Pharmaceutical Manufacturers and Consumer-Directed Information – Enhancing the Safety of Prescription Drug Use

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COMMENT

PHARMACEUTICAL MANUFACTURERS AND CONSUMER-DIRECTED INFORMATION—ENHANCING THE SAFETY OF PRESCRIPTION DRUG USE

The Food and Drug Administration (FDA), the agency of the federal government responsible for protecting the public against impure and unsafe drugs, classifies as prescription drugs all drugs which cannot be made completely safe due to their nature or to the current state of pharmacology. When accompanied by an appropriate manufacturer warning, prescription drugs are considered to be unavoidably unsafe but not unreasonably dangerous.

The traditional source of warnings about the dangers and possible side-effects of prescription drugs has been the prescribing physician. Prescription drug manufacturers have had no legal duty to inform consumers directly about their products because the prescribing physician has acted as a learned intermediary between the manufacturer and the consumer. The duty to

1. The Federal Food, Drug, and Cosmetic Act (codified as amended in scattered sections of title 21 U.S.C.) defines a prescription drug as (a) drug intended for use by man which ... (B) because of its toxicity or other potentiality for harmful effect ... is not safe for use except under the supervision of a practitioner licensed by law to administer such drug. ... 2. Unavoidably unsafe products are discussed in Restatement (Second) of Torts § 402A (1965). Comment k states in relevant part:

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. ... Such a product, properly prepared, and accompanied by proper directions and warnings, is not defective, nor is it unreasonably dangerous. ... 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.

Restatement (Second) of Torts § 402A comment k (1965) (emphasis in original).

3. See, e.g., Stone v. Smith, Kline & French Laboratories, 731 F.2d 1575 (11th Cir. 1984) (manufacturer’s warning made to the physician instead of the consumer is adequate as a mat-
warn only the prescribing physician has represented an exception to the widely recognized rule of law that a manufacturer's product warnings must reach the ultimate consumer in order for the producer to avoid liability for harm caused by the product.  

As a result, prescription drug manufacturers have directed their warnings toward physicians. In addition to these warnings, all other information

4. E.g., Reyes, 498 F.2d at 1276 (pharmaceutical manufacturers must warn ultimate purchasers of nonprescription drugs); McPherson v. Buick Motor Co., 217 N.Y. 382, 111 N.E. 1050 (1916) (abolishing privity requirement in products liability cases); see also RESTATEMENT (SECOND) OF TORTS § 388 (1965), which states:

Chattel Known to be Dangerous for Intended Use

One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier

(a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and

(b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and

(c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

5. There are five basic methods that manufacturers use to communicate drug information to physicians: the package insert; the Physician's Desk Reference [hereinafter cited as PDR]; product cards (reproductions of the package insert); “Dear Doctor” letters (personal letters sent directly to physicians); and pharmaceutical “detailmen” (salesmen who market prescription drugs through personal visits to physicians).

The package insert is a written brochure included in the packaging of all prescription drugs. The insert describes the characteristics of the drug compound and provides information on warnings, adverse effects, dosages, contraindications and directions for use. See James, Warnings and the Pharmaceutical Companies: Legal Status of the Package Insert, 16 HOUSTON L. REV. 140 (1978). The PDR is an annually published compilation of the current package inserts for prescription drugs manufactured for use in the United States. Edited by the various manufacturers and organized by brand name, generic name, and manufacturer, the PDR is used by many physicians, nurses, and physician's assistants as a practical reference for basic drug information. Product cards contain information identical to that in the PDR and are distributed through detailmen and at medical conferences. “Dear Doctor” letters refer to correspondences sent by manufacturers to physicians warning them of drug side effects which have been newly identified. These, however, are not considered an effective means of warning because the volume of such letters and other printed material that physicians receive by mail precludes proper attention and assimilation by the physician. See Sterling Drug, Inc. v. Yar-
necessary for the safe and effective use of prescription drugs has also been
directed toward the medical community. This is based upon the belief that
physicians, because of their education and experience, can best receive, un-
derstand and disseminate such information. Thus, consumers must obtain
almost all of the information necessary for the safe use of prescription drugs
through their doctor, or another health care professional acting on behalf of
their physician. The exact content of the information they receive is left to
the health professional’s discretion. Liability for inadequate disclosure is
based on the doctrine of informed consent.

This single-source informational system, however, may not be the most
effective means of assuring the safe use of prescription drugs. The system is
inadequate in communicating information if there is no meaningful physi-
cian-patient relationship. This situation can frequently occur in mass im-
munization clinics and hospital emergency rooms. It also arises in situations
where drugs are prescribed by telephone or are reused by a patient for subse-
quent illness. In these instances, the physician often is not in a position to

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6. Rheingold, Products Liability—The Ethical Drug Manufacturer’s Liability, 18
RUTGERS L. REV. 947, 987 (1964), cited with approval in, Tinnerholm v. Parke, Davis & Co.,
P.2d 1084, 1088 (1978). Rheingold’s oft quoted article summarizes the rationale for the
learned intermediary rule:

(1) [T]he doctor is intended to be an intervening party in the full sense of the
word. Medical ethics as well as medical practice dictate independent judgment, un-
affected by the manufacturer’s control, on the part of the doctor. (2) Were the pa-
tient to be given the complete and highly technical information on the adverse
possibility associated with the use of the drug, he would have no way to evaluate it,
and in his limited understanding he might actually object to the use of the drug,
thereby jeopardizing his life. (3) It would be virtually impossible for a manufacturer
to comply with the duty of direct warning, as there is no sure way to reach the
patient. Rheingold, supra at 987.

7. The doctrine of informed consent requires that a physician tell the patient “what a
reasonably prudent medical specialist would tell a person of ordinary understanding of the
serious risks and the possibility of serious harm which may occur from a proposed course of
therapy, so that the patient’s choice will be an intelligent one.” ZeBarth v. Swedish Hosp.
Medical Center, 81 Wash. 2d 12, 29, 499 P.2d 1, 11 (1972). The physician is not required to
disclose particular facts or warnings which he or she decides are not necessary to properly

8. See infra note 11.
teach consumers all they need to know about the safe use of a drug. Even where the traditional physician-patient relationship exists, a consumer may not remember the warnings given verbally by the physician. The patient may be hurried, anxious, intimidated or in pain. Thus, the single-source informational system may result in poor application of the information made available, thereby increasing the possibility of drug injury.9

The need for a multi-source informational system has been advocated in Congress,10 by the judiciary,11 and by the FDA.12 In the past two decades, there have been numerous strategies developed in an attempt to improve the problems inherent in the single-source system.13 All of these, however, have

9. See 44 Fed. Reg. 40,019-21 (1979) where the FDA summarized its review of the literature on the communication of drug information to patients. It has been postulated that five areas must be examined in the communication process in order to determine whether patient learning and retention has occurred. McGuire, Some Internal Psychological Factors Influencing Consumer Choice, 2 J. CONSUMER RESEARCH 302 (1976). To be properly educated, the patient must be exposed to, pay attention to, understand, accept, and remember the information communicated. 44 Fed. Reg. 40,019-20 (1979). Based on an analysis of the circumstances of many doctor-patient communications about prescription drugs in light of these five factors, the FDA determined that “oral communication of information about prescription drug products by health professionals to patients cannot be relied upon to provide patients with the information they need to use prescription drug products properly.” Id. at 40,020. See also Cohen, What Drug Information Should the Consumer Have?—A Consumer Perspective, 11 DRUG INFO. J. 34, 35 (1977) (discussing how circumstances of doctor-patient communication can lead to drug injury).


11. The judiciary has advocated a multi-source system where the absence of a physician intermediary has led to drug injuries. See Givens v. Lederle, 556 F.2d 1341, 1345 (1977) and Reyes, 498 F.2d at 1276 (both requiring the manufacturer to reach consumers with warnings where polio vaccine was given at small country health clinics); Davis v. Wyeth Laboratories, 399 F.2d 121, 131 (9th Cir. 1968) (suggesting advertisements, posters, oral warnings, or patient releases as alternative sources of information at a mass immunization clinic). Moreover, courts have expressed a willingness to impose liability based on a reasonableness standard in cases where no physician acts as an intermediary. See Dunn v. Lederle Laboratories, 121 Mich. App. 73, 79 n.11, 328 N.W.2d 576, 579 n.11 (1982) (warning must be designed to reach the ultimate consumer where no doctor discretion is called upon); Smith v. E.R. Squibb & Sons, 273 N.W.2d 476 (Mich. Sup. Ct. 1979) (warnings given to consumer where no doctor intermediary must be examined as to their reasonableness under the circumstances).

12. See, e.g., 21 C.F.R. § 310.501(a)(1) (1984). The FDA’s initiative for a multi-source system was the Patient Package Insert (PPI) program. The PPI program was a major effort spanning two decades aimed at providing consistent and easy-to-understand prescription drug information to consumers. See infra notes 97, 102 and accompanying text.

13. Various methods can be used to communicate prescription drug information to the consumer. See generally Morris, Printed Patient Oriented Prescription Drug Materials, 12 DRUG INTELLIGENCE & CLINICAL PHARMACY 161 (1978). These include stickers that are affixed directly to the drug container, checklists containing numerous warnings and directions that may be checked off by the pharmacist as appropriate. Id. at 163-64. Other methods include drug information sheets that can be distributed by physicians or nurses in hospitals
failed to provide consumers with a consistent, reliable source of prescription drug information. There is a pressing need for such information. Prescription drugs have become central to American lives, and are an absolute necessity for some people. At the same time, the number of family-oriented general practitioners has declined over the past 20 years. The traditional health care delivery system is being replaced by health maintenance organizations (HMO), clinics, and group practices. This change is leading

and clinics, and drug information written for the purpose of obtaining informed consent. Id. at 164, 167-68.

Stickers are instructional labels placed on the prescription drug containers by pharmacists before the drug is dispensed. Typically, they warn patients to take medication with meals, to avoid alcohol, to drink plenty of fluids, or to take medication on an empty stomach. Id. at 163. Checklists are also dispensed by the pharmacist and contain instructions similar to those provided by stickers, although they vary in length and specificity. Id. Checklists often provide more information than stickers, because the pharmacist can write special instructions on the sheet. Id. Many hospitals prepare drug information sheets that contain information about prescription drugs. Id. at 164. These sheets are given to the patients by the nurse upon discharge from the hospital or when the patient is seen in a clinic. Although these sheets may also be lost by the patient, they do provide specific and detailed drug information. Id.

