

Oral Contraceptives: Heading Into an Era of Unpredictability, Unlimited Liability, and Unavailability?

I. INTRODUCTION

Technological advances have placed modern man in a precarious position. Now, more than ever, man is capable of creating and producing materials suited to solve the problems of the world, yet these beneficial products frequently bear concomitant hazards which cannot be avoided; that is, "some products . . . are quite incapable of being made safe for their intended and ordinary use."¹ However, general tort principles indicate that manufacturers of such products will bear no liability if their product is properly manufactured and accompanied by adequate directions and warnings.² Consequently, the manufacturer of any product it knows or should know is dangerous bears an unquestioned duty to warn the product's consumer of its potential hazards or adverse effects.³

Yet, as with many across-the-board rules, this common law duty to warn has its exceptions. For instance, when a manufacturer sells products that are generally used under the supervision of engineers or technicians, the manufacturer fulfills its duty to warn when it supplies adequate warnings and instructions to the supervisory engineers or technicians, rather than the actual user.⁴ Similarly, when a manufacturer supplies a product to members of a trade or profession, it bears no duty to warn of hazards generally known to that trade or profession.⁵ Nowhere have there been more exceptions to the duty to warn the user than in the area of pharmaceuticals. Beginning in the mid-1960s, courts have almost universally held that manufacturers of prescription drugs have a

¹RESTATEMENT (SECOND) OF TORTS § 402A, comment k (1965).

²*Id.* This Restatement comment goes on to emphasize:

[T]he seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation 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.

Id.

³*See, e.g.,* Illinois State Trust Co. v. Walker Mfg. Co., 73 Ill. App. 3d 585, 589, 392 N.E.2d 70, 73 (1978); Craven v. Niagara Mach. and Tool Works, Inc., 417 N.E.2d 1165, 1169 (Ind. Ct. App. 1981), *rev'd on rehearing on other grounds*, 425 N.E.2d 654 (Ind. Ct. App. 1981); H.P. Hood v. Ford Motor Co., 370 Mass. 69, 75, 345 N.E.2d 683, 688 (1976).

⁴*See* Jacobsen v. Colorado Fuel and Iron Corp., 409 F.2d 1263, 1273 (9th Cir. 1969). *See also* Hopkins v. E.I. DuPont de Nemours & Co., 212 F.2d 623, 626 (3d Cir.), *cert. denied*, 348 U.S. 872 (1954).

⁵*See* Shawver v. Roberts Corp., 90 Wis. 2d 672, 686, 280 N.W.2d 226, 233 (1979).

duty to warn the user's physician, who in turn is required to warn the patient, the user of the drug, of potential adverse effects⁶ under the theory of informed consent.⁷ This exception to the common law duty to warn is premised on the doctrine of the learned intermediary.⁸ According to the learned intermediary doctrine, the physician is viewed as a knowledgeable liaison whose role is to translate warnings provided by the drug's manufacturer into meaningful advice for his patient,⁹ the drug's ultimate consumer. However, limitations on the above-cited exceptions to the common law duty to warn the consumer directly were forewarned in the Restatement (Second) of Torts section 388, comment n, which states:

Giving to the third person through whom the [product] is supplied all the information necessary to its safe use is not in all cases sufficient to relieve the supplier from liability The question remains whether this method gives reasonable assurance that the information will reach those whose safety depends on their having it¹⁰

⁶See *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972), where the court first cited *Schloendorff v. Society of New York Hospital*, 211 N.Y. 125, 129-30, 105 N.E. 92, 93 (1914), overruled in *Bing v. Thunig*, 2 N.Y.2d 656, 143 N.E.2d 3 (1957), for the proposition: " 'Every human being of adult years and sound mind has a right to determine what shall be done with his own body' " *Id.*

⁷The *Canterbury* court interpreted "informed consent" in the following way: True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each. The average patient has little or no understanding of the medical arts, and ordinarily has only his physician to whom he can look for enlightenment with which to reach an intelligent decision. From these almost axiomatic considerations springs the need, and in turn the requirement, of a reasonable divulgence by physician to patient to make such a decision possible.

Canterbury, 464 F.2d at 780. See also *Cobbs v. Grant*, 8 Cal. 3d 229, 243, 502 P.2d 1, 9, 104 Cal. Rptr. 505, 513 (1972); *Wilkinson v. Vesey*, 110 R.I. 606, 624, 295 A.2d 676, 685 (1972). For additional commentary on the development and scope of the "informed consent" doctrine, see Riskin, *Informed Consent: Looking for the Action*, 1975 U. ILL. L.F. 580 (1975); Waltz and Scheuneman, *Informed Consent to Therapy*, 64 Nw. U.L. REV. 628 (1970); Comment, *The Evolution of the Doctrine of Informed Consent*, 12 GA. L. REV. 581 (1978).

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

⁹*Id.*

¹⁰"RESTATEMENT (SECOND) OF TORTS § 388, comment n (1965), continues: Many such articles can be made to carry their own message *to the understanding of those who are likely to use them* . . . by a label or other device, indicating with substantial sufficiency their dangerous character. Where the danger involved in the ignorant use of their true quality is great and such means of disclosure are practicable and not unduly burdensome, it may well be that the supplier should be required to adopt them.

Id. (emphasis added).

Accordingly, courts confronted with factual situations in which a manufacturer's warnings to the physician were predictably relayed to the patient-consumer in an "inadequate way"¹¹ have side-stepped the doctrine of the learned intermediary to impose liability on the manufacturer for its failure to warn the consumer directly.¹²

Judicial reluctance to give recognition to the learned intermediary doctrine, which originally evolved in the area of vaccines,¹³ has most recently extended to oral contraceptives.¹⁴ This reaffirmation of the common law duty to warn the consumer directly is not viewed as surprising given the Food and Drug Administration's ("FDA")¹⁵ current requirement of patient package inserts for oral contraceptives.¹⁶ However, in *MacDonald v. Ortho Pharmaceutical Corporation*¹⁷ and two similar cases,¹⁸ the manufacturer of oral contraceptives was held liable for its failure adequately to warn the consumer directly in spite of its compliance with FDA packaging/labeling requirements.¹⁹ These cases present a puzzling question as to how manufacturers are to satisfy their duty to warn the consumer directly in the case of oral contraceptives distributed nationwide in light of the fact that each court held that the adequacy of any given warning must be determined against state negligence law as interpreted by a jury. Yet, because such adequacy standards are never concretely fashioned prior to user injury and have the potential to vary from state to state, oral contraceptive manufacturers held to these standards embark upon an era of certain unpredictability and probable unlimited liability. In addition, an analysis of the reasoning used in these

¹¹In this context, "inadequate way" describes the situation in which a manufacturer's warnings to the physician about a product's potential adverse effects were not, in turn, passed on to the patient in an understandable manner by the physician after an individualized assessment of the risks and benefits. See *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1277 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974).

¹²See *Givens v. Lederle*, 556 F.2d 1341 (5th Cir. 1977); *Reyes v. Wyeth Laboratories*, 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); *Odgers v. Ortho Pharmaceutical Corp.*, 609 F. Supp. 867 (E.D. Mich. 1985); *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379 (E.D. Mich. 1985); *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 475 N.E.2d 65, *cert. denied*, 106 S. Ct. 250 (1985).

¹³See *Reyes v. Wyeth Laboratories*, 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).

¹⁴See *Odgers v. Ortho Pharmaceutical Corp.*, 609 F. Supp. 867 (E.D. Mich. 1985); *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379 (E.D. Mich. 1985); *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 475 N.E.2d 65, *cert. denied*, 106 S. Ct. 250 (1985).

¹⁵The Food and Drug Administration is the agency of the federal government charged with protecting the public from impure and unsafe drugs.

¹⁶See 21 C.F.R. § 310.501 (1985).

¹⁷394 Mass. 131, 475 N.E.2d 65 (1985).

¹⁸*Odgers*, 609 F. Supp. 867; *Stephens*, 602 F. Supp. 379.

¹⁹See 21 C.F.R. 310.501 (1985).

recent cases causes one to ponder the future of the doctrine of the learned intermediary in relation to other prescription drugs.

This Note will initially trace the development of the doctrine of the learned intermediary and the limitations on this doctrine as they first appeared in the area of vaccines. In addition, it will briefly discuss the emergence of the oral contraceptive industry and the public's call for FDA intervention in the labeling of its products. Next, this Note will consider the application of the learned intermediary doctrine in early oral contraceptive cases and its apparent inapplicability in three recent oral contraceptive cases — *McDonald*, *Odgers*, and *Stephens*. Finally, the Note will explore the potential effects of these latest holdings on the manufacturers of oral contraceptives and the expansion of the *MacDonald* holding to other prescription drugs.

II. THE EMERGENCE OF THE LEARNED INTERMEDIARY DOCTRINE AND ITS EARLY LIMITATION: THE VACCINE CASES

Today it is well established that a prescription drug manufacturer discharges its duty to warn of its product's risks and hazards when it supplies physicians with adequate information about the drug's associated side effects.²⁰ This general tort principle, now commonly referred to as the doctrine of the learned intermediary, was originally conceived in the case of *Love v. Wolf*.²¹

In *Love*, the California Court of Appeals held that the manufacturer of chloromycitin, an antibiotic used in the treatment of minor ailments, had no specific duty to warn the patient directly.²² Instead, the manufacturer's common law duty to warn could be discharged through

²⁰See *Reyes*, 498 F.2d 1264, 1276 (5th Cir.) *cert. denied*, 419 U.S. 1096 (1974), where a prescription drug manufacturer's duty to warn was explained as follows:

[W]here *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 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 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.

Id. (emphasis in original). See also *Mauldin v. Upjohn Co.*, 697 F.2d 644, 647 (5th Cir.), *cert. denied*, 464 U.S. 848 (1983) (manufacturer of antibiotics not required to warn patient directly if physician adequately warned); *Dyer v. Best Pharmaceutical*, 118 Ariz. 465, 468, 577 P.2d 1084, 1087 (1978) (manufacturer of pharmaceutical used for anorexiants purposes was under duty to warn the physician only); *McKee v. Moore*, 648 P.2d 21, 24 (Okla. Sup. Ct. 1982) (IUD manufacturer required to warn physician); *Terhune v. A.H. Robins Co.*, 90 Wash. 2d 9, 13, 577 P.2d 975, 979 (1978) (manufacturer not required to warn IUD wearers directly); PROSSER AND KEETON, TORTS 688 (5th ed. 1984).

