. *Id.* at 1276; *accord Timm v. The Upjohn Co.*, 624 F.2d 536, 538 (5th Cir. 1980); *Davis v. Wyeth Laboratories*, 399 F.2d 121, 130 (9th Cir. 1968).

Clearly, Justice Wisdom's characterization of the learned intermediary rule recognizes the importance of the physician's role in prescribing a course of treatment which includes ethical drugs to ensure the good health of his patient. The physician is the most logical conduit for information concerning the risk associated with a drug's use because he is the only individual who has knowledge of a drug's risks and a patient's needs.

It is the physician who has the education and expertise to understand the mass of information provided by drug manufacturers concerning the benefits and risks of an ethical drug. If detailed warnings were given directly to the patient by the drug manufacturer, they might mislead patients, not to mention the interference which such warnings might cause with the physician/patient relationship.<sup>37</sup> Further, there is the practical difficulty for the manufacturer of making the warning comprehensible by the lay person and of labeling or directly communicating the information to the ultimate consumers.<sup>38</sup>

A physician is in a better position than the manufacturer to know the needs of a particular patient. The physician's knowledge of the patient and the drug are taken into account when the physician makes a medical judgment as to the appropriate course of treatment for a particular patient. In addition, the physician is likely to be aware of a patient's complete medical history and acquainted with related treatments; he may therefore avoid adverse effects from reactions between drugs. If the physician is adequately warned of adverse effects, his decision to prescribe an ethical drug will be based on an assessment of the best information available as to the benefits and risks in each individual case. Therefore risks to the patient are minimized.<sup>39</sup>

Finally, the learned intermediary rule recognizes the natural dependence of a patient upon the advice of his physician. The patient, out of necessity, relies heavily on the expertise of his physician to help make decisions in his best interest.<sup>40</sup> The physician/patient relationship is one which is infinitely more intimate than the manufacturer/consumer relationship. The physician is a real person, not a package insert or a label. The physician can articulate a warning to a patient, answering any questions which the patient might have. In addition, the physician can recognize a patient who might need more explanation. The physician is usually more accessible for follow-up questions. In other words, no matter how well the drug manufacturer may predict the circumstances under which the consumer may need to be warned regarding risks, the physician's warning is superior.

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37. *Dunkin v. Syntex Laboratories*, 443 F. Supp. 121, 123 (W.D. Tenn. 1977).

38. *Davis*, 399 F.2d at 130.

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

40. *Seley v. G.D. Searle & Co.*, 67 Ohio St. 2d 192, —, 423 N.E.2d 831, 840 (1981).

Overall, it is the physician who selects a treatment based upon the totality of the circumstances, and it is the physician who has the duty to disclose to the patient any "grave risk of injury" so that the patient may make an "informed decision" regarding the treatment.<sup>41</sup> As one court noted, the real issue is not whether the consumer should be warned of the risk; instead, the question is "who is in a better position to disclose the risks."<sup>42</sup>

### III. THE LEARNED INTERMEDIARY RULE: ANALYSIS OF RECENT DECISIONS

In the last decade, litigants have tried to erode the learned intermediary rule but have been largely unsuccessful.<sup>43</sup> However, recently inroads have begun to erode the citadel.<sup>44</sup>

#### A. *The Mass Immunization Exception*

The learned intermediary rule cannot apply if there is no doctor involved in the dispensing of an ethical drug. For this reason, two major decisions have created an exception to the rule where the manufacturer knows, or has reason to know, the drug will be dispensed without a physician's involvement.

In *Davis v. Wyeth Laboratories*,<sup>45</sup> the plaintiff contracted polio after he was vaccinated for polio at a mass immunization clinic. The manufacturer's salesman participated in the organization and promotion of the clinic and was aware that a physician would not preside over the vaccinations.<sup>46</sup> Each bottle of vaccine contained 100 doses and a copy of the Surgeon General's warning which said there was a slight risk of contracting

41. *Terhune v. A.H. Robins Co.*, 90 Wash. 2d 9, —, 577 P.2d 975, 978 n.2 (1978). See generally 1 DIXON, *supra* note 5, § 1.05(2).

