1991

Prescription Drugs and the Duty to Warn: An Argument for Patient Package Inserts

Alan R. Styles

Follow this and additional works at: https://engagedscholarship.csuohio.edu/clevstlrev

Part of the Food and Drug Law Commons

How does access to this work benefit you? Let us know!

Recommended Citation


This Note is brought to you for free and open access by the Law Journals at EngagedScholarship@CSU. It has been accepted for inclusion in Cleveland State Law Review by an authorized editor of EngagedScholarship@CSU. For more information, please contact library.es@csuohio.edu.
# PRESCRIPTION DRUGS AND THE DUTY TO WARN:
# AN ARGUMENT FOR PATIENT PACKAGE INSERTS

## I. INTRODUCTION .................................................. 112

## II. PATIENT INFORMATION ......................................... 112

### A. Introduction ................................................. 112

### B. Informed Consent ........................................... 113

#### 1. Balancing the Risks and Benefits ..................... 113
#### 2. Elective and Non-Elective Drugs ..................... 114

### C. Ensuring Safety and Efficacy .............................. 115

#### 1. Patient Instruction ..................................... 116

##### a. Patient Compliance ..................................
##### b. Drug Interactions ....................................

#### 2. Patient Warnings ....................................... 117

##### a. Recognition of Adverse Reactions ............. 117
##### b. Patient Compliance ..................................

### D. Advantages of Written Information ....................... 118

## III. PRESCRIPTION DRUGS AND THE DUTY TO WARN ............. 119

### A. The Manufacturer's Duty to Warn and the Learned Intermediary Doctrine ...................................... 119

#### 1. Rationale of the Doctrine .............................. 120
#### 2. Development of the Doctrine .......................... 121
#### 3. Decline of the Doctrine ................................. 123
#### 4. The Mass Immunization Exception ................... 124
#### 5. The Oral Contraceptive Exception .................... 125

### B. The Physician's Duty to Warn and the Informed Consent Doctrine ............................................ 127

#### 1. Rationale of the Doctrine .............................. 127
#### 2. Scope of the Duty to Warn ............................. 128
#### 3. The Doctrine and the Prescription Drugs ............ 129

## IV. FDA REGULATION OF PATIENT INFORMATION ................ 131

### A. Introduction ................................................. 131

### B. Patient Warnings ........................................... 131

#### 1. Isoproterenol ............................................. 131
#### 2. Oral Contraceptives .................................... 131

### C. Patient Package Inserts .................................... 132

### D. The Patient Package Insert (PPI) Program .............. 133

#### 1. Proposal of the Program ............................... 133
#### 2. Final Regulations Issued ............................... 134
#### 3. Stay of the Final Regulations ......................... 135
#### 4. Revocation of the Program ............................. 136

## V. RATIONALE FOR RE-ENACTING THE PPI PROGRAM .......... 136

### A. Failure of the Voluntary Programs .................... 136

### B. Increased Patient Participation ........................ 137

### C. Prescription Drug Advertising ............................ 137

## VI. CONCLUSION ..................................................... 138

Published by EngagedScholarship@CSU, 1991
I. INTRODUCTION

It has been more than ten years since the Food and Drug Administration proposed regulations which would have required detailed patient information for all prescription drugs. The proposed regulations, intended to promote the safe and effective use of prescription drugs, would have required a manufacturer to supply nontechnical, nonpromotional information, referred to as patient package inserts, directly to the patient. In response to a directive from President Reagan, the final regulations were withdrawn before implementation.

This note will analyze the need for patient information in satisfying the tort objectives of informed consent and public safety. The note will then analyze the practical effect of the learned intermediary and informed consent doctrines upon the manufacturer's and physician's duty to supply patient information. The note will then analyze the FDA regulations leading to the proposed patient package insert (PPI) program, the program itself, the rationale for the program and the reasons for its revocation. Finally, the note will present rationale for re-enacting the FDA regulations.

II. PATIENT INFORMATION

A. Introduction

Prescription drugs are dangerous compounds which can cause serious injury when used improperly and occasionally even when used properly. A patient taking a prescription drug must be supplied with information concerning the drug's proper use and symptoms of possible adverse reactions if the drug's dangerous properties are to be minimized. Providing patients with adequate information on the proper use of prescription drugs and the risks involved in their use satisfies two tort objectives.

---

2 Id. at 40,016.
3 Id. at 40,026.
4 Id. at 40,016.
6 See infra notes 15-61 and accompanying text.
7 See infra notes 62-152 and accompanying text.
8 See infra notes 153-200 and accompanying text.
9 See infra notes 201-217 and accompanying text.
First, providing adequate patient information satisfies the disclosure requirements of the informed consent doctrine. Patient information is essential if the patient's consent is to be knowledgeable and, therefore, qualify as informed consent. Second, providing adequate patient information aids in limiting the inherently dangerous properties of prescription drugs. This decreases the incidence of injury and, consequently decreases tort liability. Patient information is essential if prescription drugs are to be used safely and effectively.

B. Informed Consent

A physician must obtain the patient's informed consent before initiating therapy. The patient's consent must be knowledgeable if it is to be true consent. Therefore, the patient must be informed of the risks involved in the use of a particular medication so that the patient may balance the risks and benefits while taking into account "[his own] personal values, lifestyle and attitudes towards risk." Without adequate patient information, the patient's consent is not true consent, but merely acquiescence to the physician's choice of therapy.

1. Balancing the Risks and Benefits

The benefits of prescription drugs range from treating acne to prolonging life. The risks of prescription drugs range from mild allergic reactions resulting in minor discomfort, to thromboembolic disease, resulting in paralysis or death. The severity of the risk, however, does not necessarily increase with the benefit of the drug. For example, Accutane, used to treat severe recalcitrant acne, has been associated with major fetal abnormalities, while insulin, used to treat diabetes, generally causes only mild allergic reactions.
One argument presented to justify withholding information from the patient concerning the risks and benefits of a prescription drug is that the patient will be intimidated by the possibility of unpleasant side effects and decide to forego therapy. In some circumstances, however, the patient is more likely to forego therapy if he is not adequately informed of the risks and benefits of the prescribed medication. For example, medications used to treat hypertension often have mild but annoying side effects, while the disease itself is often symptom free. Adequate patient information must be provided if the patient is to understand the serious consequences of untreated hypertension and, therefore, be able to intelligently balance the benefits of limiting those consequences against the risks involved in taking the medication.

2. Elective and Non-Elective Drugs

Under the learned intermediary doctrine (which is discussed in more detail infra) a prescription drug manufacturer need not warn the patient directly of the risks associated with the use of a prescription drug. The oral contraceptive drugs, however, are an exception to this general rule. In justifying the oral contraceptive exception to the learned intermediary doctrine, the courts noted that oral contraceptive drugs are used "electively" and, therefore, the patient is actively involved in the decision to use the prescription drug. Extending this line of reasoning, prescription drugs can be characterized as "elective" or "nonelective." The "elective" drugs, for example, would include: the oral contraceptives, used to prevent

---

22 See infra note 146.
23 Hypertension is treated with a variety of drugs and drug combinations. The more common side effects of antihypertensive drugs include sedation, dizziness, dryness of the mouth and headache. GOODMAN & GILMAN, supra note 18, at 789 (listing side effects of methylphenidate).
24 SILBER, HEART DISEASE, 1120-21 (2d ed. 1987). Hypertension is the chronic elevation of blood pressure above the range encountered in the general population. Id. at 212. Hypertension, generally diagnosed by a physician monitoring the patient's blood pressure, is usually symptom free until the late phases of the disease when serious pathological consequences begin to appear. Id. at 1120-21.
25 Hypertension adds to the workload of the heart and arteries. If it continues for a long time, the heart and arteries may not function properly. This can damage the blood vessels to the brain, heart and kidneys, resulting in a stroke, heart failure or kidney failure. U.S. PHARMACOPEIAL CONVENTION, USPDI-ADVICE FOR THE PATIENT, 903 (1990) [hereinafter USPDII].
26 The FDA, in justifying regulations which would have required patient labeling for all prescription drugs, noted that patients with hypertension may not take their prescribed medication because they do not experience symptoms from the disease. 44 Fed. Reg. 40,016, 40,020 (1979).
27 See infra notes 74-86 and accompanying text.
28 See infra notes 113-127 and accompanying text.
pregnancy; Rogaine,\textsuperscript{30} used to treat baldness; and Accutane,\textsuperscript{31} used to treat acne. The "non-elective" drugs, on the other hand, would include: insulin, used to treat diabetes; Lanoxin,\textsuperscript{32} used to treat heart failure; and Dilantin,\textsuperscript{33} used to treat convulsions.