²¹226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964).

²²*Id.* at 395, 38 Cal. Rptr. at 193.

adequate warning given to either the physician *or* the patient.²³ Implicit in the *Love* decision was the court's reluctance to impose a direct duty to warn the patient-consumer on manufacturers, which normally have only minimal contact with the ultimate users of the drugs.²⁴ This mere reluctance of the *Love* court planted the seed that ultimately grew into the learned intermediary doctrine. The term "learned intermediary" was first coined in *Sterling Drugs, Inc. v. Cornish*,²⁵ when it was applied descriptively to denote the special liaison-like role the physician plays between patient and drug manufacturer. In *Cornish*, the primary issue on review for the Eighth Circuit Court of Appeals was whether the defendant-drug manufacturer had a duty to warn the prescribing physician of recently-discovered side effects of its product, Aralen, an anti-arthritis agent. Affirming the judgment below in favor of a plaintiff who suffered chloroquine retinopathy, a degenerative disease of the eye resulting from ingesting Aralen, the Eighth Circuit Court of Appeals emphatically held that the drug manufacturer did have a duty to warn the physician, a measure which, in the court's opinion, would minimize the number of patients injured by adverse effects.²⁶ Although the court's discussion of the learned intermediary doctrine was limited to one paragraph, this single phrase became authority for subsequent judicial rulings that a drug manufacturer has a duty to warn only the physician.²⁷

From this relatively unnoticed beginning, the doctrine of the learned intermediary emerged as a general tort principle that has been given credence either directly or indirectly in nearly every case in which a plaintiff brought a warning-related action against a prescription drug manufacturer.²⁸ Although this doctrine has been summarized in almost

²³*Id.* Specifically, Presiding Justice Pierce wrote:

In the case of a drug it has been held there is a duty to exercise reasonable care to warn of potential dangers from use even though the percentage of users who will be injured is not large [citation omitted]. But if adequate warning of potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturers to insure that the warning reaches the doctor's patient for whom the drug is prescribed [citation omitted].

Id.

²⁴*Id.* at 394, 38 Cal. Rptr. at 192.

²⁵370 F.2d 82, 85 (1966).

²⁶*Id.* In particular, the court described the patient-physician relationship as follows: . . . we are dealing with a prescription drug rather than a normal consumer item. In such a case, the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer. If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided. This is particularly true if the injury takes place slowly

Id.

²⁷See *supra* note 20.

²⁸*Id.*

as many different ways as the number of courts that have discussed it, the reasons for the learned intermediary doctrine's soundness and broad acceptance are three-fold.²⁹

The primary argument in support of limiting a prescription drug manufacturer's duty to warn so as to require only the warning of physicians springs logically from the framework of the patient-physician relationship. When an individual chooses to seek medical care, it is reasonable to assume that he places a great deal of trust in the skill and expertise of his physician.³⁰ This reliance readily translates into unquestioned compliance with "doctor's orders"; that is, the patient takes the medication the physician selects.³¹ Based on this observation of human behavior, proponents of the learned intermediary doctrine view direct warnings to the patient as extraneous materials. Instead, the manufacturer's resources are best directed to the physician, who balances a given medication's risks against its potential benefits to the patient in selecting the optimal drug. In addition, the learned intermediary doctrine is frequently justified on the basis that direct warnings to patients may, in fact, compromise the patient-physician relationship and thereby actually endanger the patient's health.³² A patient's first opportunity to read the manufacturer's information detailing a given drug's adverse effects might well occur outside the supervision of the prescribing physician. Intimidated by potential unpleasant consequences and perhaps confused by technical terminology, some patients might forego treatment but avoid informing the prescribing physician in an attempt to bypass an imagined confrontation. As a result, the patient could go for months without receiving any therapy for an ailment which otherwise could be treated virtually risk-free.³³

²⁹See *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 989, 95 Cal. Rptr. 381, 399 (1971); *Terhune v. A.H. Robins Co.*, 90 Wash. 2d 9, 14, 577 P.2d 975, 978 (1978).

³⁰See *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 989, 95 Cal. Rptr. 381, 399 (1971); *Seley v. G.D. Searle & Co.*, 67 Ohio St. 2d 192, 203, 423 N.E.2d 831, 840 (1981); *Terhune v. A.H. Robins Co.*, 90 Wash. 2d 9, 14, 577 P.2d 975, 978 (1978).

³¹See *Carmichael*, 17 Cal. App. 3d at 989, 95 Cal. Rptr. at 399; *Seley*, 67 Ohio St. 2d at 203, 423 N.E.2d at 840; *Terhune*, 90 Wash. 2d at 14, 577 P.2d at 978.

³²*Carmichael v. Reitz*, 17 Cal. App. 3d 958, 989, 95 Cal. Rptr. 381, 400; Curran, *Package Inserts for Patients: Informed Consent in the 1980's*, 305 NEW ENG. MED. J. 1564, 1570 (1981); Rheingold, *Products Liability — The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947, 987 (1964).

³³*Carmichael*, 17 Cal. App. 3d at 989, 95 Cal. Rptr. at 400. In *Carmichael*, the plaintiff suffered both pulmonary embolisms and thrombophlebitis as a result of ingesting Enovid, a product of defendant Searle, for a period of approximately one year. At trial, the treating physician testified that he had informed the plaintiff that "breakthrough bleeding, nausea and vomiting" were potential side effects of Enovid, but no warning of risk of thromboembolic disease was ever given. *Id.* at 972, 95 Cal. Rptr. at 388. In fact, the physician testified that although he had read product literature on Enovid, he was unaware of a causal relationship between thromboembolic disease and the use of Enovid. *Id.* at 973, 95 Cal. Rptr. at 388-89.

Lastly, the learned intermediary doctrine is often supported by an argument based purely on logistics. It has been asserted that direct communication between drug manufacturer and patient is "difficult if not virtually impossible."³⁴ This argument is premised on the fact that, at the time of the learned intermediary doctrine's inception, a one-on-one contact between manufacturer and the ultimate consumer was limited. At this time, magazines and television had yet to assume their function as disseminators of medical information.³⁵

Although the learned intermediary doctrine has been widely accepted, it is not without its limitations. In fact, only two years after the court in *Sterling Drug, Inc. v. Cornish* first articulated the phrase "learned intermediary,"³⁶ the Ninth Circuit Court of Appeals in *Davis v. Wyeth Laboratories*³⁷ determined that certain circumstances surrounding a prescription drug's administration could bar application of the doctrine.

In *Davis*, the plaintiff appealed a jury's verdict in favor of the defendant-manufacturer in a suit brought after he contracted polio as a result of vaccination with the manufacturer's product at a mass immunization clinic.³⁸ A representative of the manufacturer had supplied detailed instructions and warnings to those in charge of the immunization program, yet no materials concerning adverse effects reached either the vaccines' actual administrator or those who received the vaccines.³⁹ On the contrary, the plaintiff testified that those materials provided implied "that it was his civic duty to participate."⁴⁰

After noting that "[o]rdinarily in the case of prescription drugs warning to the prescribing physician is sufficient," the Ninth Circuit Court of Appeals held that, because of the particular circumstances surrounding mass immunization programs, the judicially-created learned intermediary doctrine was clearly inapplicable to that case.⁴¹ Therefore, the court revitalized the common law duty to warn the consumer directly.

³⁴Rheingold, *Products Liability — The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947, 987 (1964). See also *Carmichael*, 17 Cal. App. 3d at 989, 95 Cal. Rptr. at 400 (quoting *Rheingold*); *Terhune*, 90 Wash. 2d at 14, 577 P.2d at 978.

³⁵See Hayes, *Consumer Advertising of Prescription Drugs*, PA. MED., Dec., 1983, at 50; *Direct to Consumer Advertising of Prescription Drugs*, AM. PHARMACY, Feb., 1984, at 20; *Advertising and Ethics: Prescription Drugs on TV*, HOSP. PRAC., Oct., 1983, at 13.

³⁶370 F.2d at 85.

³⁷399 F.2d 121 (9th Cir. 1968), cert. denied, 419 U.S. 1096 (1974).

³⁸*Id.* at 122.

³⁹*Id.* at 125.

⁴⁰*Id.*

⁴¹*Id.* at 130. Specifically, the *Davis* court said:

[A]lthough the drug [polio vaccine] was denominated as a prescription drug, it was not dispensed as such. It was dispensed to all comers . . . (as in the case of over-the-counter sales of non-prescription drugs)

Id. at 131 (footnote omitted).

Two factors — the lack of a physician's individualized analysis of the vaccine's risks/benefits for each recipient and the decrease in the physician's role in the choice of whether to vaccinate or not⁴² — appeared to be paramount in the court's ultimate decision.

Similarly, six years later, the learned intermediary doctrine was ruled inapplicable in *Reyes v. Wyeth Laboratories*,⁴³ another immunization case. Like *Davis*, the injured party, the eight-month-old daughter of the plaintiff, had contracted polio after receiving the defendant-manufacturer's product at a local department of health clinic.⁴⁴ In *Reyes*, the vaccine had been administered by a registered nurse; no doctors were present.⁴⁵ Each ten-dose package contained a circular provided by Wyeth which was intended to warn doctors, hospitals, or other purchasers of potential dangers in ingesting the vaccine, but the consent form signed by the patient's mother immediately prior to vaccination contained "no warning of any sort."⁴⁶

While the *Reyes* court readily recognized the drug manufacturer's duty to warn only physicians in customary prescription drug cases,⁴⁷ it cited *Davis v. Wyeth Laboratories* and imposed a duty to warn the consumer directly when the manufacturer's product is "dispensed without the sort of individualized medical balancing of the risks to the vaccinee that is contemplated by the prescription drug exception."⁴⁸ Of primary importance to the *Reyes* court was the fact that Wyeth Laboratories knew or should have known that its vaccines were frequently administered in mass immunization settings or at rural health departments, environments where patients would receive the product without the individualized care of a physician.⁴⁹ Once a manufacturer possessed such knowledge, either actually or constructively, it could no longer rely on warnings given to the physician. At that point, the manufacturer would have to warn all foreseeable users or make certain that such users are warned by the vaccines' administrators.⁵⁰

Subsequent to *Davis* and *Reyes*, the learned intermediary doctrine was frequently held to be inapplicable in immunization cases even when the vaccine was given in a private physician's office rather than in a mass setting.⁵¹ The applicability of the learned intermediary doctrine

⁴²*Id.*

⁴³498 F.2d 1264 (5th Cir. 1974).