42. *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1232 (4th Cir. 1984).

43. See, e.g., *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1232 (4th Cir. 1984) (refusing to recognize a duty to warn consumer directly of risk associated with cardiac pacemaker); *Dunkin v. Synthex Laboratories*, 443 F. Supp. 121, 123 (W.D. Tenn. 1977) (refusing to recognize a duty to warn user directly of inherent risk associated with birth control pills); *Buckner v. Allergan Pharmaceuticals*, 400 So. 2d 820, 823-24 (Fla. Dist. Ct. App.), *petition denied*, 407 So. 2d 1102 (Fla. Dist. Ct. App. 1981) (rejecting argument that general rule should not apply because manufacturer knew or should have known that the medical profession was not warning patients of potential side effects); *Seley v. G.D. Searle & Co.*, 67 Ohio St. 2d 192, —, 423 N.E.2d 831, 839 (1981) (refusing to recognize manufacturer voluntarily assumed duty to warn user directly by issuing warning pamphlets and use instructions intended for user distribution); *McKee v. Moore*, 648 P.2d 21, 24-25 (Okla. 1982) (refusing to recognize a duty to warn patient directly of hazards associated with an intrauterine "device" as opposed to a drug).

44. Pope, *Recent Product Liability Cases Affecting the Pharmaceutical Industry*, 38 FOOD DRUG COSM. L.J. 299, 301 (1983).

45. 399 F.2d 121 (9th Cir. 1968).

46. *Id.* at 125.

polio from the vaccine. Neither the manufacturer nor the medical society running the clinic made any effort to communicate this warning to the public or to those receiving the vaccination. The polio vaccine was dispensed to "all comers" without any patient-by-patient assessment by a physician. The court found this immunization process to be analogous to the sale of over-the-counter nonprescription drugs.<sup>47</sup> The court held, therefore, that the manufacturer had not met its duty to make sure the drug warnings reached the consumers.<sup>48</sup> *Davis* created the mass immunization exception to the learned intermediary rule, and six years later in 1974, *Reyes v. Wyeth Laboratories*<sup>49</sup> expanded the exception to include polio vaccines administered in "on-going programs," such as small public health clinics, where no physician is present to make an "individualized medical balancing of the risk."<sup>50</sup>

The mass immunization exception to the intermediary rule is narrowly limited to factual situations where there is no physician involvement in the decision process and, hence, no individualized medical assessment of the risks and benefits of immunization.<sup>51</sup> Logically, if there is no physician involvement when the drug is dispensed, the learned intermediary rule cannot apply. The mass immunization exception is well reasoned and acutely perceptive because it recognizes the realities and limitations which surround mass vaccine dispensing. This exception seems to put substance over form.

### B. *Administrative Regulations—Creating a Duty to Warn*

In *Lukaszewicz v. Ortho Pharmaceutical Corp.*,<sup>52</sup> a federal district court applying Wisconsin law held that violation of a federal administrative regulation,<sup>53</sup> requiring manufacturers of oral contraceptives to give package insert warnings directly to the consumer, constituted negligence

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47. *Id.* at 131.

48. *Id.*

49. 498 F.2d 1264 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974). The court concluded that it was foreseeable that the vaccine sold to the Texas Department of Health would be distributed in an "on-going program" without the "individualized medical balancing of the risk . . . contemplated by the prescription drug exception." *Id.* at 1277. The manufacturer, therefore, breached its duty to warn foreseeable users or to see that the purchaser warned them. *Id.*

50. *Id.*

51. *See, e.g., Petty v. United States*, 740 F.2d 1428, 1440 (8th Cir. 1984) (applying Iowa law) (manufacturer's duty to warn extends to ultimate consumer in a mass swine flu immunization case); *Givens v. Lederle*, 556 F.2d 1341, 1345 (5th Cir. 1977) (applying Fla. law) (polio vaccine administered by clinic); *Cunningham v. Charles Pfizer & Co.*, 532 P.2d 1377, 1381 (Okla. 1975) (polio vaccine administered through mass immunization program).