The need for patient information, however, is not limited only to "elective" drugs. The FDA has stated that it "does not agree that information about serious adverse reactions and safety hazards should only be required for so-called "elective" drug products. The agency is confident that most patients can participate in the evaluation of the risks and benefits from drug products. . . ."\textsuperscript{34}

\textbf{C. Ensuring Safety and Efficacy}

Patient information is necessary for all prescription drugs, elective and non-elective, if they are to be used safely and effectively. Ensuring the safe and effective use of prescription drugs decreases the incidence of injury and, thus, tort liability. The safe and effective use of prescription drugs entails using the drug properly as well as limiting the occurrence and severity of adverse reactions. Patient information consists of patient instructions on the proper use of prescription drugs and patient warnings concerning the risks. Patient instructions can improve patient compliance and decrease the incidence of drug interactions, thereby decreasing the occurrence of adverse reactions.\textsuperscript{35} Patient warnings can decrease the severity of adverse reactions by allowing earlier recognition of possible adverse reactions. Patient warnings can also improve patient compliance by informing patients of frightening but minor side effects.

\textsuperscript{30} \textit{Physician's Desk Reference}, \textit{supra} note 19, at 2181. Rogaine is Upjohn Company's brand name for a 2% topical solution of minoxidil used to promote hair growth. \textit{Id.} Minoxidil is also marketed by Upjohn Company in a tablet form used for treatment of hypertension. \textit{Id.} at 2171. Patients using the tablet form of minoxidil to treat hypertension noticed elongation, thickening, and enhanced pigmentation of body hair. The drug was subsequently tested and approved for use as a hair growth stimulant.

\textsuperscript{31} See \textit{supra} note 19.

\textsuperscript{32} \textit{Physician's Desk Reference}, \textit{supra} note 19, at 778. In congestive heart failure, cardiac output diminishes due to decreasing contractile strength of the heart muscle. Lanoxin is Burroughs Wellcome Company's brand name for digoxin, a cardiac glycoside which increased cardiac output by increasing the contractile strength of the heart muscle.

\textsuperscript{33} \textit{Id.} at 1541. Dilantin is Parke Davis's brand name for phenytoin which is used to prevent and control seizures or convulsions.

\textsuperscript{34} 44 Fed. Reg. 60,764, 60,764 (1980) (is codified at 21 C.F.R. Part 203).

1. Patient Instructions

a. Patient Compliance

Informing the patient of the consequences of improperly taking a prescription drug improves patient compliance, enhancing safety and efficacy. Many prescription medications must be taken on a prescribed dosage schedule to maintain therapeutic blood levels. Taking the medication less often or at a lower dose than prescribed may result in subtherapeutic blood levels, causing the drug to be ineffective. Taking the medication more often or at a higher dose than prescribed may result in toxic blood levels, causing severe adverse reactions. For example, toxic levels of Dilantin, an anticonvulsant, actually causes convulsions. It is foreseeable that a patient with toxic blood levels of Dilantin, knowing the medication is for convulsions, may increase the dose of the medication to counteract convulsions which the medication itself is causing. A patient aware that toxic levels of Dilantin can actually cause convulsions is more likely to consult his physician before changing the dose of his medication.

b. Drug Interactions

Patient instructions include informing the patient of possible drug interactions. Some medications act differently if taken concurrently with other medication. Warning the patient of possible drug interactions can decrease the incidence of adverse reactions, enhancing safety and

---

*Goodman & Gilman, supra note 18, at 3-48. Blood levels are measured by determining the concentration of drug in the blood plasma. The concentration is generally measured in terms of the number of micrograms of drug per millimeter of plasma, or mcg/ml. The term therapeutic blood levels refers to drug concentration levels where the drug is effective without being toxic. Id.*

*Id.*

*Id.*

*Goodman & Gilman, supra note 18, at 452. A good correlation is usually observed between the total concentration of Dilantin in the blood and its therapeutic effect. Control of seizures is generally obtained with concentrations above 10mcg/ml, while toxic effects generally develop with concentrations above 20mcg/ml. Id. at 453. See also supra note 36.*

*Dilantin is one of the ten drugs included in a pilot program in FDA regulations which would have required patient package inserts for all prescription drugs. 45 Fed. Reg. 60,754, 60,758 (1980). See also infra notes 186-190 and accompanying text.*

efficacy. Coumadin, an anticoagulant, is more effective if taken with aspirin. If a patient taking both aspirin and coumadin is cut severely, the enhanced anticoagulant effect, caused by the aspirin, may make it difficult to stop the blood loss. Flagyl, an antibiotic, will cause severe nausea and vomiting if the patient drinks even a minimal amount of alcohol while taking the medication. Many over the counter cough syrups contain alcohol. A patient taking Flagyl needs to be informed of the drug's interaction with alcohol as well as the need to check the ingredients of other medications which may contain alcohol.

2. Patient Warnings

a. Recognition of Adverse Reactions

A patient who is fully informed of the risks of adverse reactions and the symptoms attending them will be better able to recognize an adverse reaction before it fully develops, thereby decreasing the severity of the reaction. For example, a patient taking Chloromycetin, an antibiotic,
may ignore a sore throat which is an early symptom of aplastic anemia, a rare but life threatening adverse reaction. In justifying regulations which would have required patient information for all prescription drugs, the FDA stated: "A patient who is informed about the potential adverse effects of a drug product is better able to monitor his or her reactions to the product and to take appropriate action if an adverse effect occurs."52

b. Patience Compliance

Warning the patient of possible mild adverse effects can improve patient compliance. A patient is less likely to discontinue a medication if he is aware that a minor side effect is not a symptom of a more severe adverse reaction. For example, Pyridium,53 used for urinary tract infections, causes the urine to turn bright orange.54 A patient who is not informed that discoloration of the urine is a normal side effect of the drug may become alarmed and discontinue the medication.

D. Advantages of Written Patient Information

In order for prescription drugs to be used safely and effectively, the patient must receive, understand and remember patient information concerning the drug's proper use and possible adverse side effects.55 The FDA conducted numerous studies, surveys and public hearings before promulgating regulations which would have required manufacturers to supply patient information for all prescription drugs.56 The FDA determined:

---

51 THE MERK MANUAL 263 (12th ed. 1972). See also USPDI, supra note 25, at 343 (listing the symptoms for blood disorders of which the patient should be aware). (USPDI-Advice for the Patient is a book providing information on prescription drugs written in lay language. The information provided includes: the generic name, common brand names, general information on the use of the medication, including: "Before Using This Medicine," "Proper Use of This Medicine," "Precautions While Using This Medicine," and "Side Effects of This Medicine.