Written drug information may also be combined with a consent form. The Center for Disease Control in Atlanta, Georgia disseminated one-page information sheets on the Swine Flu Vaccine, containing a description of the vaccine and its side effects. Id. at 167. Individuals were to sign the bottom of the sheet, indicating consent to be vaccinated. Id.

14. According to Pharmaceutical Data Services, 1.5 billion prescriptions were written in the United States in 1983. 128 DRUG TOPIC MAG. 28 (March 1984).

15. For example, 11 million Americans currently suffer from diabetes. Further, some 500,000 children and young adults with the disease are insulin-dependent, requiring daily insulin in order to live. AMERICAN DIABETES ASSOCIATION, DIABETES MELLITUS (1984).

16. In 1963, 73,489 physicians were identified as general practitioners. By 1982 this number had declined to 62,339, despite a general growth in population during those years. See AMERICAN MEDICAL ASSOCIATION, PHYSICIAN CHARACTERISTICS AND DISTRIBUTION IN THE UNITED STATES (1963-1982). See also U.S. SENATE COMM. ON LABOR AND PUBLIC WELFARE, SUBCOMP. ON HEALTH: HEALTH CARE CRISIS IN AMERICA (1971). A Consumers Union consultant has commented on the problem of the disappearance of the traditional doctor-patient relationship and the resulting problems:

The decline of the family doctor, the increase in specialization, greater patient mobility, and time pressures on physicians all combine to make it less likely than ever that the physician will be fully aware of the patient's history and physical idiosyncrasies that might affect successful drug use. A woman might neglect to mention to her dentist or ophthalmologist that she may be pregnant, yet it may be very relevant to their choice of drugs. Are these specialists likely to inquire? If the patient were more knowledgeable, she would be far more likely to volunteer the critical information. Cohen, supra note 9, at 35.

17. See 42 U.S.C. § 300e (1982). Section 300e defines a Health Maintenance Organization and sets forth the manner in which it must supply health services to its members. Section 300e(b) states in pertinent part:

A health maintenance organization shall provide, without limitations as to time or cost other than those prescribed by or under this subchapter, basic and supplemental health services to its members in the following manner: (1) Each member is to be provided basic health services for a basic health services payment . . . (3) . . . the
to a decrease in the continuity of medical care received by consumers. It is evident that if prescription drugs are to be used safely and effectively, the consumer must be able to assist the prescribing physician in weighing the risks and benefits of drug therapy, and in monitoring that course of therapy. Without the increase in consumer knowledge that would accompany the establishment of a multi-source informational system, consumers can blindly expose themselves to unnecessary dangers.

This Comment will describe the history and current status of consumer-directed prescription drug information. It will analyze the ability of consumer-directed information to address the failings of a single-source system of prescription drug information. Finally, this Comment will explore some alternative systems designed to communicate medication information to consumers.

I. THE RIGHT TO PRESCRIPTION DRUG INFORMATION—DOES DOCTOR ALWAYS KNOW BEST?

A. The Learned Intermediary Rule

It is well-settled that a drug manufacturer discharges its duty to warn the ultimate user of prescription drugs by supplying physicians with information about the drug's dangerous propensities. This legal concept is known as services of a physician which are provided as basic health services shall be provided through—(i) members of the staff of the health maintenance organization, (ii) a medical group (or groups), (iii) an individual practice association. . . .

18. Reyes, 498 F.2d at 1276. Judge Wisdom of the United States Court of Appeals for the Fifth Circuit summarized this area of law in Reyes:

[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. . . . Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.

the learned intermediary rule because the physician acts as an intermediary between the manufacturer and the consumer. The phrase "learned intermediary" was first given legal significance in 1966, in *Sterling Drug, Inc. v. Cornish*,\(^{19}\) where it was used to describe the physician's unique role in the dissemination of prescription drug warnings. *Cornish* involved an action against a drug manufacturer for failure to warn a prescribing physician about a rare, but serious side effect caused by the use of its anti-arthritis drug "Aralen."\(^{20}\) The plaintiff in *Cornish* suffered irreversible degeneration of the retina, resulting in extensive vision impairment.\(^{21}\) At issue was whether the manufacturer had a duty to warn the plaintiff's physician of the existence of this rare side effect. The court held that it did,\(^{22}\) and although discussion of the learned intermediary rule was not extensive, the term has since become synonymous with the rule that by warning the physician of possible drug side effects a drug manufacturer need not warn the ultimate consumer. The court reasoned that the intermediary role of the physician provided the best means of preventing drug-induced injury.\(^{23}\) Provided with the knowledge of possible side-effects from the manufacturer's warnings, the physician would be able to monitor the patient for adverse symptoms, safeguarding the patient from injury.\(^{24}\) The court did not address the question of whether drug safety might be further enhanced by additional warnings to the consumer. Clearly, however, a warning to the physician was viewed as being of primary importance in discharging the manufacturer's duty to warn.\(^{25}\)

Prior to the decision in *Cornish*, the learned intermediary rule had not been clearly defined. In an earlier case where the issue was considered, however, the court permitted manufacturers to warn the physician in lieu of the consumer. In *Love v. Wolf*,\(^{26}\) the Court of Appeals for the Third District of California held that the manufacturer of the antibiotic, "chloromycetin,"

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\(^{19}\) 370 F.2d 82, 85 (8th Cir. 1966). Judge McManus of the United States Court of Appeals for the Eighth Circuit introduced the term in *Cornish*:

> [I]n this case we are dealing with a prescription drug rather than a normal consumer item. . . . [T]he 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.

*Id.*

\(^{20}\) *Id.* at 83.

\(^{21}\) *Id.* at 84.

\(^{22}\) *Id.* at 85.

\(^{23}\) *Id.* See supra note 19, for the language of the court.

\(^{24}\) 370 F.2d at 85.

\(^{25}\) *Id.*

had no duty to warn the patient for whom the drug was prescribed about the possibility of developing severe, life-threatening anemia.\textsuperscript{27} The plaintiff's physician had prescribed "chloromycetin" for various minor conditions such as a sore gum and bronchitis.\textsuperscript{28} Each prescription was refilled several times.\textsuperscript{29} A few months later, the plaintiff developed aplastic anemia, a degenerative disease of the bone marrow, which required extensive treatment under the care of a hematologist.\textsuperscript{30} The manufacturer had warned the medical community of the relationship between aplastic anemia and prolonged use of "chloromycetin" in all its advertising literature.\textsuperscript{31} The court held that the manufacturer's warnings were sufficient to shift the duty of informing the plaintiff from the manufacturer to the physician.\textsuperscript{32} As a matter of law, the court held that by adequately warning the plaintiff's physician, reasonable care had been exercised to warn the small percentage of users who might have been harmed by the drug.\textsuperscript{33} The court implied that it was not willing to require a manufacturer to warn all potential users when efforts had already been made to warn the medical profession.\textsuperscript{34}

Two years later, the learned intermediary rule was developed further and an exception was introduced. In \textit{Davis v. Wyeth},\textsuperscript{35} the manufacturer of the Sabine polio vaccine was sued by a consumer who contracted polio after the vaccine was administered at a mass immunization clinic. The plaintiff received no warning about the risk of contracting polio from the vaccine.\textsuperscript{36} However, each 100-dose batch of the vaccine contained a written warning of the risk of contracting polio.\textsuperscript{37} The United States Court of Appeals for the

\textsuperscript{27} \textit{Id.} at 395, 38 Cal. Rptr. at 193. The court stated that:
[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. But 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 prescribed.]
\textit{Id.} (citations omitted).
\textsuperscript{28} \textit{Id.} at 384, 39 Cal. Rptr. at 186.
\textsuperscript{29} \textit{Id.}
\textsuperscript{30} \textit{Id.}
\textsuperscript{31} \textit{Id.} at 395, 38 Cal. Rptr. at 193.
\textsuperscript{32} \textit{Id.} The court noted that the manufacturer warned that adequate blood studies should be made during prolonged use of the drug and that the drug should not be used for minor infections. \textit{Id.} These warnings were included in letters written to every physician in the United States. \textit{Id.} The court estimated that the company had publicized warnings to the medical profession between 85 and 90 million times during the period from the introduction of the drug to the occurrence at trial. \textit{Id.}
\textsuperscript{33} \textit{Id.}
\textsuperscript{34} \textit{Id.}
\textsuperscript{35} 399 F.2d 121 (9th Cir. 1968).
\textsuperscript{36} \textit{Id.} at 125.
\textsuperscript{37} \textit{Id.}
Ninth Circuit imposed liability upon the manufacturer for failing to warn the consumer because in the case of a mass immunization clinic, no physician is present to weigh the risks and benefits of drug therapy for each individual patient. Although the court created an exception to the learned intermediary rule in Davis, it also set forth explanatory language that became the basis of the rule for other courts. Regarding the learned intermediary rule, the court stated that ordinarily a warning to the physician was "the only effective means by which a warning could help the patient." The rule is based upon the fact that the choice of treatment with a prescription drug is a medical one, and must be made with the knowledge of the medical considerations involved. The language in Davis regarding the learned intermediary rule has been quoted by many courts, and the rule is widely followed today.