⁴⁴*Id.* at 1270.

⁴⁵*Id.*

⁴⁶*Id.*

⁴⁷*Id.* at 1276.

⁴⁸*Id.* at 1277.

⁴⁹*Id.*

⁵⁰*Id.*

⁵¹*E.g.*, *Givens v. Lederle*, 556 F.2d 1341 (5th Cir. 1979); *Williams v. Lederle Laboratories*, 591 F. Supp. 381 (S.D. Ohio 1984).

underwent constant refinement in the area of immunizations until the question most recently determinative of this issue was "whether the drug is commonly administered without individualized balancing by a physician of the risks involved and the individual's needs and circumstances."⁵² However, such a test had never been applied to manufacturers of prescription drugs outside the class of immunizations.

III. THE PUBLIC'S DEMAND FOR FDA INTERVENTION IN THE AREA OF ORAL CONTRACEPTIVES AND THE FDA'S RESPONSE

While battles over the manufacturer's duty to warn the consumer directly were waged on the immunization front, other segments of the pharmaceutical industry were preparing to produce "The Pill."⁵³ G.D. Searle & Company became the first manufacturer to receive FDA approval for the marketing of an oral contraceptive, Enovid, in June, 1960.⁵⁴ Almost immediately after Enovid hit the marketplace, the FDA began receiving reports of increased incidence of thromboembolic disease in patients ingesting this oral contraceptive.⁵⁵ Sparked by increasing concern within the public sector, the FDA sponsored a committee to research the link between the use of Enovid and thromboembolic disease.⁵⁶ In 1963, this link was reported to be insignificant.⁵⁷

In April, 1965, the FDA approved the marketing of two sequential birth control pills, a development that significantly sped up the nation's race to get on the pill.⁵⁸ By 1965, the estimated number of oral contraceptive users tallied over five million women.⁵⁹ The numbers of new

⁵²*Williams*, 591 F. Supp. at 389 (S.D. Ohio 1984).

⁵³The term, "The Pill," has been freely used in a generic sense in societal conversation to denote oral contraceptives.

⁵⁴*Hearings on Present Status of Competition in the Pharmaceutical Industry Before the Subcomm. on Monopoly of the Senate Comm. on Small Business*, 91st Cong., 2d Sess., 6787 (1970) [hereinafter referred to as the *Nelson Comm. Hearings*].

⁵⁵*Id.* at 6787, 7235, 7237. Thromboembolic disease is a generic classification for the occlusion or obstruction of a blood vessel by blood clots dislodged from a vein. *STEDMAN'S MEDICAL DICTIONARY* 1295 (22d ed. 1972).

⁵⁶*Nelson Committee Hearings*, *supra* note 54, at 6787.

⁵⁷*Id.*

⁵⁸*Id.* Sequential birth control pills consist of 15 tablets containing estrogen, followed by five tablets containing a proportioned mixture of estrogen and a progesterone; such a regiment is thought to simulate a woman's natural cycle. *DAVIS & FUGO, DRUGS OF CHOICE* 618 (1968-69). It should be noted that sequential birth control pills are currently not marketed in the United States. 43 Fed. Reg. 4218 (1978). Oral contraceptives frequently prescribed today contain low doses of both estrogen and progesterone (50 micrograms estrogen and less than 1.5 milligrams progesterone); such low-dose oral contraceptives are purported to be as effective and safer than earlier preparations. *Lia, Clinical Pharmacology and Common Minor Side Effects of Oral Contraceptives*, 24 *CLINICAL OBSTETRICS AND GYNECOLOGY* 879 (1981). Langone, *At Last, Good News About The Pill*, *DISCOVER*, Feb. 16, 1985, at 8.

⁵⁹*Nelson Comm. Hearings*, *supra* note 54, at 6787. This number had increased by 150% by 1969. *Id.*

prescriptions mounted daily as women were induced to demand the pill by manufacturers' overzealous marketing⁶⁰ and comforting articles appearing in widely-read women's periodicals.⁶¹ Although no federal funds were directly allocated to study reported side effects,⁶² the FDA did establish an Advisory Committee on Obstetrics and Gynecology to consider all of the available evidence and provide the FDA with adequate scientific evidence relating to the connection between oral contraceptives and health problems. Once again, the government committee found no association between the pill and reported ill effects.⁶³ The committee did, however, make strong recommendations for measures aimed at keeping a closer surveillance on reports of thromboembolic disease among pill users, expanding studies on the laboratory level, encouraging uniform labeling of oral contraceptives, and expediting approval of low dosage products.⁶⁴

By early 1968, the recommended surveillance system was implemented and the FDA was receiving mounting reports of thromboembolic incidents among pill users.⁶⁵ Almost simultaneously, British epidemiological researchers published the results of a study, the Vessey report, in which an undeniable link between oral contraceptives and thromboembolic disease had surfaced.⁶⁶ Specifically, the Vessey report indicated that women using oral contraceptives required hospitalization for thromboembolic disease nine times more frequently than women who did not use the pill.⁶⁷ In light of the concrete evidence presented in the Vessey report, the FDA was compelled to issue its first warning of potential adverse effects from oral contraceptives in June, 1968.⁶⁸

As the number of oral contraceptive users increased, so did the number of deaths and permanent disabilities resulting from the pill's

⁶⁰*Id.* at 6788.

⁶¹See, e.g., Hellman, *Doctor's View of Birth Control Pills*, REDBOOK, April, 1969, at 132; Langmyhr, *How Safe is the Pill?*, PARENT'S MAGAZINE, Oct., 1967, at 58.

⁶²See Mintz, "THE PILL": AN ALARMING REPORT 53 (1969).

⁶³*Id.*

⁶⁴*Id.*

⁶⁵*Id.*

⁶⁶See Vessey and Doll, *Investigation of Relation Between Use of Oral Contraceptives and Thromboembolic Disease*, BRITISH MED. J., Apr. 27, 1968, at 199 [hereinafter referred to as the Vessey Report].

⁶⁷*Id.* at 205.

⁶⁸*Nelson Comm. Hearings, supra* note 54, at 7022. This initial warning took the form of a "Dear Doctor" letter. *Id.* "Dear Doctor" letters are mass-produced form letters published by either a drug manufacturer or the FDA. "Dear Doctor" letters have generally been scorned as an ineffective means of communicating warnings relating to adverse effects because their use has not been restricted to this purpose; rather, they are also frequently used as promotional materials. As a result, "Dear Doctor" letters run the risk of being deficient in giving an adequate warning. Note, *Liability of Birth Control Pill Manufacturers*, 23 HASTINGS L.J. 1526, 1536 (1972).

ingestion.⁶⁹ During the period of July 1 to December 31, 1969, the FDA surveillance system documented fifteen fatalities and twenty-eight non-fatal thromboembolic incidents unquestionably attributable to the pill.⁷⁰ By the close of 1969, over three hundred lawsuits had been filed against oral contraceptive manufacturers.⁷¹ Nevertheless, a Gallup poll conducted in February, 1970, revealed startling results: two thirds of the women surveyed had "never been told about possible hazards by their physicians."⁷²

Intensification of the public's concern about the risk associated with the use of oral contraceptives induced Senator Gaylord Nelson to hold public hearings on the use and hazards of birth control pills.⁷³ Shocked by the inadequacy of information being given to oral contraceptive users, the FDA announced on the last day of the Nelson hearings that in the future it would require oral contraceptive manufacturers to include a uniform-content leaflet in each package of the product manufactured.⁷⁴ The primary purpose of the leaflets was "to recall to the patient her discussion with the physician when she made her decision to begin taking oral contraceptives."⁷⁵ Although the original proposed text of these leaflets consisted of a detailed 600-word statement discussing the hazards related to oral contraceptive use in lay language,⁷⁶ when these leaflets reached the marketplace, they had been reduced to a 155-word warning that mentioned only an increased incidence of bloodclotting among pill users.⁷⁷ Even so, this leaflet did represent the FDA's initial response to the public's demand for more adequate direct information. In an effort to provide consumers with expanded labeling information about recent reports on the risk of blood clots, other problems of the circulatory system, cancer, and effects on the unborn child associated with the use of oral contraceptives, this original warning leaflet was replaced in 1978

⁶⁹See *Nelson Comm. Hearings, supra* note 54, at 6789.

⁷⁰*Id.* Additional reports of deaths and injuries had been received, but the FDA could not clearly identify their epidemiological origin. *Id.*

⁷¹See Note, *Products Liability and the Pill*, 19 CLEV. ST. L. REV. 468 (1970). It should be noted that all 300 actions arose from injuries caused by adverse reactions from the pill. None of these suits had been brought on a theory of breach of warranty by plaintiffs who had conceived unexpectedly while on the pill. *Id.*

⁷²*Nelson Comm. Hearings, supra* note 54, at 6628. The complete results of the poll were reported in *Poll on the Pill*, NEWSWEEK, Feb. 9, 1970, at 52.

⁷³The complete text of Senator Nelson's hearings regarding oral contraceptives are documented as *Hearings on Present Status of Competition in the Pharmaceutical Industry Before the Subcomm. on Monopoly of the Senate Comm. on Small Business*, 91st Cong., 2d Sess., 5921-7324 (1970).

⁷⁴See *Nelson Comm. Hearings, supra* note 54, at 6800.

⁷⁵*Id.*

⁷⁶For original proposed text of leaflets, see *Nelson Comm. Hearings, supra* note 54, at 6800-01.