53 PHYSICIAN'S DESK REFERENCE, supra note 19, at 1595. Pyridium is Parke-Davis's brand name for phenazopyridine, a urinary tract analgesic agent. Urinary tract infections can be very painful. Phenazopyridine helps to relieve the pain by acting as a topical analgesic as it is excreted in the urine. The local action of phenazopyridine is preferable to systemic analgesics which may cause drowsiness.

54 Id. Phenazopyridine is chemically related to the azo dyes.

55 44 Fed. Reg. 40,016, 40,019-20 (1979). The FDA determined that communicating prescription drug information to the patient can be summarized into five basic steps: 1) the patient must be exposed to the information; 2) the patient must pay attention to the information; 3) the patient must understand the information; 4) the patient must accept the information; and 5) the patient must remember the information.

56 44 Fed. Reg. 40,016, 40,018 (1979). For a bibliography of surveys and studies see id. at 40,035-38. See also infra notes 172-180 and accompanying text.
1) that most patients do not receive adequate information about prescription drugs; 2) that information, if provided, is often conveyed in technical language which the patient is unable to understand; and 3) that patients tend to forget information provided orally by the doctor.57

Written information such as patient package inserts are an efficient and effective means of providing patient information.58 Verbal information is easily forgotten by the patient, while written information such as patient package inserts can be retained by the patient and referred to at a later date.59

Providing the patient with supplemental information enhances physician-patient communication.60 A well-informed patient is less likely to be intimidated by the physician and more willing to ask questions. The physician, aware that the patient is well informed, is likely to be more attentive to the patient's questions. FDA Commissioner Kennedy stated: "[K]nowledge raises the quality of discourse between patient and physician, eliminates unfounded apprehension, increases compliance and draws the patient into active participation."61

III. PRESCRIPTION DRUG INFORMATION AND THE LEARNED INTERMEDIARY DOCTRINE

A. The Manufacturer's Duty to Warn and the Learned Intermediary Doctrine

Ordinarily under products liability law, the manufacturer of a product has a duty to warn the ultimate user of risks associated with the use of
the product.62 Prescription drugs, however, are an exception to this general rule.63 Manufacturers of prescription drugs need only warn the prescribing physician, who acts as a learned intermediary between the manufacturer and the consumer.64

1. Rationale of the Learned Intermediary Doctrine

Prescription drugs may cause injury even when used correctly; however, the benefits in treating disease generally outweigh the risk of injury. Prescription drugs, therefore, are considered "unavoidably unsafe".65 To avoid liability, the manufacturer of an "unavoidably unsafe product" must convey an adequate warning of the risks involved in the use of the product to the ultimate user.66 The manufacturer "of such products . . . 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

62 Ordinarily under products liability law, the manufacturer of a product is strictly liable for injuries caused by defects in the product, even if all due care is exercised in its manufacture. A product may be defective due to: 1) a flaw in the product (a construction defect); 2) failure to warn (an inadequate warning concerning risks associated with use of the product); or 3) a design defect (a product design which poses undue risks). PROSSER AND KEETON ON THE LAW OF TORTS 694-702 (5th ed. 1984).

63 See infra notes 74-85 and accompanying text.

64 Id.


There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. [emphasis added] An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warnings, 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 of 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 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.

66 Id.
apparently useful and desirable product, attended with a known but apparently reasonable risk.\textsuperscript{67}

A prescription drug, "properly prepared and accompanied by proper directions and warnings, is not defective nor is it unreasonably dangerous."\textsuperscript{68} [emphasis in original] The prescription drug manufacturer, however, need not convey the directions and warnings directly to the ultimate user, the patient.\textsuperscript{69} The courts have determined that the risks associated with the use of prescription drugs can only be adequately evaluated by a medical expert.\textsuperscript{70} Therefore, a special rule known as the learned intermediary doctrine has been applied to prescription drugs. Under the doctrine, a prescription drug manufacturer need only warn the prescribing physician of the risk involved in the prescription drug's use.\textsuperscript{71} The physician then acts as a learned intermediary between the manufacturer and the patient.\textsuperscript{72} It is the prescribing physician's duty to warn the patient of the risks associated with the use of the prescription drug. Liability for injury resulting from a failure to adequately warn is, therefore, shifted from the manufacturer to the physician.\textsuperscript{73}

2. Development of the Doctrine

In Marcus v. Specific Pharmaceuticals, Inc.,\textsuperscript{74} a 1948 case, the court held that a prescription drug manufacturer's duty to warn is fulfilled by giving adequate warning to the prescribing physician.\textsuperscript{75} The language of the case, however, indicates that the court was primarily concerned with the concept of privity and the fact that the manufacturer made no representations to the patient directly.\textsuperscript{76} Subsequently, in Love v. Wolf,\textsuperscript{77} a 1964 case, the 13 Court of Appeals for the Third District of California

\textsuperscript{67} Id.
\textsuperscript{68} Id.
\textsuperscript{69} See infra notes 77-86 and accompanying text.
\textsuperscript{70} See infra notes 86-88 and accompanying text.
\textsuperscript{71} Id.
\textsuperscript{72} Id.
\textsuperscript{73} Id.
\textsuperscript{74} 191 Misc. 285, 77 N.Y.S.2d 508 (N.Y. Sup. Ct. 1948). The plaintiff in Marcus brought action to recover for the death of a 13-month-old child resulting from an overdose of suppositories administered as prescribed by a physician. Plaintiff alleged that the manufacturer was negligent in failing to manufacture a suppository for use by very young infants and for not adequately informing physicians of the proper dosage for very young infants. The court granted defendant manufacturer's motion for dismissal stating: "There is no reason to believe that a physician would care to disregard his own knowledge of the effects of drugs and hence of the quantity to be administered, and substitute for his own judgment that of a drug manufacturer." Id. at , 77 N.Y.S. at 510.
\textsuperscript{75} Id. at __, 77 N.Y.S.2d at 509.
\textsuperscript{76} Id.
\textsuperscript{77} 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1984). The plaintiff in Love developed aplastic anemia, a degenerative disease of the bone marrow, after the plaintiff's physician had prescribed Chloromycetin, an antibiotic, for a mild infection. The manufacturer had warned physicians of the risk of aplastic anemia and had advised physicians that the drug should not be used for minor infections. The court stated that the manufacturer's warnings were sufficient to shift the duty of warning the patient to the prescribing physician.
held that "if adequate warning of potential dangers of a drug has been
given to doctors, there is no duty by the drug manufacturer to insure that
the warning reaches the doctor’s patient for whom the drug is pre-
scribed."778

Sterling Drugs, Inc. v. Cornish79 appears to be the first case to use the
term “learned intermediary” to describe the special role the physician
plays between the patient and the prescription drug manufacturer.80 In
Sterling, the Eighth Circuit Court of Appeals stated that in a case “dealing
with a prescription drug . . . the purchaser’s doctor is a learned inter-
mediary between the purchaser and the manufacturer.”81

As learned intermediary between the manufacturer and patient, it is
the physician’s “duty to inform himself of the qualities and characteristics
of those products which he prescribes . . . and to exercise an independent
judgment, taking into account his knowledge of the patient as well as
the product.”82 The physician balances the risks and benefits of the pre-
scription medication for the patient83 and then decides what facts con-
cerning the risks associated with prescription drugs will be told to the
patient.84 Under the learned intermediary doctrine, “[U]he patient is ex-
pected to and, it can be presumed, does place primary reliance upon that
judgment.”85

The learned intermediary doctrine has received “virtually unanimous
acceptance and remains the general rule.”86 The court in Reyes v. Wyeth

77 Id. at __, 38 Cal. Rptr. at 193.
78 Id. at -2d 82 (8th Cir. 1966). The plaintiff in Sterling developed chloroquine
retinopathy, a degenerative disease of the eye, resulting from the use of Aralen,
a drug used to treat arthritis. The court held that the manufacturer had a duty
to warn doctors of the side effect.
80 Id. at 85.
81 Id.
83 See, e.g., Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1276 (5th Cir. 1974)
(“His [the physician’s] is the task of weighing the benefits of any medication
against its potential dangers”).
84 Terhune, 90 Wash. 2d at __, 577 P.2d at 978.
85 Id.
(Boyle, J., dissenting) (stating: “Other jurisdictions have been virtually unani-
mous in adopting the learned intermediary doctrine for all prescription drugs
. . .”) (footnotes omitted). For a list of cases adopting the learned intermediary
document, see Id. at 881 n.4.