The learned intermediary issue has never been addressed by the Supreme Court, but various federal courts have reaffirmed its validity. Most recently, the United States Court of Appeals for the Eleventh Circuit affirmed an Alabama Supreme Court decision denying relief for a drug-induced hepatitis because the physician had been adequately warned. In Stone v. Smith, Kline & French Laboratories, the court refused to depart from the traditional concept of the learned intermediary in holding that the manufacturer of "Thorazine", an anti-psychotic drug, could not be held strictly liable for causing liver damage. The plaintiff had been treated with "Thorazine" while hospitalized for a psychotic illness and was instructed to continue taking the drug after discharge from the hospital. The plaintiff developed

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38. Id. at 131. See infra note 86 for the language of the court.
39. 399 F.2d at 130 (footnoted omitted).
40. Id. The court stated: "Ordinarily in the case of prescription drugs [sic] warning to the prescribing physician is sufficient. . . . [T]he choice involved is essentially a medical one involving an assessment of medical risks in the light of the physician's knowledge of his patient's needs and susceptibilities." Id.
42. See infra notes 43, 63 and accompanying text.
43. See, e.g., Stone v. Smith, Kline & French Laboratories, 731 F.2d at 1579; DeLuryea v. Winthrop Laboratories, 697 F.2d 222, 225 (8th Cir. 1983) (quoting Cornish, 370 F.2d at 85); Mauldin, 697 F.2d at 647; Brochu, 642 F.2d at 656; Lindsay v. Ortho Pharmaceutical Corp., 637 F.2d 87, 90-91 (2d Cir. 1980).
44. 731 F.2d 1575 (11th Cir. 1984).
45. Id. at 1579-80. The court quoted the learned intermediary language of Reyes and based its decision on the Reyes court's "sound reasoning." Id. at 1580. See supra note 18 for the language of the Reyes court.
46. Id. at 1577.
symptoms of liver disease shortly thereafter and was diagnosed with cholestatic jaundice, a liver condition known to be a risk of "Thorazine" use.\textsuperscript{47} The plaintiff asserted that because the risk from cholestatic jaundice was small, the physician was unable to predict the occurrence of an adverse reaction.\textsuperscript{48} Thus, the plaintiff argued, the physician was unable to make an informed choice in prescribing "Thorazine."\textsuperscript{49} The court rejected plaintiff's argument, reasoning that the physician's role was to balance the known risks and benefits of drug therapy.\textsuperscript{50} The court inferred that the possibility of a rare adverse reaction would be factored into the physician's balancing test for every patient, even though the physician would not know which patients may suffer injury.\textsuperscript{51}

The United States Court of Appeals for the Fifth Circuit also upheld the learned intermediary rule in \textit{Mauldin v. Upjohn Co.}\textsuperscript{52} In \textit{Mauldin} the plaintiff developed ulcerative colitis after using two antibiotics produced by the defendant, "Cleocin" and "Lincocin."\textsuperscript{53} Ulcerative colitis is a condition of the bowel frequently requiring extensive surgical treatment.\textsuperscript{54} The issue was whether the plaintiff's physician had been adequately warned of the risk of ulcerative colitis that the two drugs posed.\textsuperscript{55} The plaintiff's physician testified that even if the manufacturer had communicated the risk of this adverse effect, the physician might not have alerted the patient to the possibility of its occurrence.\textsuperscript{56} The physician stated that patients were not always told about all of the side effects of drug therapy.\textsuperscript{57} In this case, the plaintiff suffered from prolonged diarrhea, a symptom of ulcerative colitis, after being discharged from the primary physician's care.\textsuperscript{58} The plaintiff was examined

\begin{itemize}
\item \textsuperscript{47} \textit{Id.} at 1577, 1579.
\item \textsuperscript{48} \textit{Id.} at 1579.
\item \textsuperscript{49} \textit{Id.}
\item \textsuperscript{50} \textit{Id.} at 1579-80 (citing \textit{Reyes}, 498 F.2d at 1276).
\item \textsuperscript{51} \textit{Id.}
\item \textsuperscript{52} 697 F.2d 644 (5th Cir. 1983).
\item \textsuperscript{53} \textit{Id.} at 645-46.
\item \textsuperscript{54} \textit{See generally} T. HARRISON, \textit{PRINCIPLES OF INTERNAL MEDICINE} (9th ed. 1983).
\item \textsuperscript{55} 697 F.2d at 646. The court noted that the warning on the package insert contained the following information:
\begin{quote}
\textbf{WARNINGS}
The following reactions have been reported with the use of clindamycin [Cleocin] \textit{CASES OF SEVERE AND PERSISTENT DIARRHEA HAVE BEEN REPORTED AND HAVE AT TIMES NECESSITATED DISCONTINUANCE OF THE DRUG. THIS DIARRHEA HAS BEEN OCCASIONALLY ASSOCIATED WITH BLOOD AND MUCUS IN THE STOOLS AND HAS AT TIMES RESULTED IN ACUTE COLITIS.}
\end{quote}
\textit{Id.} at 646 n.2.
\item \textsuperscript{56} \textit{Id.} at 646-47 n.4.
\item \textsuperscript{57} \textit{Id.}
\item \textsuperscript{58} \textit{Id.} at 645.
\end{itemize}
by several different doctors who prescribed treatment, apparently unaware of the plaintiff’s medical history.\textsuperscript{59} The court held that the adequacy of the warnings to the primary physician was a question of fact for the jury,\textsuperscript{60} but that there was no obligation to warn the plaintiff of the potential adverse effects.\textsuperscript{61} The manufacturer could have discharged its duty by adequately warning the physician.\textsuperscript{62}

State courts have also generally followed the learned intermediary rule.\textsuperscript{63} In \textit{Terhune v. A.H. Robins Co.},\textsuperscript{64} the plaintiff suffered a perforated uterus and abdominal infection resulting from the migration of an intrauterine device (IUD), the Dalkon Shield, manufactured by the defendant. The Washington Supreme Court expanded the learned intermediary rule to apply it to devices, such as the Dalkon Shield, which can only be obtained through a prescription.\textsuperscript{65} The plaintiff was not told by her physician of the possibility of perforation when the advantages and disadvantages of methods of contraception were discussed.\textsuperscript{66} Nevertheless, the court held that a warning to the physician about the possibility of perforation was sufficient, because it was the physician’s duty to exercise independent judgment in deciding what to inform the patient.\textsuperscript{67}

\textit{Bacardi v. Holzman}\textsuperscript{68} is another example of a state’s acceptance of the learned intermediary rule. In \textit{Bacardi}, the plaintiff contended that defendant drug manufacturer, Lederle Laboratories, had a duty to warn about the possibility of glaucoma from ingestion of “Diamox,” a drug used for the treatment of kidney stones.\textsuperscript{69} A New Jersey superior court, however, relying on

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\textsuperscript{59. Id.} \\
\textsuperscript{60. Id. at 647.} \\
\textsuperscript{61. Id. The court stated that “[t]he manufacturer of a prescription drug is not obliged to warn each consumer of the dangers inherent in the use of its product if the prescribing physician receives adequate warnings of the potential adverse effects. Id.”} \\
\textsuperscript{62. Id.} \\
\textsuperscript{64. 90 Wash. 2d 9, 577 P.2d 975 (1978).} \\
\textsuperscript{65. Id. at 14-15, 577 P.2d at 978.} \\
\textsuperscript{66. Id. at 10, 577 P.2d at 976.} \\
\textsuperscript{67. Id. at 14-16, 577 P.2d at 978-79. The court stated that \[i]t is [the physician’s] duty to [keep informed] of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product. The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. The physician decides what facts should be told to the patient. Id. (footnoted omitted).} \\
\textsuperscript{68. 182 N.J. Super. 422, 442 A.2d 617 (1981).} \\
\textsuperscript{69. Id. at 424, 442 A.2d at 618.}
the learned intermediary principles in *Davis*, held that a drug manufacturer had no such duty. The plaintiff asserted that the learned intermediary rule should not apply because there was no individual balancing of the risks and benefits of treatment. The plaintiff had been treated with the drug for many years, and had renewed the prescription as often as thirteen times in seventeen months. Because the plaintiff-patient had seen so many doctors, he was unable to name them all. The plaintiff argued that under these circumstances, the duty to warn should have been extended to the user of the drug. The court, however, held fast to the learned intermediary rule, stating that the physician's diagnosis and treatment of the patient removed the case from the reasoning of *Davis*. The court reasoned that *Davis* and *Reyes* applied only where the prescription drug was not dispensed by a physician, as in the mass immunization cases. The court held that the exception only existed where "the unique method of administration of the prescription drug extended the duty to warn beyond the physician."

The learned intermediary concept was again addressed in *McKee v. Moore*, an Oklahoma case involving injuries sustained when an IUD perforated the plaintiff's uterus and migrated into her abdominal cavity. Although neither plaintiff nor her husband was informed of the possibility of perforation when they chose the IUD as a form of contraception, the Oklahoma Supreme Court denied plaintiff's claim because the manufacturer had included the warning of possible perforation in the package insert. The learned intermediary, the court concluded, not the patient, had the primary responsibility of deciding whether the benefits of the IUD outweighed the risk.

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70. *Id.* at 425, 442 A.2d at 619. The court quoted and relied upon the language of *Davis*, 399 F.2d 121 (9th Cir. 1968), *infra* note 86. It also acknowledged "the general rule that in the case of prescription drugs[,] warnings of potential adverse effects to the prescribing physician [are] sufficient." *Id.* at 425, 442 A.2d at 619.
71. *Id.* at 427, 442 A.2d at 620.
72. *Id.* at 425, 422 A.2d at 619.
73. *Id.*
74. *Id.* at 426, 442 A.2d at 619. *See infra* note 86 and accompanying text.
75. 182 N.J. Super. at 427, 442 A.2d at 620.
77. *Id.* at 22-23.
78. *Id.* at 23, 25.
79. *Id.* at 24. The court stated: [T]he duty of a manufacturer is satisfied if an adequate warning is given to the prescribing physician. In the absence of FDA regulations to the contrary, the manufacturer had no obligation to warn a consumer. . . . The manufacturer's duty is to warn the physician, who acts as a learned intermediary between the manufacturer and the consumer, because he is in the best position to evaluate the patient's needs, assess the benefits and risks of a particular therapy, and to supervise its use.
Thus, courts have traditionally viewed a warning to the physician as the most effective means of relieving the manufacturer of its duty and assuring that the consumer will be adequately warned as well. The manufacturer's duty to warn may be discharged by a physician in various ways. The physician may either communicate all or part of the warnings provided by the manufacturer, or may personally weigh the risks and benefits of the drug, never imparting knowledge of the dangers to the consumer. The physician's duty is to make an informed decision regarding the administration of each drug based on knowledge, experience and judgment. The consumer is expected to rely on this decision, whether or not the physician has chosen to disclose all the facts.