52. 510 F. Supp. 961 (E.D. Wis.), *amended*, 532 F. Supp. 211 (E.D. Wis. 1981).

53. 21 C.F.R. § 310.501 (1985). The package insert regulation was adopted under the Federal Food, Drug & Cosmetic Act. 21 U.S.C. §§ 301-392 (1982).

per se.<sup>54</sup> The consumer, who allegedly received no package insert warning, suffered a stroke which she claimed was proximately caused by the oral contraceptives.<sup>55</sup> The court reasoned that the federal labeling requirement was enacted to protect persons like the plaintiff. Therefore, the court ruled that Ortho had a duty to warn the plaintiff of the side effects "to the extent and in the manner provided in that regulation."<sup>56</sup> Thus, a duty to warn in the manner required by the federal regulation constituted a triable issue of fact.<sup>57</sup>

It is significant that the *Lukaszewicz* decision was strictly limited to the drug manufacturer's failure to comply "to the extent and in the manner" prescribed by FDA regulations.<sup>58</sup> Federal regulations now require manufacturers to supply patient package inserts to accompany the dispensing of all forms of prescription-only contraceptives,<sup>59</sup> estrogens,<sup>60</sup> progestational drug products,<sup>61</sup> and isoproterenol inhalation preparation.<sup>62</sup> Obviously, these regulations have limited application both in the number and nature of the products affected.<sup>63</sup> Because the federal regulations specify the form<sup>64</sup> and content<sup>65</sup> of the patient package insert, the

54. *Lukaszewicz*, 532 F. Supp. at 213.

55. *Id.*, 510 F. Supp. at 962.

56. *Id.*, 532 F. Supp. at 213.

57. *Id.*

58. *Id.*

59. 21 C.F.R. § 310.501 (a), (b) (1985) (oral contraceptives); *id.* § 310.501a (medroxyprogesterone acetate injectable for contraception); *id.* § 310.502 (I.U.D.'s).

60. *Id.* § 310.515 (a hormone used therapeutically to prevent or stop lactation and to ameliorate malignant tumors of the breast and prostate).

61. *Id.* § 310.516 (a drug with progesterone-like properties used to correct abnormalities of the menstrual cycle).

62. *Id.* § 201.305 (used in the treatment of bronchial asthma).

63. In 1980, the FDA proposed a list of 10 additional prescription drugs to be considered for patient package inserts (PPIs). The proposed regulations were never enacted, in large part due to the opposition of organized pharmacology. Pharmacists opposed the regulations on several grounds: (1) if every drug had one single use, PPI requirements would not be difficult, but many drugs have multiple uses which makes it difficult to give the required information; (2) to give this kind of information would require about 8 different PPIs; (3) it would be difficult to give general information on prescription drugs that would not unduly alarm the consumer; and (4) the PPIs would be expensive. Telephone interview with Clifford Eugene White, J.D., Assistant Dean of Students, Medical College of Virginia School of Pharmacy, Virginia Commonwealth University (Jan. 20, 1986).

64. *See, e.g.*, 21 C.F.R. § 310.501(a)(5) (1985) (specifications for print size of patient package insert for oral contraceptives); *id.* § 310.515(c) (print specifications for estrogen PPIs).

65. *See, e.g., id.* § 310.501(a)(2), (3) (required information regarding oral contraceptives); *id.* § 201.305(b), (c)(1) (adequate information for isoproterenol inhalation preparations).