In In re Certified Questions, the United States District Court for the Eastern
District of Michigan certified questions arising from two cases concerning the
manufacturer’s duty to warn patients directly of the risks associated with the use
Feb. 18, 1983) (plaintiff alleged that her paralysis was caused by a blood clot
resulting from her use of Ortho Novum, an oral contraceptive); and Granger v.
injury resulting from the use of Mellaril, an anti-psychotic drug).

The majority opinion concluded that the questions could not be decided by
applying existing case law and were best left for the legislature. In re Certified
at 691-92, 697, 358 N.W.2d at 874, 877. The dissenting opinion, adopted by the
Odgers court in its final opinion, argued that a manufacturer of oral contraceptives
does have a duty to warn; however, this duty is not imposed for other drugs. Id.
at 698-718, 358 N.W.2d at 878-87.
Laboratories articulated the rationale for the judiciary's acceptance of the learned intermediary doctrine.

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 ultimate 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.

3. Decline of the Doctrine

In spite of the judiciary's acceptance of the learned intermediary doctrine, the continued viability of the doctrine is in question. As currently applied, the learned intermediary doctrine substantially overstates the ability and willingness of the medical community to act as a learned intermediary. Patients do not receive adequate information concerning the proper use of prescription medication. Studies indicate that fifty to sixty percent of the patients using prescription drugs do not take them properly. Studies also indicated that the frequency of medication error is directly related to the inadequacy of the information received by patients. By placing the duty to warn on the physician who has sole discretion in deciding what will be told to the patient, the current system ignores the benefits of having an informed patient. "Courts, commen-

---

87 93 F.2d 1264 (5th Cir. 1974). See infra notes 98-102 and accompanying text for a discussion of the case.
86 Id. at 1276.
85 See infra notes 113-27, 172-93, 212-17 and accompanying text.
89 Thompson, supra note 49, at 143.
92 Thompson, supra note 49, at 143.
4. The Mass Immunization Exception

The vaccine cases were the first common law exception to the learned intermediary doctrine. In *Davis v. Wyeth Laboratories*, the plaintiff contracted polio after receiving the Sabin live-virus polio vaccine from a pharmacist at an immunization clinic. The Ninth Circuit Court of Appeals held that the manufacturer has a duty to warn patients directly when the vaccine is dispensed “without an individualized balancing by a physician of the risks involved.”

In *Reyes v. Wyeth Laboratories*, the daughter of the plaintiff contracted polio after receiving the Sabin polio vaccine from a registered nurse at a county health department. The manufacturer had included in the drug package a pamphlet warning of the risks associated with the vaccine, but the nurse did not inform the plaintiff of the risks. Relying on the holding in *Davis*, the Fifth Circuit Court of Appeals held that the manufacturer has a duty to warn the patient directly when the vaccine is “dispensed without the sort of individualized medical balancing of the risks to the vaccinee that is contemplated by the prescription drug exception.”

In *Givens v. Lederle*, the Fifth Circuit Court of Appeals interpreted the mass immunization exception to the learned intermediary doctrine broadly. In *Givens*, the plaintiff claimed that she had contracted polio from her child who had been recently vaccinated by a physician. In spite of the intervention of the physician between the patient and the manufacturer, the court held that the mass immunization exception to the learned intermediary doctrine applied and, therefore, the manufacturer “is responsible for taking definite steps to get the warning directly to the consumer.” The court noted the physician’s testimony that administration of the vaccine in a physician’s office “really doesn’t differ” from that in an immunization clinic.

---

95 399 F.2d 121 (9th Cir. 1968).
96 Id. at 122-23.
97 Id. at 131.
99 Id. at 1269-70.
100 Id. at 1270.
101 Id.
102 Id. at 1277.
103 556 F.2d 1341 (5th Cir. 1977).
104 Id. at 1343.
105 Id. at 1345.
106 Id.
A recent case, however, refused to extend the mass immunization exception to a "local program instituted only to immunize certain high school students who needed the vaccine..." In *Walker v. Merck*, a 1986 case, the plaintiff alleged that her child's blindness had been caused by a dose of MMR-II vaccine administered to the plaintiff while she was pregnant with the child. The plaintiff had been given the vaccine by a licensed practical nurse in a clinic-type setting at a local high school as part of a county-sponsored immunization program. The *Walker* court stated that "[t]his court will not extend the Davis-Reyes-Givens line of decisions beyond their facts, as the exception to the learned intermediary rule established for polio cases is quite narrow and highly fact specific."  

5. The Oral Contraceptive Exception

The oral contraceptive drugs were the second exception to the learned intermediary doctrine. In 1970, prompted by studies indicating that women using oral contraceptives were more likely to develop thromboembolic disease, the FDA enacted regulations requiring manufacturers of oral contraceptives to supply warnings directly to the patient. Some courts have expanded on this regulatory exception to the learned intermediary doctrine. These courts have held that manufacturers of oral contraceptives have a common law duty to warn patients directly and that the adequacy of that warning is determined by applicable state law and not by FDA regulations.
In *Lukaszewicz v. Ortho Pharmaceutical Corp.*, the court implied that manufacturers had a common law duty to warn users of oral contraceptives directly of the risks associated with the use of the "pill." In an amended opinion, however, the court stated that it was relying entirely upon the FDA regulations and not upon a common law duty to warn. Then in *MacDonald v. Ortho Pharmaceutical Corporation*, the Massachusetts Supreme Court held that "the manufacturer of oral contraceptives is not justified in relying on warning to the medical profession to satisfy its common law duty to warn, and that the manufacturer's obligation encompasses a duty to warn the ultimate user." The court also held that supplying the patient with a warning which satisfied FDA regulations did not preclude an action at common law concerning the adequacy of the warning.

In justifying the oral contraceptive exception to the learned intermediary doctrine, the court noted: 1) that oral contraceptives are elective drugs taken by healthy women who are actively involved in the decision to use them; 2) that there is a high incidence of side effects associated with the use of oral contraceptives; and 3) that due to the complexity of the information involved, oral communication by the physician does not adequately inform the patient.

---

117 510 F. Supp. 961 (E.D. Wis.), modified, 532 F. Supp. 211 (E.D. Wis. 1981). The plaintiff in *Lukaszewicz* alleged that the defendant manufactured and sold Ortho-Novum, an oral contraceptive, in a defective condition unreasonably dangerous to the plaintiff and that as a result of her use of the product she suffered a cerebral vascular accident. *Id.* at 962.

118 510 F. Supp. at 965.

119 532 F. Supp. at 211.