B. Addressing the Problems of the Learned Intermediary Rule—Judicial Exceptions and Agency Rulemaking

1. Judicial Exceptions to the Rule

Despite judicial acceptance of the learned intermediary rule, the rule has proven inadequate in some cases. For example, while Davis spells out the learned intermediary rule, it also introduces the exception to it. In Davis, the manufacturer of the polio vaccine had knowledge that the drug would be dispensed to all individuals who came to a mass immunization clinic. Although individual vials sold to the medical clinic contained package inserts with adequate warnings, the court held the manufacturer's duty was not discharged by warning only the medical personnel. The court stated

Id. 80. Davis, 399 F.2d at 130; Cornish, 370 F.2d at 85; Love, 226 Cal. App. 2d at 394, 38 Cal. Rptr. at 193.
81. McKee, 648 P.2d at 24-25.
82. Id.
83. Id. The court quoted the Terhune language supra note 67 and also stated that an exception to this general rule exists where there is an FDA regulation mandating a consumer warning. Id.
84. See 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, 399 F.2d 121 (9th Cir. 1968); Dunn v. Lederle Laboratories, 121 Mich. App. 73, 328 N.W.2d 576 (1982).
85. 399 F.2d at 131.
86. Id. The court stated that: although the drug was denominated a prescription drug it was not dispensed as such. It was dispensed to all comers at mass clinics without an individualized balancing by a physician of the risks involved. In such cases (as in the case of over-the-counter sales of nonprescription drugs) warning by the manufacturer to its immediate purchaser will not suffice. The decision (that on balance and in the public interest the personal risk to the individual was worth taking) may well have been that of the medical society and not of [the patient]. But just as the responsibility for choice is
that "the responsibility for choice is not one that a manufacturer can . . . allow his immediate purchaser to assume. [I]t is the responsibility of the manufacturer to see that the warnings reach the consumer." 87 The court suggested the manufacturer advertise prior to or during the operation of the immunization clinics, and issue releases to be read and signed by consumers at the clinic as possible means of discharging the manufacturer's duty. 88

In 1974, the United States Court of Appeals for the Fifth Circuit applied the Davis exception to the learned intermediary rule in another immunization case. *Reyes v. Wyeth* 89 involved an eight-month-old baby who contracted polio after immunization with live polio virus produced by Wyeth Laboratories. 90 Although the decision contains language reaffirming the learned intermediary rule, 91 the court found that in an immunization case, where there is no physician present to weigh the individual risks and benefits of therapy, the "very justification for the prescription drug exception evaporates." 92 Liability was imposed on Wyeth for failing to warn the consumer since the vaccine was given in a small health clinic without the benefit of a physician intermediary. 93

Recently, the Michigan Court of Appeals recognized an exception to the learned intermediary rule in a footnote in another immunization case. In *Dunn v. Lederle*, 94 the plaintiff contracted polio from her daughter, who was

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87. *Id.*
88. *Id.*
89. 498 F.2d 1264 (5th Cir. 1974).
90. *Id.* at 1269.
91. *Id.* at 1276. The court stated:
   
   we cannot quarrel with the general proposition that where prescription drugs are concerned, the manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use. This special standard for prescription drugs is an understandable exception to the Restatement's general rule that one who markets goods must warn foreseeable ultimate users of dangers inherent in his products.
92. *Id.* (footnote omitted, emphasis in original).
93. *Id.* at 1277.
94. 121 Mich. App. 73, 328 N.W.2d 576 (1982).
vaccinated with a live polio virus. The court approved the learned intermediary rule and applied it to the case, but stated in dicta that where no physician is available to exercise a medical judgment, the manufacturer must reach the consumer with the warning. The court did not suggest how this standard was to be applied, leaving prescription drug manufacturers unsure of how this would affect future litigation. As the cases illustrate, the exception to the learned intermediary rule is narrow and has only been acknowledged by the judiciary where no physician provides an individualized balancing of the risks and benefits of a prescription drug.

2. The Patient Package Insert Model: The Administrative Answer to the Learned Intermediary Problem

The Food and Drug Administration's dissatisfaction with judicial formulation of the learned intermediary rule inspired an initiative to change the single-source informational system. Beginning in 1970, the FDA promulgated regulations requiring manufacturers to provide consumer-directed information with oral contraceptives, estrogen products, intrauterine devices, and progestational drugs. The FDA required the manufacturer to include patient package inserts (PPIs) with the drug packaging in recognition that

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95. Id. at 76, 328 N.W.2d at 578.
96. Id. at 79 n.11, 328 N.W.2d at 579 n.11. The footnote states that “[i]f a doctor’s discretion is not called upon, e.g., through mass immunization or nonprescription drugs, warnings must be calculated to reach the ultimate consumer.”
97. See 21 C.F.R. § 310.516 (1978); 21 C.F.R. § 310.515 (1977); 21 C.F.R. § 310.501 (1970); 21 C.F.R. § 310.502 (1970). The first oral contraceptive labeling was proposed in April 1970 by former FDA Commissioner Charles C. Edwards. 35 Fed. Reg. 5962 (1970). The agency was aware that patient labeling represented a departure from the single-source informational system, but stated that factual information about the possible side effects and risks of oral contraceptives should be given to the users of these drugs. The agency considered the following factors in requiring patient labeling as a means of promoting the safe use of oral contraceptives: (1) that oral contraceptives are potent hormonal drugs; (2) that oral contraceptives are used by large numbers of healthy women for long periods of time; (3) that the majority of oral contraceptive use is elective in that other methods of contraception could be substituted; and (4) that because the drugs are contraceptives, they tend to be transferred between persons and used without adequate medical supervision. The text of the proposed labeling was as follows:

Oral Contraceptives
(Birth Control Pills)

The oral contraceptives are powerful, effective drugs. Do not take these without your doctor's continued supervision. As with all effective drugs, they may cause side effects in some cases and should not be taken at all by some. Rare instances of abnormal blood clotting are the most important known complication of the oral contraceptives. These points were discussed with you when you chose this method of contraception. While you are taking this drug, you should have periodic examinations at intervals set by your doctor. Notify your doctor if you notice any of the following:
these drugs were being used on an elective basis by large numbers of healthy women,\(^9\) that they were potentially dangerous, and, perhaps most importantly, that there was no assurance that the users of the products were being adequately warned about their dangers.\(^9\)

Based on several considerations, including studies of the effectiveness of PPIs for these four products,\(^1\) the FDA determined that consumer-directed information was necessary for the safe and effective use of all prescription drugs, whether or not they were being used electively or for general treatment of disease.\(^1\) In 1979, the FDA proposed regulations requiring PPIs for almost all prescription drugs.\(^2\) At the heart of this proposal was

1. Severe headache
2. Blurred vision
3. Pain in the legs
4. Pain in the chest or unexplained cough
5. Irregular or missed periods

\(\text{id.}\) Patient labeling for diethylstilbestrol (DES) regarding its use as a post-coital oral contraceptive (the "morning-after" pill) was later added to § 310.501. 38 Fed. Reg. 26,809 (1973).

\(^9\) The Advisory Committee on Obstetrics and Gynecology estimated that as of 1969, 8.5 million women used oral contraceptives in the United States for contraceptive purposes. FDA, SECOND REPORT ON THE ORAL CONTRACEPTIVES BY THE ADVISORY COMM. ON OBSTETRICS AND GYNECOLOGY 3 (1969).


\(^1\) See 45 Fed. Reg. 60,764 (1980). Regarding the final regulations establishing PPI requirements, 45 Fed. Reg. 60,754, the FDA stated:

"FDA 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 even when the use is not elective, and has revised the requirement to state specifically that patient package inserts must advise the patient of those adverse reactions and safety hazards that may help the patient evaluate the benefits and risks of the drug. There is no reason to believe that warning information about nonelective products will be any more or less confusing, frightening, or incomprehensible than similar statements about any elective drug. 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."


\(^2\) 44 Fed. Reg. 40,016 (1979). Based on its authority to assure the safe and effective use of drug products through the monitoring of drug labeling, 21 U.S.C. §§ 355(d), (e), the FDA
the FDA's conviction that the learned intermediary rule and the single-proposed regulations requiring PPIs for nonelectrically used prescription drugs. The agency's goal was to promote the safe and effective use of prescription drug products by patients and to ensure that patients have the opportunity to be informed of the benefits and risks involved in the use of prescription drug products. See 44 Fed. Reg. 40,016 (1979). The agency noted that the practice of providing prescription drug information solely to the physician did not encourage the safe use of prescription drugs. Id. at 40,017. Former Commissioner Donald Kennedy gave insight into the FDA rationale behind the PPI program by stating “[The FDA] bring[s] to this process no preconceived conclusions, other than the conviction that some way must be found to demystify the relationship between the physician and the patient.” Kennedy, Remarks of the Commissioner, 32 FOOD DRUG COSM. L.J. 384, 387 (1977). Kennedy urged physicians to “look at patient labeling not as an intrusion, but as an educational resource for a particular drug . . . . [K]nowledge raises the quality of discourse between patient and physician, eliminates unfounded apprehension, increases compliance and draws the patient into active participation.” Id. at 386-87. The agency cited several studies showing that consumers wanted and needed more information about prescription drugs. Eighty-eight percent to ninety-seven percent of 1,720 oral contraceptive users responding in a nationwide survey stated that they would like to receive patient labeling for other types of drugs including antibiotics, cough and cold medications and tranquilizers. Mazis, Patient Attitudes About Two Forms of Oral Contraceptive Information, 16 MEDICAL CARE 1045, 1051 (1978). Likewise, a national study of 2,002 adults showed that two out of three individuals responding believed that patient labeling was an important adjunct to oral consultations with physicians. THE ROPER ORGANIZATION, ROPER REPORTS no. 78-3, (1978). The FDA also conducted extensive public discussions on the issue of PPIs, including a national symposium sponsored jointly by the FDA, the Drug Information Association (DIA) and the American Medical Association (AMA). Over 700 health professionals, interested organizations, and consumer representatives attended the symposium held in 1976. The proposed regulations were also based on the evaluation of over 1,000 comments received from the November 7, 1975 notice of rulemaking, 40 Fed. Reg. 48,918 (1975), 750 of which were from consumers who favored patient labeling, 44 Fed. Reg. 40,019 (1979), and on a review of a consumer consortium petition in 1975 asking the FDA to require patient labeling. Id. at 40,018. Members of the consortium included the Consumers Union, Consumer Action for Improved Food and Drugs, the National Organization for Women, the Women's Equity Action League, and the Women's Legal Defense Fund. Id.