If a regulation does not mandate the wording of patient labeling, the regulation requires the FDA to make available, through publication in the *Federal Register*, sample patient labeling which includes all the required information. *See id.* §§ 310.501(a)(8), 310.515(f), 310.516(f). The regulations further provide that the ethical drug manufacturer who adopts the current version as published in the *Federal Register* has complied with the regulation. *Id.*

manufacturer need only comply with the regulations to fulfill its duty to warn the consumer directly.<sup>66</sup>

Only in rare circumstances will a drug manufacturer fail to enclose a package insert. *Lukaszewicz* was a fluke, and it is suggested that most manufacturers will have no problems complying with the regulations. The *Lukaszewicz* decision seems to be another exception to the learned intermediary rule, but that is not the case. The *Lukaszewicz* court merely utilized an alternate theory for recovery—violation of a federal regulation. The *Lukaszewicz* court never addressed the learned intermediary rule.

### C. Oral Contraceptives: Exception to the Learned Intermediary Rule?

Whereas *Lukaszewicz* eroded the learned intermediary rule by using an alternate theory of recovery instead of an outright exception, three 1985 cases have gone much farther<sup>67</sup> and have created an exception to the rule where oral contraceptives are involved. In these three decisions, the courts examined the purpose of the learned intermediary rule<sup>68</sup> and concluded that there are valid reasons why a manufacturer of oral contraceptives, and not the physician, should warn the consumer directly of the dangers associated with the use of such drugs.<sup>69</sup>

In each of the three cases, the plaintiffs suffered a stroke caused by their use of the oral contraceptives. All three plaintiffs received the drugs from their personal physicians. The plaintiffs received and read the manufacturer's standard package inserts which detailed the dangers and potential side effects. In addition, two of the plaintiffs received a more de-

66. Ethical drug manufacturers do not find noncompliance with FDA regulations good business practice. Under the Federal Food, Drug, and Cosmetic Act a drug packaged or labeled in violation of a regulation is misbranded. 21 U.S.C. § 352 ¶ (1985).

Misbranding of a drug is a prohibited act which may result in imprisonment or a fine or both. *Id.* §§ 331(b), 333(a), (b).

67. See *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379 (E.D. Mich. 1985); *Odgers v. Ortho Pharmaceutical Corp.*, 609 F. Supp. 867 (E.D. Mich. 1985); *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 475 N.E.2d 65, cert. denied, 106 S. Ct. 250 (1985).

The defendant manufacturers in both *Stephens* and *Odgers* moved for summary judgment. Their principal arguments related to whether an ethical drug manufacturer had a duty under Michigan law to warn patients directly of the risk and potential side effects associated with the use of oral contraceptives. *Stephens*, 602 F. Supp. at 381; *Odgers*, 609 F. Supp. at 869.

The question was subsequently certified to the Supreme Court of Michigan by Judge Cohn of the United States District Court for the Eastern District of Michigan. Eighteen months after accepting the certification question for review, a divided Michigan Supreme Court responded that there was no rule of law in Michigan that would resolve the issue and declined to state a rule of law regarding the certification question. *In re Certified Questions*, 419 Mich. 686, 358 N.W.2d 873 (1984).

68. See *supra* text accompanying notes 39-52.

69. *Stephens*, 602 F. Supp. at 381; *Odgers*, 609 F. Supp. at 878; *MacDonald*, 394 Mass. at —, 475 N.E.2d at 70.

tailed booklet published by the manufacturer which discussed, in lay person's language, the potential risks associated with the use of oral contraceptives.<sup>70</sup>

All three courts decided the learned intermediary rule did not apply in cases involving oral contraceptives, and all three courts advanced similar rationales for distinguishing oral contraceptives from other ethical drugs. *MacDonald v. Ortho Pharmaceutical Corp.*,<sup>71</sup> the only state case of the three, expressed three main reasons for making such a distinction.<sup>72</sup>