⁷⁷21 C.F.R. § 130.45(d)(1) (1971).

by the current patient package insert program.⁷⁸ Presently, the FDA requires oral contraceptive manufacturers to provide users of the pill with two types of informational materials: (1) a brief summary containing essential information to be included in each package as it is dispensed to each user,⁷⁹ and (2) a longer, more detailed labeling device to be included in or dispensed with each package as it is distributed.⁸⁰ In the preamble to the 1978 replacement, the FDA Commissioner, Charles Edwards, responded to manufacturers' concerns focusing on the immense difficulty of preparing *understandable* direct patient warnings that would be considered legally adequate, and the consequential potential for adverse jury determinations on the issue of adequacy.⁸¹ Commissioner Edwards adamantly stated that the federal regulation of warning labels enacted in 1978 would have no adverse effect on the standard of civil tort liability imposed on the oral contraceptive industry.⁸² Rather, Edwards stated that the liability of oral contraceptive manufacturers for their products' adverse effects would continue to be determined on a case-by-case basis, taking into consideration the applicable state negligence law, which could be altered to reflect state approval or disapproval of federally-implemented patient package insert programs.⁸³

IV. THE JUDICIARY'S ANSWER TO PLAINTIFFS INJURED BY THE INGESTION OF ORAL CONTRACEPTIVES

Amid court battles against the manufacturers of vaccines and conflicting signals by the FDA concerning a manufacturer's duty to warn oral contraceptive users of their products' associated risks, several oral contraceptive users filed suit for injuries sustained as a result of ingesting

⁷⁸*Id.* In 1974, the FDA withdrew 21 C.F.R. § 130.45 and replaced it in its renumbered version, 21 C.F.R. § 310.501. The text of the warning leaflet was unaltered. However, as previously noted, this leaflet warning was totally replaced by new text in 1978. Since its original passage in 1978, this text of the patient package insert has remained virtually unchanged.

⁷⁹21 C.F.R. § 310.501(a)(1). For specific requirements of information to be included within the brief summary, see 21 C.F.R. § 310.501(a)(2). Generally, brief summary must include information on the drug's effectiveness, contraindications for use, the serious side effects of contraceptive use, and the most common side effects of contraceptive use.

⁸⁰21 C.F.R. § 310.501(a)(1). For specific requirements of information to be included within the detailed patient labeling, see 21 C.F.R. § 310.501(a)(3). Generally, the detailed patient labeling must include the same types of information as the brief summary; however, the text of this information is to be more extensive and specific.

⁸¹43 Fed. Reg. 4214 (1978).

⁸²*Id.* Edwards believed that improved warning programs would bring reduced risk of liability "due to improved patient compliance with physician directions and self-monitoring of adverse effects, and a corresponding decrease in drug-induced injury." 43 Fed. Reg. 4214 (1978).

⁸³*Id.*

the pill.⁸⁴ For the most part, manufacturers were relieved of any liability; the courts applied the learned intermediary doctrine and held that where the manufacturer had adequately warned the physician, either directly or indirectly, no common law duty to warn the consumer existed.⁸⁵ Thus, the primary issue rarely involved to whom a warning was owed, but whether the warning given the physician had been adequate.⁸⁶ Then in 1985, three surprising cases were decided that completely disregarded the doctrine of the learned intermediary in the area of oral contraceptives and imposed a duty on the manufacturer to warn the ultimate consumer, the patient, directly.⁸⁷

A. MacDonald v. Ortho Pharmaceutical Corporation

In *MacDonald v. Ortho Pharmaceutical Corporation*,⁸⁸ the Massachusetts Supreme Court reviewed the propriety of an action brought by a plaintiff who suffered a stroke with resultant permanent disabilities after ingesting Ortho's product, Ortho-Novum, for a period spanning at least three years.⁸⁹ Unquestionably, the plaintiff had received both the brief summary and detailed warning pamphlet as dictated by FDA regulations.⁹⁰ Both materials referred to abnormal blood clotting as a potential side effect of Ortho-Novum, yet neither contained the specific word "stroke."⁹¹ Accordingly, the plaintiff testified that she had never

⁸⁴*Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652 (1st Cir. 1981); *Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87 (2d Cir. 1980); *Skill v. Martinez*, 91 F.R.D. 498 (D.N.J. 1981), *aff'd*, 677 F.2d 368 (3d Cir. 1982); *Goodson v. Searle Laboratories*, 471 F. Supp. 546 (D. Conn. 1978); *Dunkin v. Syntex Laboratories, Inc.*, 443 F. Supp. 121 (W.D. Tenn. 1977); *Chambers v. G.D. Searle & Company*, 441 F. Supp. 377 (D. Md. 1975), *aff'd*, 567 F.2d 269 (4th Cir. 1977); *Hamilton v. Hardy*, 37 Colo. App. 375, 549 P.2d 1099 (1976); *Mahr v. G.D. Searle & Company*, 390 N.E.2d 1214 (Ill. 1979); *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541 (Ind. Ct. App. 1979); *Cobb v. Syntex Laboratories*, 444 So. 2d 203 (La. Ct. App. 1983); *Leibowitz v. Ortho Pharmaceutical Corp.*, 224 Pa. Super. 418, 307 A.2d 449 (1973).

⁸⁵*See* cases cited at *supra* note 84. *But see* *Lukaszewicz v. Ortho Pharmaceutical Corp.*, 510 F. Supp. 961 (E.D. Wis. 1981) (court held that manufacturer had a duty to warn patient directly but compliance with FDA regulations would satisfy such duty). *Id.* at 965.

⁸⁶*But see* *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375, 528 P.2d 522 (1974) in which the court recognized the learned intermediary doctrine but extended the duty to warn to encompass treating physicians as well as prescribing physicians.

⁸⁷*See* *Odgers v. Ortho Pharmaceutical Corp.*, 609 F. Supp. 867 (E.D. Mich. 1985); *Stephens v. G.D. Searle & Company*, 602 F. Supp. 379 (E.D. Mich. 1985); *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 475 N.E.2d 65, *cert. denied*, 106 S. Ct. 250 (1985).

⁸⁸394 Mass. at 132, 475 N.E.2d at 66, *cert. denied*, 106 S. Ct. 250 (1985).

⁸⁹*Id.* The action in *MacDonald* was actually brought by two plaintiffs, the injured user and her husband. *Id.* at 131, 475 N.E.2d at 65.

⁹⁰*Id.* at 132-33, 475 N.E.2d at 66-67.

⁹¹*Id.* at 133, 475 N.E.2d at 67. Ortho's detailed warning pamphlet did contain the following passage:

realized that abnormal blood clotting included the possibility of stroke.⁹²

In reversing the lower court's final disposition of the case,⁹³ the Massachusetts Supreme Court openly abandoned the learned intermediary rule in cases involving injuries caused by oral contraceptives and imposed on the defendant-manufacturer a duty to warn the consumer directly.⁹⁴ Explaining the reasoning underlying its decision, the *MacDonald* court stated that oral contraceptives and the circumstances under which they are frequently prescribed necessitate the revitalization of the common law duty of a manufacturer of a dangerous product to warn the user directly of potential adverse effects.⁹⁵ Specifically, the court noted that oral contraceptives are drugs not taken out of medical necessity; rather, oral contraceptives are drugs personally selected by the patient amid a myriad of other available birth control plans.⁹⁶ Because the consumer plays a significantly more active role in deciding to use the pill, the physician's role as a learned intermediary between manufacturer and consumer becomes nearly non-existent. A prescription for oral contraceptives is not the result of a physician's skilled balancing of individual benefits and risks, but rather originates as a product of patient demand.⁹⁷

In addition, the *MacDonald* court emphasized that oral contraceptives are frequently prescribed for protracted periods of eleven or twelve months in which the patient may ingest numerous doses without re-examination or direct supervision by the prescribing physician.⁹⁸ Such a setting is unlikely to favor the formation of a strong patient-physician relationship. Therefore, the consumer may develop multiple concerns and questions relating to her oral contraceptive regimen without ever having the opportunity to present these to the prescribing physician.⁹⁹

Finally, the *MacDonald* court referred to federal regulations imposed on the manufacturers of oral contraceptives to support implicitly the

About blood clots:

Blood clots occasionally form in the blood vessels of the legs and the pelvis of apparently healthy people and may threaten life if the clots break loose and then lodge in the lung or if they form in other vital organs, such as the brain.

Id. at 133 n.4, 475 N.E.2d at 67 n.4.

⁹²*Id.* at 134, 475 N.E.2d at 67.

⁹³*Id.* at 135, 475 N.E.2d at 68. At the trial court level, the jury found that Ortho had adequately warned the plaintiff's physician of risks inherent in the use of Ortho-Novum, but had failed to provide the plaintiff with sufficient information. The jury reasoned that this insufficiency had proximately caused the plaintiff's injury and that the defendant-manufacturer was liable for the resultant damages. However, the trial court judge granted Ortho's motion for judgment notwithstanding the verdict, basing his decision on the applicability of the learned intermediary doctrine. *Id.* at 135, 475 N.E.2d at 68.

⁹⁴*Id.* at 135, 138-39, 475 N.E.2d at 68, 70.

⁹⁵*Id.* at 137, 475 N.E.2d at 69.

⁹⁶*Id.*

⁹⁷*Id.*

⁹⁸*Id.*

⁹⁹*Id.*

imposition of a common law duty to warn.¹⁰⁰ Inferrable from the court's reiteration of factors leading to the FDA's implementation of a direct patient warning program,¹⁰¹ the court reasoned that these same factors readily justified a judicial abandonment of the learned intermediary doctrine in civil cases dealing with oral contraceptives.¹⁰² In addition, oral contraceptive manufacturers' nationwide compliance with FDA regulations proved that direct information provided to the patient-user was a feasible, economical means of disseminating warnings of potential adverse effects.¹⁰³ Given all these considerations, the *MacDonald* court had little or no difficulty in holding that the defendant-manufacturer bore a duty to warn the patient-consumer directly.¹⁰⁴

Having made this decision as to the scope of Ortho's duty to warn, the *MacDonald* court next examined the adequacy of the warning Ortho had supplied directly to the plaintiff in an attempt to comply with FDA requirements.¹⁰⁵ The text of the warning received by the plaintiff in both the brief summary and more detailed warning pamphlet had been explicitly approved by the FDA.¹⁰⁶ However, the *MacDonald* court initially cited Commissioner Edwards' statement in the preamble to the FDA's 1978 replacement of section 310.501 of Title 21 of the Code of Federal Regulations for the proposition that "the boundaries of civil tort liability for failure to warn are controlled by applicable State law," rather than by FDA labeling requirements.¹⁰⁷ The *MacDonald* court joined with the majority of jurisdictions to hold that federally-based requirements have

¹⁰⁰*Id.* at 137-38, 475 N.E.2d at 69-70.