120 394 Mass. 131, 475 N.E.2d 65 (1985), cert. denied, 474 U.S. 920 (1985). The plaintiff in *MacDonald* alleged that a stroke and resulting injuries were caused by the manufacturer's failure to warn users of the risk of stroke. *Id.* at 132-35, 475 N.E.2d at 66-68.

121 *Id.* at 138, 475 N.E.2d at 70.

122 See *supra* note 114.

123 394 Mass. at 139, 475 N.E.2d at 70. In justifying its holding the court noted a statement made by the FDA Commissioner in the preamble to the regulations amending and expanding the labeling requirements for oral contraceptives. *Id.*

The Commissioner stated:

The Commissioner does not agree that the imposition of a requirement for patient labeling will necessarily affect adversely the standard of civil tort liability which is imposed on drug manufacturers or dispensers. Whether or not a corporation or individual is to be held liable in a given situation will depend upon the facts surrounding the manufacture, sale, and use of the drug product, and on the nature of the injury. It will also depend on the applicable state law, which the Commissioner notes can be adjusted by state courts and legislatures in light of the facts presented by patient labeling.

43 Fed. Reg. 4214, 4214 (1978). The court interpreted the Commissioner's statement as supporting the creation of standards under state law which may exceed the FDA requirements. *MacDonald*, 394 Mass. at 139, 475 N.E.2d at 70. For a discussion of the difficulties accompanying individual state standards, see *infra* notes 128-29 and accompanying text.

In two federal cases decided in the same year as MacDonald, the District Court for the Eastern District of Michigan also held that manufacturers of oral contraceptives have a common law duty to warn patients directly of the risks associated with the use of oral contraceptives and that supplying a warning which complies with FDA regulations does not necessarily preclude an action at common law concerning the adequacy of the warning.

Expansion of the oral contraceptive exception to the learned intermediary doctrine on a jurisdiction by jurisdiction basis may result in inconsistent labeling requirements for oral contraceptive manufacturers. With the benefit of hindsight, a jury may determine that a manufacturer's warning was inadequate. The manufacturer faced with a vague and nebulous standard which might differ from jury to jury would be forced to provide warnings concerning every possible risk regardless of its severity or probability. Faced with a lengthy document detailing every possible consequence, patients are less likely to read the information, thus defeating the purpose of patient information. A comprehensive regulatory program, such as that proposed by the FDA (discussed in more detail infra), could avoid conflicting warning requirements by mandating that a warning complying with regulations is adequate as a matter of law.

B. The Physician's Duty to Warn and the Informed Consent Doctrine

1. Rationale of the Doctrine

"[T]herapy not authorized by the patient may amount to a tort, a common law battery, by the physician." To avoid liability, therefore, the

---

125 Odgers v. Ortho Pharmaceutical Corp., 609 F. Supp. 867 (E.D. Mich. 1985) (plaintiff alleged that her use of Ortho-Novum, an oral contraceptive manufactured by defendant, caused a blood clot resulting in her paralysis, and that the defendant had failed to adequately warn her of the risk); Stephens v. G.D. Searle & Co., 602 F. Supp. 379 (E.D. Mich. 1985) (plaintiff alleged that her use of Ovulen, an oral contraceptive, caused her stroke and that defendant was negligent in not adequately warning her of the risk).


127 Odgers, 609 F. Supp. at 877-78 ("I am of the opinion that the FDA's regulation of oral contraceptives was not intended in any way to preclude imposition of tort liability for failure to warn."); Stephens, 602 F. Supp. at 381 ("It is clear to this Court that the adequacy of a warning in a products liability case is a question for the jury.").

128 See supra notes 120-127 and accompanying text. See also Brushwood & Simonsmeier, supra note 17, at 297-98; Fern, The Decline and Fall of the Learned Intermediary Doctrine, 28 FOR THE DEFENSE 10, 17 (1986); Knicke, Oral Contraceptives: Heading Into an Era of Unpredictability, Unlimited Liability, and Unavailability, 19 IND. L. REV. 615, 634-41 (1986).

129 Brushwood & Simonsmeier, supra note 17, at 298.

physician must obtain the patient's consent before initiating therapy. True consent is the informed exercise of choice and requires that the patient have the opportunity to knowledgeably evaluate the therapeutic options available and the risks involved in those options. In order to ensure that the patient's consent is knowledgeable and to protect the common law rights of self determination and bodily integrity, the courts developed the informed consent doctrine. The informed consent doctrine is premised on the fundamental concept that "[e]very human being, of adult years and sound mind" has a right to determine "what shall be done with his own body."

2. The Scope of the Duty to Warn

The informed consent doctrine imposes upon the physician a duty to warn the patient of the risks associated with a proposed therapy. There are currently two standards for determining the scope of the duty to warn. Under the traditional customary-practice standard, the scope of the duty to warn is determined by the standard of practice in the medical community. The physician is not under a duty to warn unless the medical community has determined that the disclosure is necessary. One

---

131 Id. at 782.
132 Id. at 780.
134 Canterbury, 464 F.2d at 780 (quoting Schloendorff v. Society of N.Y. Hosp., 211 N.Y. 125, 105 N.E. 92, 93 (1914)).
135 For a detailed analysis of the informed consent doctrine in reference to prescription drugs, see Tietz, supra note 133; Schultz, From Informed Consent to Patient Choice: A New Protected Interest, 95 YALE L.J. 219 (1985).
136 Tietz, supra note 133, at 368. There are three elements which must be proven to establish a breach of the duty to warn: 1) whether the physician had a duty to warn; 2) the scope of that duty; and 3) if the duty was breached, whether the breach proximately caused the patient's injury (that is, whether the patient would have refused consent had he been adequately informed). Id. at 371-72.
138 See Kaiser v. Suburban Transp. Sys., 65 Wash. 2d 461, 464, 398 P.2d 14, 16 (1965) (to determine what warnings are to be given with a prescription drug, a court should look to what the medical community usually discloses); Natanson v. Kline, 186 Kan. 393, 350 P.2d 1093, 1106 (1960) ("The duty of the physician to disclose . . . is limited to those disclosures which a reasonable medical practitioner would make under the same or similar circumstances."). Tietz, supra note 133, at 372 n.28.
commentator has noted that courts have found the current standard of practice for physicians in some communities is to keep the patient completely ignorant. 139

The courts, recognizing the inherent conflict in allowing physicians to determine for themselves the scope of the duty to warn, developed the reasonable-patient standard. Under the reasonable-patient standard, the scope of the physician's duty to warn is determined by what information a reasonable patient would find material in weighing the risks and benefits of the proposed therapy. 140

Canterbury v. Spence 141 is the leading case establishing a reasonable-patient standard. In Canterbury, the District of Columbia Court of Appeals found that the duty to warn is independent of the patient's request for disclosure and that the standard for review is not the standard set by custom of physicians practicing in the community. 142 The Canterbury court stated: "Respect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves." 143

3. The Doctrine and Prescription Drugs

Canterbury dealt with the patient's consent to a surgical procedure. 144 In the case of prescription drugs, however, the courts almost universally continue to apply the more limited customary-practice standard. 145 As currently applied, the informed consent doctrine overstates the willingness of the medical community to adequately inform patients of the risks associated with the use of prescription drugs. When prescribing prescrip-