First, the *MacDonald* court noted that healthy consumers of oral contraceptives actively participate in the decision to use this method of birth control instead of alternative products. This heightened participation is quite different from the patient's minimal involvement in the decision-making process concerning drugs used to treat illness.<sup>73</sup> In the first situation, the prescribing physician is "relegated to a relatively passive role," whereas in the second, the ill patient must rely on the physician's judgment and advice for treating illness.<sup>74</sup>

Second, unlike the patient who uses a drug for therapeutic reasons, a patient using contraceptives often has no ongoing relationship with the doctor. The physician may examine the patient and prescribe a full year's supply of oral contraceptives with only annual examinations thereafter.<sup>75</sup> Because the consumer uses the drug for an extended time without an individualized medical assessment of the risk, she may seldom have an "opportunity to explore her questions and concerns about the medication with the prescribing physician."<sup>76</sup>

Finally, FDA regulations require manufacturers of oral contraceptives to furnish written information to consumers regarding the benefits and risks associated with the drug's use.<sup>77</sup> These regulations for direct warnings to the consumer were based on findings by the FDA that oral contraceptives are generally taken electively by healthy women who have alternative methods of birth control available to them and that there is a high incidence of serious side effects associated with use. Also, many women

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70. *Stephens*, 602 F. Supp. at 380, 382; *Odgers*, 609 F. Supp. 867 (the facts for *Odgers* may be found in *In re Certified Questions*, 419 Mich. at \_\_\_, 358 N.W.2d at 875-76); *MacDonald*, 394 Mass. at \_\_\_, 475 N.E.2d at 67.

71. 394 Mass. 131, 475 N.E.2d 65.

72. The manufacturer's duty to warn is governed by state law. Two decisions written by the United States District Court for the Eastern District of Michigan were made in the absence of controlling state law. See *supra* text accompanying note 69. The two federal district court decisions adopted reasons which are, for the most part, the same as those the *MacDonald* court adopted.

73. *MacDonald*, 394 Mass. at \_\_\_, 475 N.E.2d at 69.

74. *Id.*

75. *Id.*

76. *Id.*

77. *Id.* at \_\_\_, 475 N.E.2d at 69-70.

do not remember the complex information required to make an informed decision.<sup>78</sup> Thus, the majority in *MacDonald* found that "oral communications between physicians and consumers may be insufficient or too scanty standing alone fully to apprise consumers of the product's dangers at the time the initial selection of a contraceptive method is made, as well as at subsequent points when alternative methods may be considered."<sup>79</sup>

#### D. *Possible Effects of a Contraceptive Exception to the Learned Intermediary Rule*

With the exception of *Lukaszewicz*, every contraceptive case prior to *MacDonald* involving the scope of the contraceptive manufacturer's duty to warn adhered to the learned intermediary rule.<sup>80</sup> These contemporaneous decisions, however, found that with oral contraceptives "patient choice plays a much more prominent role than in the case of drugs prescribed for the treatment of illness or injury."<sup>81</sup>

While contraceptives available by prescription only may be distinguishable from other drugs because their predominant use is for non-therapeutic purposes,<sup>82</sup> this supposition ignores the physician's duty to exercise professional judgment before prescribing any drug.<sup>83</sup> The court in *MacDonald*, although limiting its decision to manufacturers of oral contraceptives,<sup>84</sup> may reflect a liberal trend towards the courts' willingness to find exceptions to the learned intermediary rule.

An initial reaction might be that such a legal distinction is justified; however, a closer look at *MacDonald* might cause one to reconsider. In *MacDonald*, the plaintiff received the patient insert required by the FDA and a booklet distributed by Ortho which included information about "the increased risk to pill users that vital organs such as the brain might be damaged by abnormal blood clotting."<sup>85</sup> The warning also indicated that abnormal blood clotting could be "fatal."<sup>86</sup> The word "stroke" was

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78. 43 Fed. Reg. 4215 (1978), quoted in *MacDonald*, 394 Mass. at \_\_\_, 475 N.E.2d at 69-70.