¹⁰¹*Id.* In particular, the *MacDonald* court cited 43 Fed. Reg. 4215 (1978), at which the FDA stated the primary reasons for implementation of 21 C.F.R. § 310.501 as follows:

Because oral contraceptives are ordinarily taken electively by healthy women who have available to them alternative methods of treatment, and because of the relatively high incidence of serious illnesses associated with their use, . . . users of these drugs should, without exception, be furnished with written information telling them of the drug's benefits and risks.

43 Fed. Reg. 4215 (1978). In addition, the *MacDonald* court cited 35 Fed. Reg. 9002 (1970), for the FDA's reasoning supporting its earlier regulations codified at 21 C.F.R. § 130.45. The FDA considered direct patient warnings necessary because the use of oral contraceptives is "too complex to expect the patient to remember everything told her by the physician," and, as a result, patient users need information "in an organized, comprehensive, understandable, and handy-for-future-reference form." 35 Fed. Reg. 9002 (1970).

¹⁰²394 Mass. at 137-38, 475 N.E.2d at 70.

¹⁰³The impracticability of a manufacturer's providing warnings directly to the consumer concerning adverse effects had frequently been given as an argument in favor of the learned intermediary doctrine. See, e.g., sources cited at *supra* note 34.

¹⁰⁴394 Mass. at 137-38, 475 N.E.2d at 68, 70.

¹⁰⁵*Id.* at 139, 475 N.E.2d at 70.

¹⁰⁶*Id.*

¹⁰⁷*Id.* (citing 43 Fed. Reg. 4214 (1978)).

no preemptive effect on state tort law.¹⁰⁸ Although compliance with FDA standards could be offered as evidence of due care, the *MacDonald* court distinctly noted that, in the absence of the learned intermediary doctrine's applicability, the common law required that warnings of a product's adverse effects be provided in a manner "comprehensible to the average user and . . . convey[ing] a fair indication of the nature and extent of the danger to the mind of a reasonably prudent person."¹⁰⁹ In the opinion of the *MacDonald* court, the jury could reasonably have found that the omission of the specific word "stroke" from FDA-approved warning materials minimized the warning's impact to render the warning inadequate for the average consumer.¹¹⁰

In summary, Ortho's liability for failing to warn the consumer-patient directly resulted from the combined effect of two factors. First, the *MacDonald* court decided to void the applicability of the learned intermediary doctrine in cases dealing with injuries induced by oral contraceptives. Second, the jury determined as lay persons that the FDA-approved warning given directly to the plaintiff by Ortho was inadequate under the rigors of state negligence doctrine.

B. *Odgers v. Ortho Pharmaceutical Corporation*

While the *MacDonald* action was progressing through the Massachusetts state court system, two similar actions were just beginning in the federal district court of Michigan.¹¹¹ In *Odgers v. Ortho Pharmaceutical Corporation*,¹¹² the plaintiff allegedly suffered partial paralysis as a result of a blood clot induced by her ingestion of Ortho-Novum, a product of the defendant-manufacturer.¹¹³ The oral contraceptive man-

¹⁰⁸See, e.g., *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 658 (1st Cir. 1981); *Hubbard-Hall Chem. Co. v. Silverman*, 340 F.2d 402, 405 (1st Cir. 1965); *Ferebee v. Chevron Chem. Co.*, 552 F. Supp. 1293, 1304 (D.D.C. 1982), *aff'd*, 736 F.2d 1529 (D.C. Cir. 1984), *cert. denied*, 105 S. Ct. 545 (1984); *Skill v. Martinez*, 91 F.R.D. 498, 508 (D.N.J. 1981), *aff'd*, 677 F.2d 368 (3d Cir. 1982); *Wooderson v. Ortho Pharmaceutical Corp.*, 235 Kan. 387, 409, 681 P.2d 1038, 1055, *cert. denied*, 105 S. Ct. 365 (1984); *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375, 386, 528 P.2d 522, 534 (1974); *Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51, 64, 507 P.2d 653, 661, 107 Cal. Rptr. 45, 53 (1973).

¹⁰⁹394 Mass. at 140, 475 N.E.2d at 71 (quoting *Ortho Pharmaceutical Corp. v. Chapman*, 180 Ind. App. 33, 49, 388 N.E.2d 541, 552 (1979)). In addition, the *MacDonald* court felt very strongly that the sufficiency of any given warning is always a question for the jury. 394 Mass. at 140, 475 N.E.2d at 71. As a result, the liability of an oral contraceptive manufacturer based on failure to warn the consumer adequately remains unknown until the final poll of the jury.

¹¹⁰394 Mass. at 141, 475 N.E.2d at 71-72.

¹¹¹See *Odgers v. Ortho Pharmaceutical Corp.*, 609 F. Supp. 867, *Stephens v. G.D. Searle & Company*, 602 F. Supp. 379.

¹¹²609 F. Supp. 867 (E.D. Mich. 1985).

¹¹³*Id.* at 868.

ufacturer had provided the plaintiff's physician with package inserts.¹¹⁴ The plaintiff had received her prescription only after careful examination by her physician¹¹⁵ and receipt of a brief summary of adverse effects and a warning pamphlet, both prepared by Ortho in accordance with the applicable FDA regulations.¹¹⁶ Despite these measures, the plaintiff maintained that Ortho had failed to warn her adequately of its product's potential side effects.¹¹⁷ In opposition, the drug manufacturer contended that it had more than fulfilled its duty of due care, relying on its compliance with FDA regulations and the learned intermediary doctrine for support.¹¹⁸

Following a verdict for the plaintiff, the trial court granted Ortho's motion for a new trial on the ground that the jury had been improperly instructed on the scope of Ortho's duty to warn¹¹⁹ and certified a question concerning Ortho's duty to the Michigan Supreme Court in *In re Certified Questions*.¹²⁰ However, the majority of the Michigan Supreme Court refused to decide whether Ortho had a duty to warn the consumer directly of the dangers associated with the use of oral contraceptives.¹²¹

The majority in *In re Certified Questions* maintained that to render any decision on the issue of Ortho's duty would require

a choice between different systems for allocating between manufacturers, physicians, and pharmacists the duty to warn patients of the risks and potential side effects associated with the use of prescription drugs. . . . [A]ny decision of this Court implicates the obligations of members of professions who are involved in

¹¹⁴See *In re Certified Questions*, 419 Mich. 686, 694, 358 N.W.2d 873, 875, *reh'g denied*, 421 Mich. 1201 (1984). *In re Certified Questions* is cited here to provide facts not discussed in *Odgers*, 609 F. Supp. 867.

¹¹⁵419 Mich. at 694, 358 N.W.2d at 876.

¹¹⁶21 C.F.R. § 310.501. It should be noted that not only were the brief summary and warning pamphlet FDA approved, but the text of the brief summary had been drafted by the FDA. *In re Certified Questions*, 419 Mich. at 694, 358 N.W.2d at 875.

¹¹⁷*Odgers*, 609 F. Supp. at 868.

¹¹⁸*Id.* at 869, 877.

¹¹⁹Specifically, the trial judge had instructed the *Odgers* jury that "Ortho owed her [the plaintiff] the duty of reasonable care in the preparation of the booklet [warning pamphlet] accompanying the drug that, under federal regulations, Ortho was required to distribute." *In re Certified Questions*, 419 Mich. at 694, 358 N.W.2d at 876. Because the trial judge cited to *Smith v. E.R. Squibb & Sons, Inc.*, 405 Mich. 79, 90, 273 N.W.2d 476, 484, in determining that the above instruction was improper, it appears that a correct jury instruction in *Odgers* would have called upon the jury to determine whether the warnings actually given were reasonably adequate, not whether the manufacturer acted reasonably. See generally *Smith v. E.R. Squibb & Sons, Inc.*, 405 Mich. 79, 90, 273 N.W.2d 476, 483-84 (Mich. 1979) (discussion of proper jury instruction in products liability action based on breach of duty to warn).

¹²⁰419 Mich. 686, 358 N.W.2d 873.

¹²¹*Id.* at 692, 698, 358 N.W.2d at 874, 877-78.

the distribution of prescription drugs but not represented in these proceedings.¹²²

In fact, the majority in *In re Certified Questions* stated that to determine judicially the scope of Ortho's duty to warn would be to assume a function best left to state legislative bodies.¹²³

On the other hand, three dissenting justices in *In re Certified Questions* had no difficulty in imposing a duty on Ortho to warn the users of oral contraceptives directly.¹²⁴ The dissent's reasoning focused on the absence of any of those arguments commonly used to validate the learned intermediary exception to the common law duty to warn in oral contraceptive cases¹²⁵ because the drugs were used solely for nontherapeutic purposes. The dissent initially noted that, unlike other prescription drug users, oral contraceptive users generally do not rely on their physician's skill, but demand to have the pill.¹²⁶ Direct-to-the-consumer warnings, therefore, are less likely to dampen patient use of the contraceptive because it is the patient who chooses the medication.

In addition, the *In re Certified Questions* dissent noted, like the *McDonald* court, that oral contraceptives are frequently prescribed on a long-term basis without intermittent examination and evaluation by the physician.¹²⁷ Thus, the original goal of the learned intermediary doctrine, the reduction of patient injuries via physician monitoring,¹²⁸ is most likely unachievable in the oral contraceptive industry.¹²⁹ Finally, the dissent noted that the FDA regulations requiring direct warnings undercut the argument that it is impossible for drug manufacturers to give these warnings to consumers.¹³⁰ Thus, in the absence of any reason previously used to validate the application of the learned intermediary doctrine, the dissent would not have hesitated to impose a duty on pill producers to warn consumers directly.¹³¹

¹²²*Id.* at 697-98, 358 N.W.2d at 877.

¹²³Specifically, the *In re Certified Questions* majority stated:

The allocation of the duty to warn patients is a public policy question involving the marketing system and economics of a major industry and the everyday practice of an essential profession. We believe that the Legislature is in a better position to allocate those duties.

419 Mich. at 691-92, 358 N.W.2d at 874.

¹²⁴*Id.* at 716, 358 N.W.2d at 886 (Boyle, J., dissenting).

¹²⁵*Id.* at 711, 358 N.W.2d at 884-85.