Examples of the type of labeling which would be acceptable under the proposed regulations were provided by the FDA. 45 Fed. Reg. 60,788 (1980). The example for propoxyphene, commonly known by the brand-name “Darvon” reads in part:

Propoxyphene
(pronounced proe-POX-i-feen)

Summary

Propoxyphene is used to relieve pain but can be dangerous when mixed with other drugs or alcohol. Limit your intake of alcohol when taking this drug. Also do not take any tranquilizers, sleep aids, antidepressants, antihistamines, or any other drugs that make you sleepy unless your doctor tells you to do so. Combining any of these with propoxyphene may lead to an overdose. Propoxyphene may make you sleepy. Use care driving a car or using machines until you see how the drug affects you. Do not take more of the drug than your doctor prescribed. Dependence has occurred when patients have taken propoxyphene for a long period of time at a dose greater than recommended.

The rest of this leaflet gives you more information about propoxyphene. Please read it and keep it for future use.

Cautions

Other drugs: Combinations of excessive doses of propoxyphene, alcohol, and tran-
source informational system it had generated were inadequate to insure the safe and effective use of prescription drugs. The FDA contended that PPIs would facilitate the safe use of prescription drugs by reinforcing drug information given by the physician. It argued that in the traditional tranquilizers may be dangerous. Make sure your doctor knows you are taking tranquilizers, sleep aids, antidepressant drugs, antihistamines, or any other drugs that make you sleepy. The use of these drugs with propoxyphene increases their sedative effects and may lead to overdose symptoms, including death (see “Overdose” below).

Alcohol: Heavy use of alcohol with propoxyphene is hazardous and may lead to overdosage symptoms (see “Overdose” below). THEREFORE, LIMIT YOUR INTAKE OF ALCOHOL WHILE TAKING PROPOXYPHENE.

Regular Activities: Propoxyphene may cause drowsiness or impair your mental and/or physical abilities, therefore, use caution when driving a vehicle or operating dangerous machinery. DO NOT perform any hazardous task until you have seen your response to this drug.

Who Should Not Take Propoxyphene

Do not take propoxyphene during pregnancy unless your doctor knows you are pregnant and specifically recommends its use.

The effects of propoxyphene in children under 12 has not been studied. Therefore use in this group is not recommended.

Make sure your doctor knows if you have ever had an allergic reaction to propoxyphene, aspirin, or acetominophen.

Some forms of propoxyphene contain aspirin to help relieve the pain. Do not take propoxyphene in this form if you have ulcers or if you are taking an anti-coagulant (“blood thinner”). The aspirin may irritate the ulcer and cause it to bleed. . . .

Overdose

An overdose of propoxyphene alone or in combination with other drugs including alcohol is likely to exaggerate the drug’s normal effects. It may cause extreme drowsiness, weakness, breathing difficulties, and confusion. A large overdose may lead to unconsciousness and death.

When the propoxyphene product contains acetominophen, overdose symptoms are nausea, vomiting, lack of appetite and abdominal pain. An overdose may lead to liver damage, coma and death.

When the propoxyphene product contains aspirin, symptoms of taking too much of the drug are headache, dizziness, ringing in the ears, difficulty hearing, dim vision, confusion, drowsiness, sweating, thirst, rapid breathing, nausea, vomiting and occasionally, diarrhea.

In any suspected overdose situation, GET EMERGENCY HELP IMMEDIATELY. Keep this drug and all drugs out of the reach of children.

Possible Side Effects

When propoxyphene is taken as directed, side effects are infrequent. Among those reported are drowsiness, dizziness, nausea, and vomiting. If these effects occur, it may help to lie down and rest.

Less frequently reported side effects are constipation, abdominal pain, skin rashes, lightheadedness, headache, weakness, minor visual disturbances, and feelings of elation or discomfort.

If any of these side effects occur and becomes bothersome, contact your doctor.

103. See Kennedy, supra note 102, at 386-87.
Prescription Drug Information

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sician's office setting, the information is usually given on a one-time, verbal basis. The recipient may be anxious or ill. In addition, drug information is usually given at the conclusion of an office visit, after the patient has already been exposed to possibly disturbing information regarding diagnosis and plan of care. The FDA maintained that a written source of information that the patient can read and refer to continuously would be an effective means of reinforcing the information given by the physician and serve as a standing reminder to the patient of the proper purposes and use of the prescribed drug.\(^{105}\)

Comments received in response to the notice of proposed rulemaking on the PPI program indicated strong public dissatisfaction with the single-source informational system.\(^{106}\) While physicians were considered to be the most important source of prescription drug information, consumers desired supplemental information because they did not feel adequately knowledgeable about the drugs they took.\(^{107}\) On the other hand, various medical and pharmaceutical groups argued that the public interest would not be served by consumer-directed labeling.\(^{108}\) Their opposition was based on the belief

106. Comments from individual consumers in response to the November 7, 1975 notice of rulemaking were supportive of the requirement of a written source of information apart from the physician source. 44 Fed. Reg. 40,019 (1979). Proponents of the PPI program include: the consumer consortium described supra note 102; individual consumers, some individual physicians and pharmacists, see Fleckenstein, infra note 108; and the American Nurses Association, see Letter from Anne Zimmerman (President ANA) to Paul Rogers (Chairman Health and Environment Subcomm. of the Comm. on Interstate and Foreign Commerce), May 25, 1978 (commenting favorably on the consumer labeling provision of H.R. 11,611).
107. The CBS Television Network conducted an extensive study of consumer information needs for prescription drugs. CBS ECONOMICS AND MARKETING DESIGN, CBS TELEVISION NETWORK, CBS CONSUMER MODEL (1983) [hereinafter cited as CBS STUDY]. The study was designed to provide concrete documentation of consumer attitudes and behavior regarding prescription drugs in an effort to provide scientific, reliable information useful for the debate on prescription drug advertising. Major areas of concern regarding prescription drug use were identified by consumer groups assembled in three geographically distinct areas of the country. A questionnaire was developed based on the areas identified by the groups, and a pretest was given to evaluate the clarity, completeness and appropriateness of the questionnaire. A nationally projectable sample of 1,233 households was given the questionnaire through personal in-home interviews. All questions were randomly rotated to prevent ordering effects. The results were only projectable to the eight million U.S. households who have used prescription drugs in the past, as all households studied reported some experience with prescription drugs. The study reported that the general public is marginally informed about prescription drugs. Of those 1233 households who answered the survey, 33% stated they were well informed about prescription drugs, while 38% reported they were not well informed and 28% stated they were somewhat informed. CBS STUDY, supra, at 21, table 16. Similarly, a study on health care practices conducted by the Proprietary Association found 11% of the survey respondents used prescription drugs already in the home to treat their health problems. HARRY HELLER RESEARCH CORP., HEALTH CARE PRACTICES AND PERCEPTIONS 15, figure 13 (1984).
108. Medical groups that generally opposed the FDA oral contraceptive labeling included
that (1) consumer-directed labeling would interfere with the doctor-patient relationship, (2) that it would so alarm patients that some may refuse necessary drug treatment, and (3) that a PPI could not possibly supply all the information necessary for the safe and effective use of prescription drugs.109

3. Legislative Dissatisfaction—Attempts to Mandate PPI Requirements

As a result of consumer dissatisfaction with the learned intermediary rule, several bills were introduced in Congress to require PPIs.110 The Drug Regulation Reform Act of 1978111 was intended, inter alia, to revise the federal law regarding all drugs for human use to ensure that such drugs are safe and effective.112 The bill would have mandated a patient labeling requirement that included the use of PPIs.113 One rationale for the requirement was that

the American Medical Association (AMA), the Association of American Physicians and Surgeons, the American College of Obstetrics and Gynecology, the American Society of Internal Medicine, and the AMA Interspecialty Committee. See 35 Fed. Reg. 9001 (1970). Pharmaceutical manufacturers, speaking through the Pharmaceutical Manufacturers Association, Wyeth Laboratories, Syntex, Ortho, and Parke, Davis, opposed the concept of consumer-directed labeling because they believed that drug information must be given on an individual basis by the physician. See 35 Fed. Reg. 9002 (1970). Interestingly, a study of 205 individual physicians and pharmacists showed that a majority of the respondents favored PPIs. See Fleckenstein, Attitudes Toward the Patient Package Insert—A Survey of Physicians and Pharmacists, 11 Drug Information J. 23, 25 (1977). Seventy-two percent of the physicians and sixty-six percent of the pharmacists responded affirmatively when asked whether they favored the development of the patient package insert. Id. The advantages of consumer-directed labeling perceived by this group were a better informed patient population, better compliance with drug regimens, and avoidance of drug interactions and adverse reactions. Id.


111. The Drug Regulation Reform Act of 1978 was comprised of bills introduced by the Senate and the House calling for comprehensive reform of the federal drug laws. See supra note 110, infra notes 112-13 and accompanying text.

112. A sponsor of H.R. 11611, Representative Paul Rogers of Florida, stated that if implemented, the Drug Regulation Reform Act would "bring . . . the benefits of promising new drug therapies to the marketplace more rapidly . . . better inform . . . citizenry about the proper use and intended effects of drugs . . . [and] result in much safer use of drugs than can be the case today." Introductory statement of Paul Rogers, Drug Regulation Reform Act of 1978: Hearings on H.R. 11611 before the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce, 95th Cong., 2d Sess. 1 (1978).

113. Section 151(b)(2)(c) of H.R. 11611, supra note 10 states,

CONTENTS—Information labeling for patients for a drug product shall contain the following information (1) Adequate directions for use, including—(A) the purposes or indications for which the drug product is intended, (B) the proper method of administration of the drug product, (C) precautions to be taken during the use of the
better patient compliance with prescription drug therapy could be achieved through more complete understanding and knowledge regarding prescription drugs.\textsuperscript{114} Also emphasized were the same arguments advanced in support of the FDA's PPI program.\textsuperscript{115} The patient labeling provision of the Act was supported by consumer groups and opposed by organized medicine and the pharmaceutical industry.\textsuperscript{116} The PPI requirement of the Act was a small part of a larger effort to effect major changes in the federal drug law. The legislation contained provisions altering aspects of the investigational use of drugs,\textsuperscript{117} the export of drugs,\textsuperscript{118} drug promotion and education,\textsuperscript{119} and the penalties involved for prohibited acts.\textsuperscript{120} Opposition to these other provisions of the Act, in addition to opposition to the consumer labeling provision, ultimately proved too strong to overcome.\textsuperscript{121} Consumer groups and legislators were unable to muster the necessary political force to pass a bill containing such fundamental changes in federal drug laws.\textsuperscript{122}


\textsuperscript{114} Several studies were cited that demonstrated the relationship between increased knowledge of prescription drugs and compliance with the drug treatment plan. Madden, Evaluation of Outpatient Pharmacy Patient Counseling, 13 J. AM. PHARMACEUTICAL A. 437 (1973); Colcher, Penicillin Treatment of Streptococcal Pharyngitis: A Comparison of Schedules and the Role of Specific Counseling, 222 J.A.M.A. 657 (1972); see also Marston, Compliance with Medical Regimens: A Review of the Literature, 19 NURSING RESEARCH 312 (1970).