139 Thompson, supra note 49, at 148 (citing M. Dixon, Drug Product Liability § 7.23, 7-110 (1974)).
140 Tietz, supra note 133, at 368.
141 464 F. 2d 772, (D.C. Cir.) cert. denied, 409 U.S. 1064 (1972). The plaintiff in Canterbury, a youth troubled by back pain, submitted to a laminectomy, an operation to correct the condition. The plaintiff was not informed of the risk of paralysis incidental to the procedure. The day after the operation the youth fell from his hospital bed after being left unattended. A few hours after the fall, the lower half of plaintiff's body was paralyzed. Despite another operation and extensive medical care the plaintiff remained partially paralyzed. Id. at 776. The court held that every human being, and thus every medical patient, of adult years and sound mind has a right to determine what shall be done with his own body and that true consent is the informed exercise of choice, entailing opportunity to evaluate knowledgeably the options available and the risks attendant upon each. Id. at 780.
142 Id. at 783-84. The court held that the physician is under an obligation to communicate specific information to the patient when required by the exigencies of reasonable care. Id. at 781. The court stated that the test for determining whether a particular risk must be disclosed is its materiality to the patient's decision. Id. at 786-87.
143 Id. at 784.
144 Id. at 776.
145 Tietz, supra note 133, at 369. See also supra note 138.
tion drugs, physicians tend not to inform patients of the less common but more severe adverse reactions as they believe the patient may be frightened into not taking the medication. \(^{146}\) The current standard of practice for physicians in some communities is to keep the patient completely ignorant of the risks involved in the use of prescription drugs. \(^{147}\) A Gallup poll taken before FDA regulations required patient package inserts for oral contraceptives indicated that two-thirds of the women surveyed had not been told of the risks associated with the use of oral contraceptives. \(^{148}\)

"Optimally for the patient, [disclosure] of a risk would be mandatory whenever the patient would deem it significant to his decision...." \(^{149}\) Physicians should be required to inform patients of therapeutic alternatives, the risks involved and any other information material to the patient's informed choice. \(^{150}\)

As currently applied, the informed consent doctrine also overstates the ability of physicians to adequately inform patients of the risks involved in the use of prescription drugs. Advances in science have increased the quantity and complexity of the information available concerning prescription drugs. The sheer volume of drug literature concerning prescription drugs is overwhelming and "militates against the physician being informed of all the hazards of a particular drug...." \(^{151}\) Patient information in the form of patient package inserts (discussed in more detail \textit{infra}), would not result in similar inundation as the patient is not concerned with knowing the risk of a broad spectrum of drugs but only risks of the drug prescribed. \(^{152}\)

---


\(^{147}\) \textit{See supra} note 139.


\(^{149}\) Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.), \textit{cert. denied}, 409 U.S. 1064 (1972), 474 F.2d at 787. However, after stating that optimally the patient's subjective concerns should be considered, the court then stated such a requirement would place an undue demand upon the medical profession and, therefore, the scope of the standard is not subjective as to either the physician or the patient but remains objective as to the patient's informational needs and with suitable leeway for the physician's situation. \textit{Id}.

\(^{150}\) Tietz, \textit{supra} note 133, at 374.

\(^{151}\) Thompson, \textit{supra} note 49, at 145.

\(^{152}\) \textit{Id}.
IV. FDA REGULATION OF PATIENT INFORMATION

A. Introduction

The FDA has promulgated certain regulatory exceptions to the learned intermediary doctrine. Beginning in 1968, the FDA determined that certain drugs were not safe unless labelled with nontechnical, nonpromotional information provided directly to the patient. The FDA regulations challenged the assumption which the courts had been making in support of the learned intermediary doctrine that prescription drugs were safe and effective if warnings were supplied only to the prescribing physician.

B. Patient Warnings

1. Isoproterenol

In 1968, the FDA issued regulations requiring manufacturers to warn patients directly of the hazards associated with the use of isoproterenol. Excessive use of isoproterenol, an inhalation drug used by asthmatics, had been shown to cause severe bronchoconstriction making it more difficult for the asthmatic to breathe. Noting that isoproterenol is a self-administered drug whose frequency of use is necessarily determined by the patient, the FDA promulgated regulations requiring that the inhaler dispensed to the patient be labeled with a specific warning advising the patient of the danger associated with excessive use.

2. Oral Contraceptives

In 1970, prompted by studies indicating that women using oral contraceptives were more likely to develop thromboembolic disease than

---

154 Id. at 40,026.
155 Id. at 40,016.
156 Schwartz, Consumer Warnings for Oral Contraceptives: A New Exception to the Prescription Drug Rule, 41 FOOD DRUG COSM. L.J. 241, 246 (1986).
158 Id.
159 Id. The regulations required that the warning be attached to the medication container or shipped separately with instructions to the pharmacist to label the container before dispensing. The required notice stated: "Warning: Do not exceed the dose prescribed by your physician. If difficulty in breathing persists, contact your physician immediately." Id.
nonusers, the FDA issued regulations requiring that a brief patient warning be inserted in each package of oral contraceptives. The regulations further required that the warning advise the patient that a more detailed pamphlet was available from the patient's physician. The FDA noted: 1) that oral contraceptives contain potent steroid hormones; 2) that they are used for long periods of time by a large number of women who, for the most part, take them as a matter of choice; and 3) that because of their indications, they are sometimes used without adequate medical supervision. The FDA determined that "[t]hey represent, therefore, the prototype of drugs for which well-founded patient information is desirable."

In 1974, under the advice of the National Food and Drug Advisory Committee, the FDA began a patient prescription drug labeling project to investigate whether FDA patient labeling should be expanded to other prescription drugs. The FDA discussed the program with interested parties, interviewed parties likely to be affected by the legislation, reviewed the literature concerning patient needs, and conducted research to evaluate the effectiveness of labeling in communicating information to patients.

C. Patient Package Inserts

In 1977, the FDA amended the regulations requiring patient warnings to include the estrogen drugs and in 1978, revised the patient warning to include more detailed information. The amended regulations also

---

DO NOT TAKE THIS DRUG WITHOUT YOUR DOCTOR'S CONTINUED SUPERVISION.
The oral contraceptives are powerful and effective drugs which can cause side effects in some users and should not be used at all by some women. The most serious known side effect is abnormal blood clotting which can be fatal.
35 Fed. Reg. at 9002-03.
162 Id. at 9003.
164 Id.
166 Id. at 40,018-19. See also id. at 40,035-38 (bibliography of references).
167 42 Fed. Reg. 37,636 (1977) (codified at 21 C.F.R. § 310.515). The Commissioner concluded that the safe and effective use of drug products containing estrogens requires that patients be fully informed of the benefits and risks involved in the use of these drugs. Id. at 37,641.
168 43 Fed. Reg. 4,214 (1978) (codified at 21 C.F.R. § 310.501). The FDA stated that the action was taken to provide consumers with expanded labeling information reflecting recent reports about the risk of blood clots, other problems of the circulatory system, cancer and effects upon unborn children associated with the use of oral contraceptives. Id.
required that an individual patient package insert be included with each prescription dispensed.\textsuperscript{169}

Unlike isoproterenol and oral contraceptives, the estrogen drugs are not packaged in unit-of-use containers, and the manufacturer must rely on the pharmacist to dispense the patient warning or patient package insert. In \textit{Pharmaceutical Mfrs. Ass'n v. FDA},\textsuperscript{170} drug manufacturers and pharmaceutical groups challenged the FDA's authority to require patient package inserts for estrogen drugs. The Third Circuit Court of Appeals upheld the FDA's regulations based on the FDA's authority to prohibit misleading labeling of prescription drugs.\textsuperscript{171} The court determined that without the patient package insert the estrogen labeling was misleading.\textsuperscript{172}