79. *MacDonald*, 394 Mass. at \_\_\_, 475 N.E.2d at 70.

80. *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, \_\_\_, 475 N.E.2d 65, 73 (1985) (O'Connor, J., dissenting).

81. *In re Certified Questions*, 419 Mich. 686, \_\_\_, 358 N.W.2d 873, 884 (1984) (Boyle, J., dissenting), cited with approval in *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379, 380 (E.D. Mich. 1985).

82. *In re Certified Questions*, 419 Mich. at \_\_\_, 358 N.W.2d at 884 (Boyle, J., dissenting).

83. *MacDonald*, 394 Mass. at \_\_\_, 475 N.E.2d at 73 (O'Connor, J., dissenting).

84. *Id.* at \_\_\_, 475 N.E.2d at 70. The two cases from the United States District Court for the Eastern District of Michigan also limited their holding to manufacturers of oral contraceptives. *Stephens*, 602 F. Supp. at 381; *Odgers v. Ortho Pharmaceutical Corp.*, 609 F. Supp. 867, 881 (E.D. Mich. 1985).

85. *MacDonald*, 394 Mass. at \_\_\_, 475 N.E.2d at 67.

86. *Id.* at \_\_\_, 475 N.E.2d at 71.



not used in the manufacturer's literature.<sup>87</sup> The court stated that a "jury may well have concluded . . . that the absence of a reference to 'stroke' in the warning . . . failed to make the nature of the risk reasonably comprehensible to the average consumer."<sup>88</sup>

If such a warning is inadequate, what warning might a manufacturer give to the consumer? It would appear that the standard of what is "reasonably comprehensible to the average consumer" is an impractical standard. As pointed out by Justice O'Connor's dissent in *MacDonald*, the allocation of the duty to warn between the physician and the manufacturer is meant, after all, to ensure that the consumer receives the information needed to make an informed decision.<sup>89</sup>

Faced with such a vague and nebulous duty to warn the consumer, a duty which might differ from jury to jury, a drug manufacturer may find that no warning is sufficient to meet the vague standard in *MacDonald*. It is possible that the *MacDonald* standard imposes an "absolute liability" which could inevitably prompt oral contraceptive manufacturers to withdraw their product from the market.<sup>90</sup> However, if the physician and the manufacturer both take active roles in warning oral contraceptive users, what the user does not understand can be clarified by the physician. As long as physicians prescribe contraceptives, it is not implausible to require them to give adequate warnings concerning the drugs.

#### E. *Back to Basics: A Sounder Suggestion*—Kirk v. Michael Reese Hospital & Medical Center

In *Kirk v. Michael Reese Hospital & Medical Center*,<sup>91</sup> the plaintiff was injured in an automobile accident.<sup>92</sup> On the day of the accident, the driver had been treated as a patient at a hospital and, on doctors' orders, was given Thorazine for oral consumption and an injection of Prolixin

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87. *Id.* at \_\_\_, 475 N.E.2d at 67.

88. *Id.* at \_\_\_, 475 N.E.2d at 71-72.

89. *Id.* at \_\_\_, 475 N.E.2d at 74 (O'Connor, J., dissenting).

90. It is not overstating the case to say ethical drug manufacturers would cease to market oral contraceptives. Consider the history of the National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, § 2, 90 Stat. 113 (1976) (codified at 42 U.S.C. § 247b (j)(1) (1982)) (amended 1978). Fearing a swine flu epidemic, the federal government attempted in 1976 to inoculate the adult population of this country in the largest immunization program in our history. However, ethical drug manufacturers refused to produce the virus vaccine until Congress enacted a measure making the government liable under the Federal Tort Claims Act for any injury or death caused by the inoculation. 42 U.S.C.A. § 247b(k)(1)(B)-(k)(3) (West 1982). For a written opinion of a case litigated under this act in which the court gives a synopsis of the circumstances surrounding the bill's passage, see *Alvarez v. United States*, 495 F. Supp. 1188 (D. Colo. 1980).