¹²⁶*Id.* at 711, 358 N.W.2d at 884. Succinctly, the dissent stated that "patient choice plays a much more prominent role [in oral contraceptive use] than in the case of drugs prescribed for the treatment of illness or injury. The role of patient choice in this process supports the need for a direct patient warning. *Id.* at 712, 358 N.W.2d at 884.

¹²⁷*Id.* at 714, 358 N.W.2d at 885.

¹²⁸*Sterling Drug, Inc. v. Cornish*, 370 F.2d at 82, 85 (8th Cir. 1966).

¹²⁹*In re Certified Questions*, 419 Mich. at 714, 358 N.W.2d at 885.

¹³⁰*Id.* at 714, 358 N.W.2d 885-86.

¹³¹*Id.* at 716, 358 N.W.2d 886.

The certification's result still left the federal judge in *Odgers v. Ortho Pharmaceutical Corporation* without any concrete statement of an oral contraceptive manufacturer's duty to warn under Michigan law. However, after fully justifying the ability of a federal judge to elucidate unsettled matters of state substantive law,¹³² the *Odgers* court inferred from the Michigan Supreme Court's reluctance to apply the learned intermediary doctrine to oral contraceptives that Ortho had a duty to warn the consumer directly in the case of oral contraceptives used for nontherapeutic purposes.¹³³ In support of its decision, the trial court drew from the rationale of the dissent in *In re Certified Questions*.¹³⁴ The *Odgers* court reasoned that none of the customary arguments invoking the learned intermediary exception applied when the prescription drug in question was an oral contraceptive used for contraceptive purposes.¹³⁵

C. *Stephens v. G.D. Searle & Company*

In the second Michigan federal case, *Stephens v. G.D. Searle & Company*,¹³⁶ which was decided after the ruling in *In re Certified Questions* but before *Odgers*, a similar duty was imposed.¹³⁷ The *Stephens* court was asked to rule on the oral contraceptive manufacturer's motion for summary judgment in an action brought by a plaintiff alleged to have suffered a stroke as a result of her ingestion of the defendant's product.¹³⁸ In denying Searle's motion for summary judgment, which had been based both on a predicted application of the learned intermediary doctrine¹³⁹ and Searle's compliance with FDA regulations concerning

¹³²The ability of a federal judge to decide matters of state substantive law are beyond the scope of this Note. See *Odgers v. Ortho Pharmaceutical Corp.*, 609 F. Supp. at 869-70.

¹³³*Odgers*, 609 F. Supp. at 878.

¹³⁴*Id.* at 870-78. Specifically, the *Odgers* court relied heavily upon the language of *MacDonald*, citing at length from its text. *Id.* at 874-75. The *Odgers* court then noted that the rationale of the dissent in *In re Certified Questions* closely paralleled that of *MacDonald* in the reasons that were espoused for imposing a duty to warn the consumer directly:

use attributed to consumer demand rather than physician's advice, use for extended periods without medical assessment, and FDA regulations requiring direct warnings to patients.

609 F. Supp. at 875. In addition, the *Odgers* court noted the *In re Certified Questions* dissent's emphasis on the fact that "consumers of oral contraceptives are subjected to much laudatory publicity attributable to the manufacturers and aimed directly at consumers." *Id.*

¹³⁵*Id.* at 875.

¹³⁶602 F. Supp. 379 (E.D. Mich. 1985).

¹³⁷*Id.* at 381.

¹³⁸*Id.* at 380.

¹³⁹*Id.*

patient warnings,¹⁴⁰ the *Stephens* court relied heavily on the dissenting opinion of *In re Certified Questions* to impose a duty to warn the consumer directly on the manufacturer when its product had been used solely for contraceptive purposes.¹⁴¹ In addition, the *Stephens* court, like the *MacDonald* court, held that compliance with FDA standards did not conclusively determine the issue of warning adequacy, a question which is exclusively a matter of state negligence law.¹⁴²

In summary, all three cases — *MacDonald*, *Ogders*, and *Stephens* — held that the doctrine of the learned intermediary simply is not applicable to the distribution of the pill, at least in cases in which oral contraceptives are used solely for contraceptive purposes. The basis of these decisions rests primarily on the particular characteristics attendant to the distribution and ingestion of the pill. Oral contraceptives are readily chosen by healthy normal women, frequently as a result of product advertising rather than reliance on the advice of their personal physician. In addition, oral contraceptives are most often prescribed for significant portions of a woman's childbearing years and ingested daily with only intermittent, if any, medical supervision and assessment of the user's condition. These two factors, combined with the apparent feasibility of direct warnings as evidenced by the manufacturers' compliance with FDA regulations, induced the courts to impose on the oral contraceptive manufacturer a duty to warn the patient-consumer directly. Once such a duty was found, the courts then applied the negligence law of their particular jurisdiction and allowed the jury to determine whether the manufacturer in question had met its duty. Thus, *McDonald* and its progeny unquestionably unleashed a theory of liability to be used against the prescription drug industry: a new duty to warn, the adequacy of which can never be predicted until after the damage is done.

V. THE RAMIFICATIONS OF *MacDonald* AND ITS PROGENY: AN ERA OF UNPREDICTABILITY, UNLIMITED LIABILITY, AND UNAVAILABILITY?

For a short period in the development of products liability law, the learned intermediary doctrine stood unquestioned as an exception to the common law duty of every manufacturer to warn a product's user of dangers inherent to its use.¹⁴³ Shortly thereafter, *Davis*¹⁴⁴ and *Reyes*¹⁴⁵ created limitations on this doctrine that somewhat undermined its vitality. Today *MacDonald*, *Stephens*, and *Ogders* appear to reject completely

¹⁴⁰*Id.* at 382.

¹⁴¹*Id.* at 381.

¹⁴²*Id.* at 382.

¹⁴³See *supra* note 20.

¹⁴⁴*Davis*, 399 F.2d at 131.

¹⁴⁵498 F.2d at 1277.

the application of the learned intermediary doctrine in oral contraceptive cases by imposing a common law duty to warn the consumer directly. This revitalization of a common law duty to warn the consumer and the policies behind it bear serious ramifications for both society and the pharmaceutical industry in terms of unpredictability, unlimited liability, unavailability. The logical existence of these unpleasant ramifications is readily supported by analogy to the initial limitation of the learned intermediary doctrine in mass immunization cases and its resultant effect on the vaccine sector of the drug industry. As originally espoused by *Davis* and *Reyes*, the court-created limitations on the learned intermediary doctrine applied only where vaccines, which are prescription drugs, were "not dispensed as such,"¹⁴⁶ that is, where vaccines were administered in mass immunization settings. Subsequently, the vaccine manufacturer's duty to warn the consumer directly was extended to encompass virtually all immunization situations including those in which the manufacturer's product was administered in a private physician's office.¹⁴⁷

Once the duty to provide direct warnings to consumers became firmly entrenched as the rule in vaccine-related litigation, judicial focus then turned to the adequacy of the manufacturer's warning. In almost every case, the warning given the patient-consumer was determined to be inadequate because the fact situation of the case allowed a jury to "reasonably" find, under applicable state negligence law, that the manufacturer's warning had not sufficiently alerted vaccinees of potential risks.¹⁴⁸ In the face of mounting liability based on inadequacy of warning and other theories of liability,¹⁴⁹ manufacturers producing diphtheria-pertussis-tetanus (DPT) vaccines which bear inherent, but rare, serious side effects are opting out of the marketplace or threatening to do so, absent government intervention.¹⁵⁰

DPT is a vaccine which is given to nearly every American child¹⁵¹ to combat three serious childhood diseases,¹⁵² yet it is estimated that

¹⁴⁶*Davis*, 399 F.2d at 131.

¹⁴⁷See *Givens v. Lederle*, 556 F.2d 1341 (5th Cir. 1979); *Williams v. Lederle Laboratories*, 591 F. Supp. 381 (S.D. Ohio 1984).

¹⁴⁸See *Ezagui v. Dow Chemical Corp.*, 598 F.2d 727, 736 (2d Cir. 1979); *Givens v. Lederle*, 556 F.2d at 1345.

¹⁴⁹Prevalent theories of liability in immunization cases frequently involve allegations of failure to manufacture an optimum vaccine or failure to manufacture a vaccine which is as safe as a competitor's product. See, e.g., *Tomer v. Lederle Laboratories* (No. 84-3906, S.D. Idaho 1984), discussed in *Nat'l L.J.*, Apr. 1, 1985, at 26, col. 2; *Tom v. Wyeth Laboratories* (No. 82 L 17548, N.D. Illinois 1983), discussed in *Nat'l L.J.*, Apr. 1, 1985, at 27, col. 1.

¹⁵⁰*Nat'l L.J.*, Apr. 1, 1985, at 27, col. 2.

¹⁵¹Currently, 41 states require that every child be immunized with DPT vaccines prior to entering school. *Nat'l L.J.*, Apr. 1, 1985, at 1, col. 3.

¹⁵²DPT vaccines protect against diphtheria, pertussis ("whooping cough") and tetanus ("lock jaw").

one child out of every 310,000 vaccinees will suffer serious injury, such as brain damage.¹⁵³ As a result of these injuries, nearly 150 lawsuits are already on file against DPT producers, although defendant-manufacturers claim that the vaccine is "as safe as medical science can make it."¹⁵⁴

Following the vaccine's introduction into the marketplace, nearly a dozen companies produced the vaccine, yet this number dwindled to three in 1984 and one in 1985.¹⁵⁵ The factor cited most often for production withdrawal was the cost of defending DPT litigation.¹⁵⁶ Today, Lederle Laboratories remains as the sole producer of DPT vaccines.¹⁵⁷ However, even its days of production may be numbered. DPT-related lawsuits currently pending against Lederle bear dollar demands amounting to a sum two hundred times greater than Lederle's gross sales of the product in 1983.¹⁵⁸ In an effort to continue supplying DPT, Lederle urged Congress to pass legislation that would insulate it from the harsh liability demands of plaintiffs injured by a vaccine, allegedly incapable of safer production.¹⁵⁹ Such legislation, however, has been slow to develop. Time alone will determine whether an immunity program is passed prior to Lederle's withdrawal from the marketplace. Although it may be difficult to summon much sympathy for the liability woes of a multi-million dollar pharmaceutical company whose product undeniably causes injury, problems of the producer ultimately translate into problems for the consumer. The increasing liability of DPT manufacturers and their resultant withdrawal from production has led to an obvious decrease in the availability of DPT vaccine materials.¹⁶⁰ In fact, the shortage of these products resulted in an unprecedented request from the Centers for Disease Control in Atlanta: "a request for physicians and other health care providers to delay giving DPT booster shots in order to insure a sufficient supply of the vaccine to immunize infants from these highly contagious diseases."¹⁶¹ In economic response to decreased supply, the cost of DPT vaccines skyrocketed. In 1983, the average cost of a single

¹⁵³Nat'l L.J., Apr. 1, 1985, at 1, col. 3.