\textbf{D. The PPI Program}

1. Proposal of the PPI Program

In 1979, the FDA proposed a program requiring mandatory patient package inserts, written in nontechnical, nonpromotional language for almost all prescription drugs.\textsuperscript{173} The FDA noted that previous patient labeling regulations had centered on drugs which presented significant risks but also afforded the patient the ability to participate with the physician in choosing whether to use the medication.\textsuperscript{174} The FDA stated that it was taking this action to promote the safe and effective use of prescription drugs by patients and to ensure that patients have the opportunity to be informed of the benefits and risks involved in the use of prescription drugs.\textsuperscript{175}

The proposal was based on studies showing: 1) that most patients do not receive adequate information from their physician concerning prescription drugs;\textsuperscript{176} 2) that oral information from the physician is generally in technical language, not easily understood;\textsuperscript{177} 3) that oral information

\textsuperscript{169} \textit{Id.} at 4220-21.
\textsuperscript{170} 484 F. Supp. 1179 (D. Del. 1980), aff'd, 634 F.2d 106 (3d Cir. 1980).
\textsuperscript{171} 634 F.2d at 108.
\textsuperscript{172} \textit{Id.}
\textsuperscript{173} \textit{See supra} notes 1-6 and accompanying text.
\textsuperscript{175} \textit{Id.} at 40,016.
\textsuperscript{176} 44 Fed. Reg. 40,016, 40,020 (1979). In a national telephone survey of patients, forty-eight percent of the respondents said that their physician did not talk to them about their prescription medication. \textit{Id.} In a study at a clinic that allowed direct observation of physicians instructing patients, the length of therapy was discussed in only ten percent of the cases, the dosage frequency in only seventeen percent of the cases, and in seventeen percent of the cases the drug was never discussed at all. \textit{Id.}
\textsuperscript{177} 44 Fed. Reg. 40,016, 40,020 (1979). One study revealed, for example, that a mother did not understand that her child was to be hospitalized when she was told that the child would have to be "admitted for a work up." \textit{Id.} Although patients may not understand what physicians tell them, they may be unwilling to ask for clarification as they do not want to appear stupid or do not want to bother the physician with "silly" questions. \textit{Id.}
is easily forgotten;\textsuperscript{178} and 4) that written patient information is more effective.\textsuperscript{179} The FDA stated that it believes that patient labeling that is well designed and well written will augment oral communication and will help overcome the problems which hamper the communication to patients of important information about prescription drugs.\textsuperscript{180}

2. Final Regulations Issued

In 1980 under the Carter Administration, the FDA issued final regulations requiring patient package inserts for prescription drugs (the PPI Program).\textsuperscript{181} The FDA stated that the regulations resulted from the agency's more than ten years of experience with patient labeling for specific drugs and that patient package inserts represented a significant initiative for improving health care.\textsuperscript{182} The FDA noted that traditionally the extent of patient knowledge on prescription drugs was not available independently to patients, but that recently such information is generally available at bookstores.\textsuperscript{183} Patients, however, are not necessarily aware of the information's availability nor of its veracity.\textsuperscript{184} The FDA stated that it believes that providing complete and understandable information to patients can help maximize benefits from prescription drugs, while reducing their potential harm.\textsuperscript{185}

The final regulations established a pilot program intended to allow the agency time to evaluate the costs and benefits of patient package inserts before moving to a full scale program.\textsuperscript{186} The pilot program, to be implemented over a three year period, would have required patient package inserts for ten prescription drugs or drug classes.\textsuperscript{187} The regulations re-

\textsuperscript{178} 44 Fed. Reg. 40,016, 40,020 (1979). The FDA noted that although a physician may provide oral information to the patient, the patient may not be able to process all of the information. \textit{Id.} Studies conducted in a clinic show that patients remember only about half of the statements made to them about their treatment, even when interviewed within minutes after leaving the physician's office. \textit{Id.} The FDA also noted that the order in which medical information is presented affects how easily patients remember it. In general, patients tend to remember what they are told first. In addition, a patient's natural anxiety during an examination may interfere with the patient's ability to focus attention on the information provided. \textit{Id.}


\textsuperscript{180} \textit{Id.}


\textsuperscript{182} \textit{Id.}

\textsuperscript{183} \textit{Id.}

\textsuperscript{184} \textit{Id.}

\textsuperscript{185} \textit{Id.}

\textsuperscript{186} 45 Fed. Reg. 60,754, 60,756-57 (1980).

\textsuperscript{187} \textit{Id.} The drugs or drug classes included: ampicillin, the benzodiazepines, cimetidine, clofibrate, digoxin, methoxsalen, propoxyphene, phenytoin, thiazides, and warfarin. These drugs and drug classes were selected because the agency believed that patient package inserts for these products would significantly enhance their safe and effective use. \textit{Id.} at 60,758.
quired the manufacturer to prepare and supply patient package inserts, which were to be dispensed by a pharmacist or other drug dispenser with the prescription drug.\textsuperscript{188} The content of the patient package insert was to include: product identification, route of administration, indications, contraindications, serious side effects, precautions and general information.\textsuperscript{189} "Guideline PPI's," examples of patient package inserts that complied with the regulations, were described by the regulations for the ten drugs or drug classes included in the pilot program.\textsuperscript{190}

The regulations stated that the patient package inserts were to supplement the information traditionally provided by the physician and did not relieve the physician of his duty to provide information to the patient.\textsuperscript{191} The regulations also provided that the physician could direct that the patient package insert not be provided if he believed it would be in the patient's best interest, although the dispensing pharmacist would still be required to provide the insert upon the patient's request.\textsuperscript{192} FDA Commissioner Kennedy urged physicians to consider "patient labeling not as an intrusion, but as an educational resource . . . [which] eliminates unfounded apprehension, [and] increases compliance.\textsuperscript{193}

3. Stay of the Final Regulations

In 1981 under the new Reagan Administration, the new FDA Commissioner Arthur Hayes stayed the effective date of the pilot program.\textsuperscript{194} Commissioner Hayes issued the stay in response to a Presidential Memorandum requiring agencies in the executive branch to suspend for sixty days all regulations that were to become effective within a sixty day period.\textsuperscript{195} The Presidential Memorandum was followed by Executive Order 12,291, which required the suspension of major regulations to permit agencies to reconsider their necessity and cost.\textsuperscript{196}

\begin{itemize}
\item Id. at 60,756.
\item Id. at 60,781-82.
\item Id. at 60,788-817.
\item Kennedy, Remarks of the Commissioner, 32 Food Drug Cosm. L.J. 384, 386 (1977).
\end{itemize}
4. Revocation of the Program

In September of 1982, the FDA revoked the regulations which would have established the PPI program.\(^{197}\) Although the PPI program was favored by consumer groups, the FDA withdrew the regulations under pressure from drug manufacturers and medical associations.\(^{198}\) The primary reason given by the FDA for its revocation of the PPI program was the belief that voluntary programs could accomplish the goal of supplying patient information and concern that the PPI program would stifle the voluntary programs currently underway.\(^{199}\) Subsequent surveys indicate, however, that patients remain inadequately informed.\(^{200}\)

V. RATIONALE FOR RE-ENACTING THE PPI PROGRAM

A. Failure of the Voluntary Programs

In revoking the PPI program, the FDA did not revoke its commitment to providing patient information, nor did it revoke its findings concerning the effectiveness of written information.\(^{201}\) The FDA revoked the program because the agency believed that written patient information could be supplied more cost effectively via voluntary programs such as that proposed by the American Medical Association (AMA).\(^{202}\)

The American Medical Association opposed the PPI program on behalf of physicians who were concerned about how mandatory PPIs would affect the physician-patient relationship and who desired discretionary rather than mandatory distribution.\(^{203}\) The AMA initiated a voluntary program

---


\(^{199}\) Id. at 39,148-49.