\textsuperscript{115} See supra notes 97-102 and accompanying text.

\textsuperscript{116} See supra notes 106, 108 and accompanying text. Not surprisingly, the interested parties lined the same side of the fence for debate on the Act as they did for the original PPI debate. The American Association for Retired Persons, the National Consumers League, and the American Nurses Association, all read statements favorable to the labeling requirements into the record during the hearings on H.R. 11611. The American Pharmaceutical Manufacturers Association, the American Society of Internal Medicine, the AMA, the National Association of Retail Druggists and others spoke out against the labeling provisions.


\textsuperscript{118} Id. §§ 134-136, at 122-27.

\textsuperscript{119} Id. §§ 161-170, at 158-80.

\textsuperscript{120} Id. §§ 146-150, at 130-40.

\textsuperscript{121} Telephone interview with John McLaughlin, Counsel, House Subcomm. on Health and Environment (Sept. 14, 1984).

\textsuperscript{122} Id.
II. CONSUMER-DIRECTED PRESCRIPTION DRUG INFORMATION: TWO DECADES OF ABORTED STRATEGIES

Although the learned intermediary rule continues to be followed in most American jurisdictions, there is growing consumer interest in abandoning the single-source system in favor of consumer-directed prescription drug information. The problems of the single-source informational system persist despite attempts over the past twenty years to supplement drug information provided by physicians.

The judicial response to the learned intermediary problem has been to develop exceptions to the learned intermediary rule on a case-by-case basis. Generally, courts have imposed a duty to warn the consumer only where no physician is present to act as a learned intermediary. In addition, the manufacturer must have been able to anticipate the absence of a physician-intermediary at the time when the drug was administered. The advantages of a case-by-case approach are threefold. First, the approach results in a judicial remedy based only on a narrow set of facts. Broad, sweeping changes in what has been a well-settled area of law are thereby avoided. Second, if the rule is uniformly applied, the approach is predictable. Manufacturers, physicians and patients can base their actions on the outcomes of prior controversies. Finally, any liability imposed through case-by-case determinations is easily anticipated by manufacturers if courts adhere to precedent.

The disadvantage of the case-by-case approach, however, is that the numerous problems associated with the single-source informational system demand a comprehensive solution that cannot be satisfied through case-by-case adjudication. The present system does not effectively promote the safe use of prescription drugs. It simply provides an after-the-fact remedy for the injured consumer. In addition, it is costly and inefficient to litigate each controversy on a case-by-case basis. Finally, any information requirements that were imposed by case-by-case adjudication would lack uniformity. Comprehensive change in so settled an area of law and public policy is better undertaken legislatively or administratively.

The narrow approach favored by the courts is illustrated in Bacardi v. Holzman. In Bacardi, no effective doctor-patient relationship existed because the patient saw many different physicians over an extended period of

123. See supra notes 42, 63 and accompanying text.
124. See supra note 84 and accompanying text.
125. Davis, 399 F.2d at 131.
time.\textsuperscript{127} For all practical purposes, there was no individualized weighing of the risks and benefits of the drug therapy after the initial diagnosis and prescription. In the words of the \textit{Reyes} court, "the very justification for the prescription drug exception evaporate[d]."\textsuperscript{128} The drug injury might possibly have been avoided had the patient been aware of the dangers presented by long-term treatment with the drug so that the history of extended use could be adequately stressed to subsequent physicians. Yet, the court specifically refused to extend the learned intermediary exceptions beyond the mass immunization cases, where an exception to the rule was dictated by the fact that a physician did not administer the drug.\textsuperscript{129} A similarly harsh result can be imagined in the many cases today where a physician prescribes the drug by telephone. Although technically the physician has prescribed the drug, the patient does not receive the benefits of a learned intermediary because there is no meaningful doctor-patient relationship.

Case-by-case adjudication of the single-source problem lacks uniformity because each court must determine whether the manufacturer has a duty to the consumer on the basis of the individual facts of each case.\textsuperscript{130} Under the \textit{Dunn v. Lederle} case, for example, a manufacturer is required to warn the consumer where no physician is present.\textsuperscript{131} The \textit{Dunn} court, however, failed to fashion a concrete standard, leaving the details of applying the rule of law open for future determination.

The most serious inadequacy of the case-by-case approach to the single-source problem is that it fails to provide a method for improving the safety of prescription drug use. In the learned intermediary decisions, courts have focused on whether a manufacturer should be held liable for drug-induced injuries when the physician has been adequately warned. The outcomes of the learned intermediary cases demonstrate that the consumer has no legal right to receive information about prescription drugs from the manufacturer.\textsuperscript{132} A manufacturer's duty to reach the consumer is discharged by warning the physician where the physician is present to balance the risks and benefits of drug therapy.\textsuperscript{133} The learned intermediary rule was derived from an analysis of the physician's unique role in the distribution of the manufac-

\begin{footnotes}
\footnote{127. \textit{Id.} at 425, 442 A.2d at 619.}
\footnote{128. 498 F.2d at 1276.}
\footnote{129. 182 N.J. Super. at 427, 442 A.2d at 620.}
\footnote{130. \textit{Smith}, 273 N.W.2d at 479. The \textit{Smith} court stated that "[d]etermination of whether [the duty to warn the consumer] has been breached in the context of a negligence claim necessitates that the warnings given be examined as to their reasonableness under the circumstances." \textit{Id.}}
\footnote{131. \textit{Dunn}, 121 Mich. App. 73, 79 n.11, 328 N.W.2d at 579 n.11.}
\footnote{132. \textit{See supra} note 3 and accompanying text.}
\footnote{133. \textit{Id.}}
\end{footnotes}
turer's product, and it adequately resolves the liability issue in a prescription drug injury case. Resolving apportionment of liability, however, does not assure that prescription drug use will be safer in the future. While the judiciary is rightly concerned with the liability issue in the short-run, it also should be concerned with the improvement of prescription drug use in the long-run. The judiciary has never attempted to address this issue because it is not a problem that is easily framed by an individual controversy.

The learned intermediary rule has contributed to drug manufacturers' unwillingness to provide consumer-directed labeling. From an economic standpoint, there is no reason to provide consumers with information where no liability is imposed. Additionally, judicial language suggesting that consumer-directed labeling is not effective to communicate warnings to consumers further dampens manufacturer incentive to provide such information. Although the learned intermediary rule may be adequate for determining liability, it exacerbates the single-source problem by discouraging manufacturers from providing consumer-directed labeling.

The administrative approach, manifested by the FDA's PPI program, addresses the broader issue of prescription drug safety. An administrative mandate requiring consumer-directed prescription drug labeling takes the learned intermediary rule one step further. The physician's primary responsibility in receiving drug information is not challenged by the concept of the PPI. The administrative approach requires that the manufacturer reach consumers as well as physicians to effectively decrease the dangers of prescription drug use. Thus, consumer-directed labeling would neither replace the physician's responsibility to communicate warnings nor replace the learned intermediary system of apportioning liability.

The administrative approach, characterized by the FDA's PPI program, provides benefits similar to the legislative initiative in that a regulatory requirement could be well planned and uniform in effect. Certainty would be given to adversarial disputes regarding a manufacturer's duty to give information to the consumer. The FDA initiated a far-reaching effort to gather public comment from interested parties prior to its 1979 PPI rulemaking.

134. See supra notes 6, 18 and accompanying text.
135. See infra notes 149-52 and accompanying text.
136. Id.
137. The Patient Prescription Drug Labeling Project was initiated by the FDA, in part to solicit input regarding the PPI program. The project included numerous meetings with physician, pharmacy and consumer advocacy groups. In addition, the project included a national symposium held in 1975 to solicit the viewpoints of various interested parties. See Special Supplement THE DRUG INFORMATION J. (1977) (symposium proceedings). In addition, the FDA received 1,000 comments regarding the PPI program in response to the 1975 notice of rulemaking. 40 Fed. Reg. 52,075 (1975).
Nevertheless, an administrative agency must be responsive to the political climate in which its regulations are promulgated, and a PPI requirement necessitates an atmosphere favorable to the regulation of the prescription drug manufacturer. Thus, in light of the changes in policy resulting in reduced business regulation fostered by the Reagan administration, final regulations establishing a PPI requirement for all prescription drugs (to be applied to ten drugs in an initial implementation program) were withdrawn after promulgation but before implementation.\(^\text{138}\)

III. CONSUMER-DIRECTED PRESCRIPTION DRUG INFORMATION—THE BEST ANSWER TO AN ONGOING PROBLEM

The problems that have emerged from the use of a single-source informational system flow from the fact that such a system does not promote the safest possible use of prescription drugs. The single-source system depends upon the physician or a substitute to educate the consumer about prescription drugs. The physician, however, does not give drug information to patients under circumstances which are optimal for patient learning to occur.\(^\text{139}\) Moreover, where there is no physician to fulfill the teaching function, there is no formal method through which the consumer may obtain the information. Consumers may acquire access to a package insert, containing information intended for the health care practitioner through the Physician’s Desk Reference (PDR), which is available commercially to the public.\(^\text{140}\) Technical medical knowledge, however, is a prerequisite to proper understanding and use of the package insert. The package insert contains detailed information about a prescription drug’s chemical makeup, pharmacological action, and physiological effects.\(^\text{141}\) It sets forth the onset and duration of

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\(^{139}\) See supra note 9 and accompanying text.