¹⁵⁴*Id.*

¹⁵⁵*Id.* at 27, col. 2.

¹⁵⁶*Id.*

¹⁵⁷*Id.*

¹⁵⁸*Id.*

¹⁵⁹The National Childhood Vaccine-Injury Compensation Act was introduced in the Senate, but it never progressed beyond the hearing stage. Such legislation would establish a "no-fault, national program to compensate children who are injured by a childhood vaccine. S. 827, 99th Cong., 1st Sess., 131 CONG. REC. S3844. Lederle is also in the process of drafting a compensation program, but Lederle's proposed program would be privately funded. Nat'l L.J., Apr. 1, 1985, at 27, col. 3.

¹⁶⁰See Notice, *Diphtheria-Tetanus-Pertussis Vaccine Shortage*, 34 MORBIDITY AND MORTALITY WEEKLY REPORT 103 (1985). See also 131 CONG. REC. S3844 (daily ed. Apr. 2, 1985).

¹⁶¹S. 827, 99th Cong., 1st Sess., 131 CONG. REC. S3844.

dose was eleven cents; in April, 1985, the same dose cost \$2.80.¹⁶² Decreased supply plus increased cost equals an increased incidence of pertussis for the public in general. The number of reported cases of pertussis, more commonly known as "whooping cough," increased by nearly thirty-three percent between 1982 and 1983.¹⁶³ Of these documented cases, sixty-six percent of the children under six years old affected had not received the full complement of three doses required to immunize completely against the disease.¹⁶⁴ Given the current state of DPT vaccine production, these numbers are likely to rise in the future. Thus, what started as a judicial attempt to provide compensation for injury sustained by a limited group of plaintiffs has actually acted to the detriment of society as a whole, a detriment resulting from unavailability, increased cost, and increased disease.

A similar result in the area of oral contraception is not beyond imagination or logic. Just as *Davis* and *Reyes* opened a whole new avenue of liability for the manufacturers of vaccines, *MacDonald* and its progeny created a new theory of liability to be wielded against the producers of the pill: the failure to warn the patient-consumer directly and adequately. Given the ability of oral contraceptive manufacturers to comply with FDA warning regulations and given the fact that direct patient warnings do enhance patient compliance,¹⁶⁵ the imposition of a duty to warn the patient-consumer is neither impractical nor unbeneficial from the standpoint of both manufacturer and consumer. However, the resolution of the adequacy issue on a case-by-case basis must seriously be questioned, for it will inevitably lead the producers of the pill down the well-trodden path once traveled by the manufacturers of DPT vaccines. The courts' general denial of the determinative effect of compliance with FDA patient package insert regulations may well coincide with similar rulings in other areas of products liability law,¹⁶⁶ yet it leaves the oral contraceptive manufacturer with no predictable basis of liability. The adequacy of any given warning, even those approved

¹⁶²*Id.*

¹⁶³The total number of pertussis cases reported in 1982 was 1,895, while 2,463 cases were reported in 1983. *Current Trends, Pertussis-United States, 1982 and 1983*, 33 MORBIDITY AND MORTALITY WEEKLY REPORT 573 (1984).

¹⁶⁴*Id.* Those cases reported for the age group of six years and under comprised approximately 82% of all reported cases. *Id.* at 573-74.

¹⁶⁵See generally *The Meaning of Medications: Another Look at Compliance*, 20 SOC. SCI. MED. 29 (1985).

¹⁶⁶See, e.g., *Howard v. McCrory Corp.*, 601 F.2d 133 (4th Cir. 1979) (flammability of children's attire); *LaGorga v. Kroger Co.*, 275 F. Supp. 373 (W.D. Pa. 1967), *aff'd*, 407 F.2d 671 (3d Cir. 1969) (flammability of children's attire); *Buccery v. General Motors Corp.*, 60 Cal. App. 3d 676, 132 Cal. Rptr. 605 (1976) (lack of headrest on vehicle); *Rumsey v. Freeway Manor Minimax*, 423 S.W.2d 387 (Tex. Civ. App. 1968) (failure to warn of absence of antidote to pesticides).

by the FDA, will never be settled until after a user is injured and a jury returns a verdict. The thought that a manufacturer will "know better the next time" can hardly be considered solace to either plaintiff or defendant. Perhaps if one uniform, adequate set of warnings had been available and complied with, both injury and liability could have been avoided. The marketplace effect of this expanded manufacturer liability on the oral contraceptive consumer is uncertain. Given both the pill's widespread use¹⁶⁷ and its presumably wide profit margin, oral contraceptive manufacturers may well be able to weather the threatening storm of increased liability. However, it is equally plausible that smaller oral contraceptive manufacturers or the manufacturers of contraceptives holding only a small percentage of the marketshare will simply close shop rather than bear the risk of making large capital investments to meet enhanced warning requirements, only to find out later that such attempts were in vain within a particular jurisdiction. At the very least, it is likely that oral contraceptive manufacturers may distribute their products selectively rather than nationally in the future. Pill producers may readily distribute their product in areas of previously "jury-established" law or in jurisdictions that recognize the exculpatory effect of compliance with FDA patient package insert regulations.¹⁶⁸ Yet those same producers may simply refuse to distribute the pill in areas where the law is "in flux" or consistently "anti-manufacturer." Thus, tomorrow's population of American women may well face a scarcity of oral contraceptives of the proportion currently being realized among potential DPT vaccinees. Increased costs predictably accompany decreased supply. Increased costs, in turn, may place oral contraceptives, once heralded as the future of birth control,¹⁶⁹ beyond the reach of poorer segments of the American population and off the shelves of free university facilities and federally-funded public clinics. Unavailability inevitably leads to rising birth rates. In the litigation arena, the holdings of *MacDonald* and its progeny bear a perversion for potential plaintiffs. Jurisdiction-by-jurisdiction, jury determination of direct warning adequacy will invariably lead to forum shopping on the part of injured pill users. Current nationwide distribution of oral contraceptives by major manufacturers subjects such producers to *in personam* jurisdiction na-

¹⁶⁷It is currently estimated that 10 million-plus women currently choose oral contraceptives as their means of birth control. Lia, *Clinical Pharmacology of Common Minor Side Effects of Oral Contraceptives*, 24 CLINICAL OBSTETRICS AND GYNECOLOGY 879 (1981).

¹⁶⁸See 21 C.F.R. § 310.501 (1985). For a court's recognition of the general exculpatory effect of FDA compliance, see *Lukaszewicz v. Ortho Pharmaceutical Corp.*, 510 F. Supp. 961 (E.D. Wis. 1981).

¹⁶⁹See generally Brown, *Nothing Will Affect Our Lives More*, *The Evening Bulletin*, Dec. 28, 1971, at 41, col. 7.

tionwide.¹⁷⁰ Thus, potential diversity plaintiffs could pick and chose between federal jurisdictions to select one where relevant choice of law leads to precedential jury-determinations most favorable to the circumstances surrounding their injury.

Having reflected upon the pitfalls resulting from the determination of a given warning's adequacy by a jury, the issue becomes whether the adequacy of a manufacturer's direct patient warning can ever be effectively dictated by state negligence law as espoused by all three recent oral contraceptive decisions. The question is likely to be answered in the negative. The urgent need for uniform standards determining the adequacy of oral contraceptive warnings transcends current state capabilities. Possible state-based solutions to this need could focus on the passage of legislation or codes by standing state legislatures or specially-created commissions. However, three problems with such plans come immediately to mind. The first of these drawbacks, cost, might appear trivial, but the added cost of creating such standards is a burden which must be borne by someone, most likely every taxpayer of a jurisdiction. Second, one must question the wisdom of placing the delicate task of determining the adequacy of a warning describing the use and potential side effects of oral contraceptives in the hands of a state political machine, most members of which probably having little medical training and/or exposure to the pill. Last, and most importantly, the determination of patient-direct warning standards by state legislative or administrative bodies may lend predictability to oral contraceptive manufacturers' liability but would still result in a varying set of standards¹⁷¹ which may ultimately prove uneconomical and unpalatable to oral contraceptive manufacturers. Assuming that every state jurisdiction immediately enacted oral contraceptive patient warning standards, such a system could conceivably leave pill producers facing compliance with fifty similar, but distinguishable, standards. Compliance would entail the printing and stocking of fifty state-dictated warning devices in addition to the brief summaries and warning pamphlets currently mandated by FDA regulations.¹⁷² Also, manufacturers would be confronted with increased prob-

¹⁷⁰See *Keeton v. Hustler Magazine, Inc.*, 465 U.S. 770 (1984), where the United States Supreme Court stated:

[T]he victim . . . may choose to bring suit in any forum with which the defendant has "certain minimum contacts . . . such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.'" "

Id. at 780-81 (quoting *International Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)).

¹⁷¹In the area of product safety, laws promulgated at the state and local level have been described as a "hodge-podge of tragedy-inspired responses" and all generally characterized by "narrow scope, diffuse jurisdiction, miniscule budgets, absence of enforcement, mild sanctions, and casual administration." See FINAL REPORT, NATIONAL COMMISSION ON PRODUCT SAFETY 2, 81-88 (1970).