\(^{200}\) Gifford, From PPI to PIL to PMI: Can the Private Sector Do It Better?, 50 CLEV. CLINIC Q. 26 (1983).
to provide Patient Medication Instruction (PMI) sheets to physicians for distribution to patients. PMIs cost less than one cent each and are available for approximately one hundred frequently prescribed drugs or drug classes.204

Studies indicate, however, that patients are still inadequately informed. In a 1984 survey, only twenty-six percent of the patients sampled were told about precautions, twenty-three percent were informed about side effects and only five percent received written information.205 A 1985 survey indicated that seventy-four percent of the patients surveyed were not informed of side effects,206 and a 1987 survey indicated that four out of five patients were not informed of potential side effects.207

B. Increased Patient Participation

In today's medically conscious society, patients desire to be active participants, not passive recipients of prescription drug therapy.208 Surveys indicate that patients desire more patient information and are willing to pay for it. A nationwide survey indicated that forty-nine percent of the respondents wanted additional information about prescription drugs, particularly written information in nontechnical language to be dispensed with the prescription drug.209 Another survey of television viewers reported that sixty-nine percent of noon viewers and fifty-seven percent of evening viewers were willing to pay an additional thirty cents per prescription to receive patient package inserts.210 FDA estimated that patient package inserts would cost nine cents per prescription if applied to new and refilled prescriptions and eighteen cents per prescription if applied only to new prescriptions.211

C. Prescription Drug Advertising

Within the last few years, manufacturers have begun to advertise prescription drugs directly to consumers, and television viewers of certain
cable networks have the opportunity to see advertisements for prescription drugs which are supposedly aimed at the physician.\textsuperscript{212} Prescription drug advertising is currently opposed by the FDA which is attempting to establish guidelines for public advertising of prescription drugs.\textsuperscript{213}

The advent of prescription drug advertising may be used by some courts to impose a duty on prescription drug manufacturers to warn consumers directly.\textsuperscript{214} Aggressive marketing techniques and advertisements assuring women of the safety and efficacy of oral contraceptives were two factors considered by the courts holding that oral contraceptive manufacturers have a common law duty to warn consumers directly.\textsuperscript{215} A prescription drug manufacturer who advertises a product is voluntarily bypassing the physician as learned intermediary. The goal of advertising is to create demand for a product and even though the physician is necessarily involved in the patient's actual receipt of the prescription drug product, the manufacturer has departed from its traditional role of dealing exclusively with the physician.\textsuperscript{216} But as noted by the majority opinion in \textit{In re Certified Questions},\textsuperscript{217} an expansion of such a well settled area of law is best left to the legislature.\textsuperscript{218}

VI. CONCLUSION

Prompted by the FDA regulations, recent cases have recognized an oral contraceptive exception to the learned intermediary doctrine, thus imposing upon manufacturers of oral contraceptives a common law duty to warn patients directly.\textsuperscript{219} The courts in these cases reasoned that oral contraceptives are an "elective" drug with a relatively high incidence of severe adverse reactions.\textsuperscript{220} It is foreseeable that the courts will extend this reasoning to other "elective" drugs and gradually to the "non-elect-
The exceptions are likely to engulf the rule, thus imposing upon the prescription drug manufacturers a common law duty to warn patients directly for all prescription drugs. Also, the advent of prescription drug advertising, which effectively bypasses the physician as learned intermediary, may result in the courts' imposing upon prescription drug manufacturers a common law duty to warn patients directly.

A common law duty to warn is likely to result in labeling requirements which vary from jurisdiction to jurisdiction. Manufacturers could be forced to provide warnings concerning every possible risk, resulting in lengthy warnings which patients are unlikely to read. Administrative regulation of patient information, such as that proposed by the FDA, could ensure that the consumers receive patient information in a standardized, understandable format.

The regulations should require that prescription drug manufacturers warn the patient directly where a warning can readily be conveyed in lay person's language. "A manufacturer's failure to warn the consumer directly should result in liability for any injury to the consumer proximately caused by use of the drug." On the other hand, some drugs present potential for adverse effects not easily communicated in lay language. In such cases the physician should have the duty to warn the patient. To avoid conflicting labeling requirements imposed by state law, the regulations should specify that patient package inserts meeting the standards set by the regulations constitute adequate disclosure by law. To satisfy the rare instance where non-disclosure is in the patient's best interest, the regulations may allow the physician to specify that the patient package insert be withheld. Although logic dictates that patient information is best utilized by the patient before he leaves the physician's

---

221 See supra notes 29-34 and accompanying text. See also Flannagan, Products Liability: The Continued Viability of the Learned Intermediary Rule as it Applies to Product Warnings for Prescription Drugs, 20 U. RICHMOND L. REV. 405 (1986); Fern, The Decline and Fall of the Learned Intermediary Doctrine, 28 FOR THE DEFENSE 10 (1986).

222 Id.

223 See supra notes 212-217 and accompanying text.

224 See supra notes 128-129 and accompanying text.

225 Id.

226 Id.

227 Id.

228 Id.

229 See supra notes 181-193 and accompanying text.

230 See supra notes 128-29, 223-24 and accompanying text.

231 The FDA allowed for certain exemptions from the patient package insert dispensing requirements. One of the exemptions allowed the prescribing physician to direct on the prescription in his or her handwriting that the patient package insert not be provided to the patient. 45 Fed. Reg. 60,754, 60,783 (1980) (codified at 21 C.F.R. § 203.26).
office, practicality in enforcement of the regulations and time constraints upon the physician dictate that the pharmacist is the best choice as dispenser of patient package inserts.\textsuperscript{231}

The patient package insert is a workable solution as attested to by the fact that they are still required for oral contraceptives.\textsuperscript{232} There is little doubt that patients are better informed of the risks associated with the oral contraceptives than the risks associated with other prescription drugs which do not require patient package inserts.\textsuperscript{233} In today's medically conscious society, the patient should be regarded as a consumer of a product.\textsuperscript{234} As a consumer, the patient should be an active participant in prescription drug therapy, not a passive recipient of whatever information the physician deems best.\textsuperscript{235}

\textbf{ALAN R. STYLES}

\textsuperscript{231} The FDA noted: 1) that pharmacists traditionally serve as dispensers of prescription drugs and are best able to collate, store, and provide labeling to patients; 2) that physicians prescribe drugs by telephone and may not have the opportunity to dispense the patient package insert; and 3) that dispenser distribution is more appropriate under FDA'S statutory authority for the regulating and labeling of drug products. 44 Fed. Reg. 40,016, 40,033 (1979). The FDA stated that it agrees that physicians have primary responsibility for advising patients about prescription drugs. Nevertheless, patient labeling is intended to serve primarily as an informational adjunct to the patient-physician encounter to reinforce and augment the information given to the patient by the physician. 44 Fed. Reg. 40,016, 40,032 (1979). The FDA stated further that although the regulations do not require a physician who is not the dispenser of the drug to provide the patient with the patient package insert, physicians are encouraged to present and discuss the patient package insert with the patient. \textit{Id}.


\textsuperscript{233} A Gallup poll taken before FDA regulations required patient package insert for oral contraceptives indicated that two-thirds of the women surveyed had not been told of the risks associated with the use of oral contraceptives. Kincke, \textit{supra} note 148, at 625.

\textsuperscript{234} McGarey, \textit{supra} note 208, at 143.

\textsuperscript{235} \textit{Id}. 