\(^{140}\) The CBS Study, supra note 107, found that 35% of all the households studied, or 27 million households, used the PDR for information regarding prescription drugs and 18%, or 14 million, actually owned a PDR for similar use. CBS Study, supra note 107, at 8, table 3. For a discussion of the consequences of consumer reliance on the package insert for prescription drug information, see text.

\(^{141}\) Compare the following excerpt from the PDR providing technical information on propoxyphene (trade name “Darvon”) with the proposed PPI on propoxyphene, supra note 102.

Description: Darvon (propoxyphene hydrochloride, Lilly) is an odorless white crystalline powder with a bitter taste. It is freely soluble in water. Chemically, it is alpha(+)4(Dimethylamino)3methyl1, 2diphenyl2butanol Propionate Hydrochloride.

Clinical Pharmacology: Propoxyphene is a centrally acting narcotic analgesic agent. Equimolar doses of propoxyphene hydrochloride or napsylate provide similar plasma concentrations. Following administration of 65, 130, or 195 mg of propoxyphene hydrochloride, the bioavailability of propoxyphene is equivalent to that of 100, 200, or 300 mg respectively of propoxyphene napsylate. Peak plasma concentrations of propoxyphene are reached in two to two and one-half hours. After a 65-mg
pharmacologic action, where the drug is broken down and excreted, and possible adverse interactions with other drugs. Moreover, it details any adverse effects of the drugs reported, no matter how rare. The package insert also provides guidelines for indications and dosages, although a physician may use a different dosage according to the specific needs of the patient. Information reaching consumers in this manner does not promote the safe use of prescription drugs, because much of the technical information is susceptible to misinterpretation by the consumer. For example, a package insert may state that a certain antibiotic drug is contraindicated for persons with kidney disease. The reason for such a warning—that the drug is excreted mainly by the kidney, and that a person with compromised kidney function would not efficiently excrete the drug—may not be noted by the package insert. A physician, however, when faced with the necessity of prescribing this particular antibiotic, may safely have prescribed a lower dosage.

oral dose of propoxyphene hydrochloride, peak plasma levels of 0.05 to 0.1 mcg/ml are achieved. Repeated doses of propoxyphene at six-hour intervals lead to increasing plasma concentrations with a plateau after the ninth dose at 48 hours.

Propoxyphene is metabolized in the liver to yield norpropoxyphene. Propoxyphene has a half-life of six to 12 hours, whereas that of norpropoxyphene is 30 to 36 hours.

Drug Dependence—Propoxyphene, when taken in higher-than-recommended doses over long periods of time, can produce drug dependence characterized by psychic dependence and, less frequently, physical dependence and tolerance. Propoxyphene will only partially suppress the withdrawal syndrome in individuals physically dependent on morphine or other narcotics. The abuse liability of propoxyphene is qualitatively similar to that of codeine although quantitatively less, and propoxyphene should be prescribed with the same degree of caution appropriate to the use of codeine.

Usage in Ambulatory Patients—Propoxyphene may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks, such as driving a car or operating machinery. The patient should be cautioned accordingly.

Precautions: General Precautions—Kidney disease, often irreversible, has been noted with doses of phenacetin of 1 gm or more per day taken for one to three years and with total ingestion of 2 kg or more. It is not known whether prolonged ingestion of doses of phenacetin lower than 1 gm per day might also result in kidney disease.

Salicylates should be used with extreme caution in the presence of peptic ulcer or coagulation abnormalities.

Drug Interactions—The C.N.S.-depressant effect of propoxyphene is additive with that of other C.N.S. depressants, including alcohol. Salicylates may enhance the effect of anticoagulants and inhibit the uricosuric effect of uricosuric agents.

Usage in Pregnancy—Safe use in pregnancy has not been established relative to possible adverse effects on fetal development. Instances of withdrawal symptoms in the neonate have been reported following usage during pregnancy. Therefore, propoxyphene should not be used in pregnant women unless, in the judgment of the physician, the potential benefits outweigh the possible hazards.

of the drug to compensate for inefficient excretion. In such an example, the physician would be aware of other factors which negate the apparent warning of the package insert.

A consumer who has neither sufficient information to weigh the risks and benefits of a prescription drug nor a learned intermediary to do so for him, risks exposure to an unreasonably dangerous product. The learned intermediary rule gives physicians the sole authority to decide what information should be shared with the patient and what should be withheld. In today's medically conscious society, however, the patient should be regarded as a consumer of a product. The consumer should be an active participant in the plan of care, rather than a passive recipient of whatever information the physician deems best. Detailed information tailored to the needs of the consumer must be available so that the risks and benefits of a proposed drug therapy can be properly weighed. If the consumer/patient took a more active role in his/her care, the burden would no longer rest solely with the physician to decide what the consumer should know about prescription drugs.

Although the problems of the single-source system may be clear, the solutions to those problems are not so evident. Pharmaceutical manufacturers and physician groups maintain that providing prescription drug information directly to consumers would create difficulties without improving on the present system. They raise several arguments critical of consumer-di-

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143. In discussing H.R. 11611 and the Drug Regulation Reform Act in general, Representative Rogers stated that although he had received numerous and substantial criticism of the bill itself, not one person who has discussed the bill with me . . . has suggested that the existing drug law is appropriate or that the status quo should be maintained. I think there is all but unanimous agreement that the existing law is archaic and is badly in need of revision. *Drug Regulation Reform Act of 1978: Hearings on H.R. 11611 before the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce, 95th Cong., 2d Sess. (1978)* (statement of Rep. Rogers).

144. Organized medicine, represented by various associational groups, opposed the FDA PPI program from its inception in 1970. 35 Fed. Reg. 9001 (1970). See also 45 Fed. Reg. 60,756 (1980). The American Medical Association has stated:

As to information pertaining to side effects, contraindications, adverse effects, and purposes or indications of a drug, there should be no requirement that all such information be in patient labeling for all drugs. Should requirements or regulations mandating the inclusion of such information in patient labeling for all prescription drugs be promulgated, the public interests would not be served. Interference in the physician/patient relationship would result, and patients' medical needs would not be met,
rected information. The arguments, however, are outweighed by the positive gains anticipated from, and actually demonstrated by the use of a multi-source informational system. The evidence suggests that society has much to gain from relieving physicians of some of the burdens of imparting prescription drug information and diversifying the sources from which consumers may learn about their drugs.

A. The "Self-Medication" Argument

The basic premise of the learned intermediary rule is that the physician must be free to exercise independent judgment in deciding what facts to disclose to the consumer.\(^\text{145}\) Traditionally, the consumer had to rely upon the physician's background and skill in evaluating the risks and benefits of a prescription drug.\(^\text{146}\) One rationale for this practice is that information directed toward the consumer could result in the dangerous practices of self-diagnosis and attempted self-medication.\(^\text{147}\) Therefore, consumer-directed labeling should be limited to non-prescription medications. This view represents an approach to treatment with prescription drugs that may be outdated. Statistics show that the wants and needs to take a more active role in public medical care.\(^\text{148}\)

Self-diagnosis and self-medication are not goals of consumer-directed labeling. Consumer labeling is designed and intended only to reinforce and remind the consumer of information which is ideally provided by a physician.\(^\text{149}\) Former FDA Commissioner Kennedy has stated that the labeling

\[\text{See Smith, Patient Package Inserts and the U.S. Food & Drug Administration—Where Do We Stand at the Moment?, 11 Drug Information J. 30, 31 (1977).}\]

\[\text{145. See e.g., Terhune v. A.H. Robins Co., 90 Wash. 2d 9, 14, 577 P.2d 975, 978 (1978).}\]

\[\text{146. Id.}\]

\[\text{147. 43 Fed. Reg. 4220 (1978). In its statement before the Subcommittee on Health and Environment during the hearings on H.R. 11611, the AMA stated}\]

\[\text{Medical information regarding drug therapy prescribed for the patient originates with the physician, who is in the best position to determine the scope and complexity of information that would be appropriate for the individual patient. Mandatory detailed patient labeling . . . could discourage proper patient use of a drug and encourage inappropriate self-medication by patients for themselves and their families.}\]


\[\text{148. See supra notes 100, 107, 114 and accompanying text.}\]

\[\text{149. 42 Fed. Reg. 37,637 (1977).}\]
requirements are not intended to supersede the physician's responsibility or judgment in providing drug information to the consumer.\textsuperscript{150} In fact, oral contraceptive labeling directs the consumer to consult with a physician regarding any pertinent medical history the user may have.\textsuperscript{151} Recognizing the primary role of a physician in selecting and disseminating information regarding prescription drugs, the FDA also asserted that warnings directly to the consumer may result in "improved patient compliance with physician's directions . . . self-monitoring of adverse effects, and a corresponding decrease in drug-induced injury."\textsuperscript{152}

\textbf{B. Paternalism Lives: The "Too Technical" Argument}

Another criticism of consumer-directed labeling is that consumers do not have the requisite medical knowledge, education, or experience to properly evaluate complex and technical warnings.\textsuperscript{153} In addition, consumer warnings might dissuade consumers from consenting to necessary therapy.\textsuperscript{154}

\begin{itemize}
\item\textsuperscript{150} See, e.g., 42 Fed. Reg. 37,636 (1977). In the final rules requiring PPIs for all estrogenic drug products, effective September 20, 1977, former Commissioner Kennedy stated:
\begin{quote}
The Commissioner does not agree that the requirement for patient labeling interferes with the physician/patient relationship or infringes on the practice of medicine. Indeed, by directing the patient to consult with her physician the labeling requirement explicitly recognizes the primary responsibility of the prescribing physician to convey to the patient, [sic] information regarding prescribed drugs. This regulation, therefore, is not intended to preempt the physician's responsibility, nor will it have that effect. Rather, in situations where physicians are conscientious in describing the relative benefits and risks of these drugs with their patients, the patient labeling will simply reinforce what the physician has explained to the patient and serve as a written reminder that can be referred to by the patient during the course of therapy.
\end{quote}


\item\textsuperscript{152} 43 Fed. Reg. 4214 (1978).

\item\textsuperscript{153} See supra note 6 and accompanying text.