91. 136 Ill. App. 3d 945, 483 N.E.2d 906 (1985).

92. *Id.* at \_\_\_, 483 N.E.2d at 909-10.

Decanoate.<sup>93</sup> The jury found that the driver had lost control of the vehicle because of diminished mental and physical abilities caused by these drugs.<sup>94</sup> The injured plaintiff brought an action against the drug manufacturers, the physicians, and the hospital, claiming that each had failed to provide adequate warning of the adverse effects associated with use of the drugs.<sup>95</sup>

On appeal from dismissal for failure to state a cause of action, the appellate court held that the doctors, the hospital, and the ethical drug manufacturers each owed a legal duty to adequately warn of adverse side effects associated with the use of a drug which could result in injury to members of the public.<sup>96</sup> Further, the court held that the duty to warn was nondelegable and the negligence of the hospital or doctor did not relieve the manufacturer from liability for any injury caused by the manufacturer's failure to adequately warn.<sup>97</sup> The court noted that the adequacy of an ethical drug manufacturer's warning is a question of fact "determined by taking into account all aspects of the warnings, including the content of the warnings and how and to whom the warnings are conveyed."<sup>98</sup> The adequacy of a warning is not dependent upon a single act or document; rather it is a question for "the trier of fact in light of all the information provided by the manufacturer and all the information that it was reasonably possible to provide."<sup>99</sup> Thus, in one case, the trier of fact may find an ethical drug manufacturer's warning was adequate if given only to the physician, while in another case the drug manufacturer may have a duty to warn the consumer.<sup>100</sup>

The public interest dictates full redress for all who are injured as a result of an ethical drug manufacturer's inadequate warning.<sup>101</sup> But, as noted in *Kirk*, the ethical drug manufacturer's duty "simply requires a warning, not control or prevention."<sup>102</sup> Under a public policy analysis, "the desirability . . . of extending any duty relating to doctors, hospitals and [ethical] drug manufacturers must be determined by balancing dichotomous public concerns. The problem is to balance the just claims . . . 'against the public's claim not to be victimized by needless swollen medical costs.'"<sup>103</sup>

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93. *Id.* at \_\_\_, 483 N.E.2d at 909.

94. *Id.* at \_\_\_, 483 N.E.2d at 909-10.

95. *Id.* at \_\_\_, 483 N.E.2d at 910.

96. *Id.* at \_\_\_, 483 N.E.2d at 913.

97. *Id.* at \_\_\_, 483 N.E.2d at 911-13 n.5.

98. *Id.* at \_\_\_, 483 N.E.2d at 911 n.2.

99. *Id.*

100. *Id.*

101. *Id.* at \_\_\_, 483 N.E.2d at 912.

102. *Id.*

103. *Id.* (quoting Editorial, *Compromise on Malpractice*, Chi. Tribune, June 8, 1985, § 1, at 10).

*Kirk* applied a more practical standard for determining when and to whom an ethical drug manufacturer owes a duty to warn. Unlike the vague standard in *MacDonald*, the *Kirk* standard is flexible and more fair. Although *MacDonald* dealt with oral contraceptives, it is submitted that the *Kirk* standard, which applies to all other ethical drugs, should apply to oral contraceptives as well. *Kirk*, while it imposed a duty to warn on the manufacturer, did not let the hospital or physician off the hook. It is possible that if both the manufacturer and physician have a duty to warn, both will take responsibility for protecting the innocent consumer.

#### IV. CONCLUSION

*MacDonald* exemplifies that the scope of an ethical drug manufacturer's duty to warn is a complex issue. Before analyzing to whom he must give a product warning, the drug manufacturer must consider what circumstances give rise to that duty and what constitutes an adequate warning.