¹⁷²21 C.F.R. § 310.501 (1985).

lems in product packaging and inventory control; a state-varied warning system would demand considerable effort to make certain "the right lots with the right warnings got to the right state." Finally, as actions premised on failure to warn adequately arose, as they inevitably would, nationwide distributors would be faced with the costly task of tailoring a defense viable within a given jurisdiction. Such complexity might lead to the selective distribution of oral contraceptives or withdrawal from the marketplace by pill producers. Practical, predictable state-based resolutions to the adequacy issue are non-existent. Consequently, renewed reliance on uniform FDA regulations detailing the scope and extent of direct patient warnings required of oral contraceptive manufacturers surfaces as the best, though judicially-refused solution. It may well be that current FDA mandates¹⁷³ do not result in warnings which "make the nature of the risk reasonably comprehensible to the average consumer."¹⁷⁴ Yet such a failing warrants a revamping of the standards, not a total disregard of their existence. The solution to the inadequacy problem lies in the careful, thorough revision of section 310.501 of Title 21 of the Code of Federal Regulations based on the input of consumers, health care providers, and manufacturers alike, not its juxtaposition by unpredictable state determinations. This realization, however, places an ethical burden on all parties involved. For the FDA, necessary revision of current regulations requires the agency to remain open and responsive to the demands and comprehension of the public at large rather than the purse strings of expansive pharmaceutical conglomerates. Likewise, for oral contraceptive manufacturers, a call for federal revamping of warning regulations necessitates a more brass-tacks approach to the adequacy problem. In the future, manufacturers must make a concerted effort to review the nature and extent of danger conveyed by a brief summary or a warning pamphlet from the eyes of a typical consumer. A stroke must be called a stroke, rather than "abnormal blood clotting which can be fatal."¹⁷⁵ However, the greatest burden will be borne by patient-consumers and health care providers. This burden requires an awareness of current oral contraceptive warning regulations, an assessment of the meaning and adequacy of them, and the revelation of needed revisions to those who can effect changes: manufacturers, consumer lobbyists, and the FDA itself. Finally, the determination of inadequate warning cases based on revamped federal

¹⁷³*Id.*

¹⁷⁴*MacDonald*, 394 Mass. at 140, 475 N.E.2d at 71-72.

¹⁷⁵*Id.* at 141, 475 N.E.2d at 71. It should be noted that subsequent to the events surrounding the *MacDonald* case, the FDA did amend its warning requirements to include specific reference to the word stroke. 394 Mass. at 134 n.6, 475 N.E.2d at 67 n.6 (citing 43 Fed. Reg. 4221 (1978)).

regulations will impose a burden on the judiciary. Barring a clear Congressional intent to preempt in the area of direct patient warnings federally, federal and state judges must recognize that revised FDA standards represent the ultimate product of consumer demands and medical/manufacturing expertise and, as such, must be considered determinative of the adequacy issue. Even the most comprehensive attempt to revamp FDA warning standards based on consumer demand and understanding will be thwarted unless judges accept compliance with such standards as conclusive on the adequacy issue.

Undoubtedly changes in oral contraceptive warning regulations at the federal level will be costly in terms of time, effort, and monetary expenditures. In addition, some injured patient-users may be left without compensation if the adequacy of a given patient warning is determined against an evolving federal standard. Yet, when these costs are evaluated against those potentially resulting from the courts' resolution of the adequacy issue on a jurisdiction-by-jurisdiction poll of the jury basis, risks of unpredictability, unlimited liability, and unavailability make a federal regulation system the most economical and practical solution to the warning problem.

VI. A BRIEF LOOK TO THE FUTURE

The potential effect of *MacDonald* and its progeny on the prescription drug industry in general is uncertain in light of the limited precedential sphere of the courts in which those decisions were rendered. *MacDonald* is the product of the supreme court of a single state, Massachusetts, while *Odgers* and *Stephens* were both decided by a federal district court interpreting the negligence law of Michigan alone. In addition, both *Odgers* and *Stephens* appear to be self-limiting, imposing a duty to warn the oral contraceptive user directly only where the pill is used for non-therapeutic purposes.

MacDonald, *Stephens*, and *Odgers* do, however, represent a judicial reaffirmation of the common law duty to warn a product's user directly. Refusing to apply the learned intermediary doctrine, all three courts emphasized the lack of individualized medical assessment of a prescription drug's risks/benefits in reaching their ultimate decisions to impose a duty to warn the oral contraceptive user directly. This same reasoning was previously applied in the mass immunization cases, which emphasized the increasing role of the patient in the drug choice. Certain societal factors in America today forewarn that future courts may determine that other prescription drugs warrant the imposition of a similar duty on manufacturers of additional drug classes. Initially, it should be noted that the American public is "trending-away" from the type of one-on-one patient-physician relationship that was prevalent at the inception of

the learned intermediary doctrine.¹⁷⁶ Induced by life's fast pace and mobility, the modern patient no longer places his complete reliance and medical fate in the hands of one multi-talented, fatherly, family physician. Instead, America appears to be buying its health care from a stock selection of "fast-food" medicine served up at walk-in medical facilities.¹⁷⁷ A growing number of the population are procuring their prescriptions from medical personnel manning locally-based emergency clinics, health maintenance organizations, and university and employment health facilities.¹⁷⁸ In all of these situations, the physician is likely to be seen on a chance basis and may well serve only as a figurehead to services provided by nurses and other technical assistants. Thus, it is questionable whether the modern patient establishes the type of patient-physician relationship envisioned by the creators of the learned intermediary doctrine.

In addition, diet and exercise are being increasingly realized as valuable in the treatment of common diseases.¹⁷⁹ As diet and exercise programs continue to develop, they may eventually displace to some extent medication as standard treatment. In the future, an individual ingesting a prescription drug might truly be doing so of his own reasoned choice because alternative diet and exercise regimens are unsuitable for his lifestyle. This situation is readily analogous to a woman's choice of the pill among various other forms of birth control and could consequently induce additional limitations on the learned intermediary doctrine. Finally, increased feasibility of direct patient warnings is certain to augment the growing list of prescription drugs requiring such information. In the era which spawned the learned intermediary doctrine, prescription drugs were most frequently shipped in bulk or as raw ingredients to be counted out or compounded by the local pharmacist.¹⁸⁰ Today, however, medication comes prepacked and sealed.¹⁸¹ Thus, any warning label

¹⁷⁶See generally Katz, *Free-Standing Treatment Centers*, POSTGRADUATE MED., Aug., 1983, at 291.

¹⁷⁷"Fast-food" medicine has generally been defined as the type of service a patient receives at free-standing emergency clinics, ambulatory surgery clinics, and birthing centers. *Id.* at 291. Basically, such a label denotes medical service received at facilities on a walk-in, first-come-first-served basis.

¹⁷⁸See Katz, *Free-Standing Treatment Centers*, POSTGRADUATE MED., Aug., 1983, at 291; Mestarz, *HMO's Contracting with FEC's*, HOSP., July, 1984, at 36.

¹⁷⁹See, e.g., Harbcom, *Therapeutic Value of Graded Aerobic Exercise Training in Rheumatoid Arthritis*, 28 ARTHRITIS AND RHEUMATISM 32 (1985); *Diet and 20-Year Mortality Rates in Coronary Heart Disease*, 312 NEW ENG. J. MED. 811 (1985).

¹⁸⁰Parker and Kilsoonk, *Drug Distribution: A Recap and Future Trends*, 1 TOPICS IN HOSPITAL PHARMACY MANAGEMENT 47, 49 (1981); *The Burger Opinion: What Pharmacists Had to Say*, NS16 JOURNAL OF AMERICAN PHARMACEUTICAL ASSOCIATION 492 (Sept., 1976); *Viewpoint: Hospital Pharmacy's Changing Roles*, 1 TOPICS IN HOSPITAL PHARMACY MANAGEMENT 87, 88 (1981).

¹⁸¹Parker and Kilsoonk, *Drug Distribution: a Recap and Future Trends*, 1 TOPICS AND HOSPITAL PHARMACY MANAGEMENT 47, 49 (1981).

affixed to the manufacturer's container could undoubtedly reach the product's ultimate consumer, the patient.¹⁸² Such a deviation in distribution from that prevalent at the onset of the learned intermediary doctrine essentially eliminates one primary argument proffered in its favor: the general impracticability of requiring direct patient warnings. Thus, as new developments alter the complexion of medical care and pharmaceutical distribution, society's expectations of and dependence on the physician as learned intermediary are diminishing with a predictable concomitant increase of judicial limitations on the doctrine, once created to protect this almost sacrosanct patient-physician relationship. If such limitations are accompanied in the future by a judicial reliance on state negligence law as the determinative factor in deciding the adequacy of a given direct patient warning, that development is likely to lead to problems currently occurring in the vaccine industry: unpredictability and unlimited liability for the manufacturer with resultant unavailability for the consumer.

VII. CONCLUSION

The holdings of *MacDonald*, *Stephens*, and *Odgers* can generally be divided into two components. First, the manufacturer of oral contraceptives has a duty to warn the patient-consumer directly of risks inherent in the use of its product. Second, compliance with FDA patient package insert regulations is not determinative of a manufacturer's liability for failure to warn adequately. Determination of adequacy is to be left to the jury and based on concepts of state negligence law. The first of these components, the imposition of a duty to warn the consumer directly, represents a refusal to apply the doctrine of the learned intermediary, which would impose on the prescription drug manufacturer a duty to warn the consumer's physician only. Those reasons espoused by *MacDonald* and its progeny, namely the enhanced role of the healthy user in the choice of the pill, with a consequential reduction of the physician's role as learned intermediary, and the common practice of prescribing the pill for protracted periods of time, call for the revitalization of a common law duty to warn the user directly. In this era of increased public knowledge and concern regarding health, the imposition of a direct patient warning is to be applauded. In addition, certain societal factors forewarn that future courts may determine that other prescription drugs warrant additional limitations to the learned intermediary doctrine. Indeed, limitations may eventually swallow the rule, making the learned intermediary doctrine an artifact of only historical interest.

The second component of the holding of *MacDonald* and its progeny, the courts' refusal to determine a warning's adequacy based on com-

¹⁸²See Perez, *New Look to Prescription Drug Labeling*, AM. PHARMACY, Feb., 1981, at 39.

pliance with FDA regulations, must be seriously questioned. The judicially-espoused alternative requires determination of the warning's adequacy based upon a jury's interpretation of applicable state negligence law. Such a holding will lead to unpredictable and unlimited liability for the manufacturers of oral contraceptives and other prescription drug manufacturers if additional limitations on the learned intermediary doctrine are pronounced in the future. Consequently, pill producers and others may counter with selective distribution or withdrawal from the marketplace, actions which ultimately result in unavailability and increased costs for the patient-consumer. A better solution would be to work within the pre-existing regulatory framework, the FDA, to produce more comprehensible, patient-oriented warnings for oral contraceptives.

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