No rational person would quarrel with the notion that an individual, sick or healthy, should receive sufficient information to make an informed decision before beginning or continuing to take a powerful drug. This does not, however, answer the question of what is the best way to ensure that consumers receive reliable, understandable information. Nor is it a guarantee to consumers that they will make the right choice.

Under the learned intermediary rule, manufacturers who fail to fulfill their duty to provide an adequate warning to the physician are liable directly to consumers for injuries caused by use of the drug.<sup>104</sup> Moreover, the disclosure standard imposed on ethical drug manufacturers may require manufacturers to warn physicians of incomprehensibly small risks.<sup>105</sup>

*MacDonald* suffered a stroke when she was thirty years old.<sup>106</sup> Risk of a stroke to users of oral contraceptives at that age are 1.5 in one hundred thousand.<sup>107</sup> It defies common sense to expect that *MacDonald's* injury would have been prevented if Ortho had inserted the word "stroke" because it is unlikely it would have altered *MacDonald's* decision to use the drug.

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104. See *supra* note 34.

105. In *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 129 (9th Cir. 1968), the court found that the chance of contracting polio from Type III Sabin vaccine was less than one in a million. By contrast, the evidence showed the chance that an adult over the age of 20 would contract polio from natural sources was .9 persons out of a million. *Id.* at 130.

106. *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 475 N.E.2d 65, 67, *cert. denied*, 106 S. Ct. 250 (1985).

107. *Ortho Pharmaceutical Corp. v. Chapman*, 180 Ind. App. 33, \_\_\_, 388 N.E.2d 541, 553 n.9 (1979).

The basis for imposing on any manufacturer a duty to warn is to prevent injury to the consumer. The learned intermediary rule embodies the distinctive roles of the manufacturer and the physician in preventing injury. The rule allocates to the drug manufacturer "the duty to gather, compile, and provide to doctors data regarding the use of their drugs, tasks for which the manufacturers are best suited."<sup>108</sup> The goal of preventing injury will not necessarily be advanced by making the learned intermediary rule inapplicable to product warnings for ethical drugs.

The law should require the ethical drug manufacturer to use the best method available to reasonably assure that all the information necessary for the safe use of its drug reaches those whose safety depends upon it.<sup>109</sup> Where a warning can readily be conveyed in lay person's language,<sup>110</sup> a drug manufacturer's failure to warn the consumer directly should result in liability for any injuries to the consumer proximately caused by use of the drug. On the other hand, many drugs present potential for adverse effects not easily communicated because of medical complexities beyond the lay person's ability to understand. In such cases the physician should also have the duty to warn the patient.

Where appropriate, the learned intermediary rule should be retained as a defense. The expansion of the ethical drug manufacturer's duty to warn unguided by practical considerations has the potential to impose absolute liability in situations where it is impossible for the manufacturer to warn the user directly. Often, the ethical drug manufacturer cannot communicate the necessary information directly to the consumer in a manner which will minimize the risk. In such a case, only the doctor is in a position to insure the safe use of the drug.

The question is "who is in a better position to disclose risks" to the consumer.<sup>111</sup> Given this approach, the answer in each case to the question whether or not an ethical drug manufacturer's warning is adequate requires an analysis rather than rules or responses.

*Barbara Pope Flanagan*

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108. *MacDonald*, 394 Mass. at —, 475 N.E.2d at 74 (O'Connor, J., dissenting).

109. RESTATEMENT (SECOND) OF TORTS § 388 comment n (1965) (chattel known to be dangerous for intended use).

110. Examples of warnings written in lay person's language are found on bottles of over-the-counter drugs such as Bufferin. The Bufferin label gives, in addition to dosage information, a caution to consult a physician immediately if pain persists for more than 10 days or redness is present. A warning is also given advising the consumer to seek the advice of a health professional before taking the drug if pregnant or nursing an infant and what to do in the event of an overdose.

111. *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1232 (4th Cir. 1984).