\item\textsuperscript{154} Id. The National Association of Chain Drug Stores (NACDS), in its statement before the subcommittee regarding H.R. 11611 stated:
\begin{quote}
Because [the PPI information currently required under FDA regulations] is so flagrantly slanted toward the undesirable aspects of therapy, it is our firm belief that under a comprehensive package insert program, a vast number of patients who receive this alarming kind of information will be frightened from taking their medications. . . . [I]f patient noncompliance increases, greater numbers of individuals might develop more serious illnesses, which could lead to higher health care costs
\end{quote}

\textbf{Drug Regulation Reform Act of 1978: Hearings on H.R. 11611 Before the Subcomm. on Health and Environment of the House Comm. on Interstate and Foreign Commerce, 95th Cong., 2d Sess. 2665 (1978) (statement of Sheldon W. Fantle, Director, National Ass'n of Chain Drug Stores). The NACDS prediction is contradicted by studies showing that increased consumer}
This argument belies a misunderstanding of the objectives of consumer-directed labeling. The public policy objective is to enhance the safety of prescription drugs by allowing consumers to make informed decisions regarding their use. For example, the FDA regulations do not require the manufacturer to disclose information to consumers that is identical to that dispensed to physicians, nor does it require complex or technical warnings. Manufacturers have shown it is possible to effectively provide information in lay terms through their directions and package inserts for nonprescription drugs as well as through the pamphlets required by the FDA for oral contraceptives.

In response to the arguments that consumer-directed labeling might result in refusal of treatment, it should be noted that the necessity of administering the drug and the reasons for its use have a bearing on whether consumer-directed information increases the safe use of a prescription drug. Where the prescription drug is used to treat an illness, the warning may serve to dissuade the consumer from using the drug even where the consumer is fully informed of the necessity and therapeutic value of its use. Nevertheless, the consumer's decision should be respected. Withholding the warning information in an attempt to ensure that the consumer will consent to the therapy that the physician has judged to be necessary ignores the principles of informed consent. Rather, the physician should give the consumer the responsibility of deciding whether to undergo the suggested treatment by communicating the information and reasoning which lead the physician to recommend the drug therapy.

The refusal-of-treatment argument is especially inappropriate where the use of the drug is considered elective. Presumably, the consumer will be less willing to incur the risks of adverse effects in such a case because even small risks may outweigh the benefits of elective drug use by a healthy consumer. While the decision whether to use a drug to cure an illness must be made

knowledge leads to better compliance with therapeutic regimens. See Colcher, supra note 114, at 657.

155. Terhune, 577 P.2d at 978.
156. 21 C.F.R. § 310.501(a)(1) (1978) (requiring the information to be in lay language).
157. Warnings and directions for use are printed in lay terms on all nonprescription drugs, showing that the manufacturer is capable of communicating technical information to the consumer. Although, by definition, nonprescription drugs are not as dangerous as prescription drugs, many are nevertheless potent medicine with the potential to cripple or kill if used improperly. Nevertheless, manufacturers are able to translate complex technical information into language allowing over-the-counter use by a lay public. Moreover, manufacturers have been supplying patient-oriented information with favorable results through oral contraception pamphlets since 1970.

with an understanding of the consequences of no treatment, where the use of
the drug is elective, the consumer need only weigh the desired results of the
drug against the possible adverse effects.

For example, where the elective drug is an oral contraceptive, the physi-
cian may be in the best position to judge whether the risk of a stroke out-
weighs the benefit of the drug for most patients. This judgment will affect
the doctor's willingness to prescribe the drug. Although the physician may
be assured by professional analysis that the risks do not outweigh the bene-
fits, the doctor is not in the best position to decide whether that consumer
would elect another form of birth control in light of the attendant risks.
Thus, under the single-source system, the consumer's right to choose could
be preempted if, in the physician's judgment, it is not necessary to communi-
cate all the factual information regarding the drug. A consumer cannot ex-
ercise an effective choice where a physician decides not to disclose a
particular risk because of a belief that the risk does not outweigh the benefit
of the drug. Further, where the drug use is considered elective, consumer-
directed labeling would facilitate the safe use of prescription drugs because a
healthy consumer is less likely to be under the close supervision of a physi-
cian. Consumer information would reinforce and remind the consumer of
factors necessary for the safe use of the drug.

C. The "Too Much Liability" Argument

Consumer-directed labeling has also been criticized as burdensome be-
cause it creates the possibility of additional manufacturer liability. The
feasibility of manufacturer warnings has been questioned because the con-
sumer normally does not receive the drug in the packaging released by the
manufacturer, nor does he have substantial contact with the manufac-
turer. Pharmaceutical manufacturers argue that imposing the duty to
warn under these circumstances would be financially burdensome. The
FDA estimates, however, that the PPI program would add only 1.5 cents to
the cost of a prescription. This amount is inconsequential in light of the

159. See supra note 6 and accompanying text.
160. Consumers Union, Petition to the FDA to Require More Adequate Patient Labeling
of Prescription Drugs, 24-29 (1975).
162. See Davis, 399 F.2d at 130; Terhune, 577 P.2d at 978.
164. Eve Bargmann, Public Citizen Health Research Group to the FDA on FDA's Pro-
posed Revocation of the Patient Package Insert Program, (April 20, 1982) (Comments). Dr.
Bargmann submitted a forceful and persuasive comment to the FDA upon the announcement
of the agency's intention to revoke the PPI requirements. Citing a study of the effects of PPIs,
Dr. Bargmann pointed out that PPIs reach patients with potentially lifesaving information,
fact that in 1983, the average cost of a prescription was $11.20.\textsuperscript{165} Considering that former FDA Commissioner Kennedy estimated that drug manufacturers spend approximately $4,000 yearly per practicing physician to promote prescription drugs,\textsuperscript{166} it is unlikely that a consumer labeling requirement would prove burdensome. In addition, the inserts mandated by the FDA are similar in nature to those inserts already distributed to physicians. Manufacturers, therefore, need only include information pamphlets with the bulk drugs.\textsuperscript{167}

With regard to the potential increase in manufacturer liability, a manufacturer could incur additional liability under a strict liability theory or negligence per se if its consumer-directed labeling failed to reach the consumer or if the labeling was inadequate.\textsuperscript{168} The manufacturers’ legal duty to warn remains physician-oriented, however, and it is unlikely that the law will change to create greater liability where the manufacturer adequately warned the physician.\textsuperscript{169} Consumer-directed labeling would supplement drug information given by the physician. Even with consumer-directed labeling, the primary responsibility for informing consumers about their prescriptions would remain with physicians. In this manner, the liability for failure to warn could be discharged by warning the physician of possible dangers inherent in the drug. Moreover, liability for failure to warn is based on a reasonableness standard, not on strict liability.\textsuperscript{170} Manufacturers who prop-

\textsuperscript{165} 50 PHARMACY TIMES 30 (1984). This figure was calculated by the National Prescription Drug Audit, using the 200 most frequently prescribed drugs in 1983.

\textsuperscript{166} Kennedy, supra note 102 at 387.


\textsuperscript{168} See Lukaszewicz v. Ortho Pharmaceutical Corp., 510 F. Supp. 961 (E.D. Wis. 1981) (failure to provide a PPI as required by FDA regulations held to be negligence per se).

\textsuperscript{169} See supra, note 3 and accompanying text.

\textsuperscript{170} See Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652 (1st Cir. 1981) (reasonable warning gives a fair indication of the dangers involved and warns with the intensity demanded by the extent of the risk); Mahr v. G. D. Searle, 28 Ill. Dec. 624, 390 N.E.2d 1214 (1979) (adequacy of warning based on a reasonableness standard). The reasonableness standard for prescription drug warnings has been reaffirmed even in light of the holding in Beshada v. Johns-Manville Prod. Corp., 90 N.J. 191, 447 A.2d 539 (1982). Beshada held that ignorance of the danger of asbestos exposure was not a defense to an action by workers suffering from asbestos-related illnesses. \textit{Id.} at 209, 447 A.2d at 549. The underlying rationale for the holding was that manufacturers of defective products could best absorb the costs of injuries resulting from the use of those products. \textit{Id.} at 205, 447 A.2d at 547. \textit{Beshada}, however, was not followed in a subsequent case involving prescription drugs because “the almost absolute liabil-
erly warn the prescribing physician and complete their statutory obligation by including a PPI with the drug would be acting reasonably to fulfill their obligation to warn. Former Commissioner Kennedy responded to the increased liability argument by stating that effective use of information by consumers could potentially decrease manufacturer liability by improving patient compliance with drug treatments, thereby reducing drug-induced injuries.\footnote{42 Fed. Reg. 37,637 (1977).}

Consumer-directed manufacturer warnings may also be criticized based on consumer disregard of important warnings because of the desensitization caused by indiscriminate warnings. FDA statements regarding the oral contraceptive regulations suggest, however, that only serious warnings need be included in the consumer information.\footnote{See 43 Fed. Reg. 4218 (1978) (stating that no warning regarding the incidence of candidiasis, a vaginal yeast infection, was necessary because the incidence was neither common nor serious).} In addition, this solution could be followed in other areas. If the warning is sufficiently important to be included in physician-directed labeling, there is little reason to believe the consumer would not be served equally by the same information in lay terms.

Another possible adverse effect of consumer-directed labeling is the opportunity for manufacturer advertising through the labeling. This problem has been addressed by the courts in a case where over-promotion of a drug to physicians resulted in dilution of an otherwise adequate warning, leading to manufacturer liability.\footnote{See Stevens v. Parke, Davis & Co., 9 Cal. 3d 51, 67, 507 P.2d 653, 662, 107 Cal. Rptr. 45, 54 (1973); Incollingo v. Ewing, 444 Pa. 263, 289, 282 A.2d 206, 220 (1971); Love v. Wolf, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964).} Liability has been imposed on the manufacturer where the warning written on the package insert was weakened by vigorous promotion of the drug by detailmen.\footnote{Id.} Inappropriate consumer-directed labeling could be handled similarly. Some drug manufacturers have, in fact, initiated consumer-directed marketing through drug advertisements.\footnote{In 1981 the Boots Company advertised Rufen, its brand name form of the anti-inflammatory analgesic ibuprofen. In addition, a prescription drug advertisement for Zovirax, a drug for herpes, was used by Peoples Drug Stores in 1982. Buc, Current Regulatory Issues in Marketing Prescription Drugs: Comparative Claims and Advertising to Consumers, 37 Food Drug Cosm. L. J. 402, 407 (1982).} Although former FDA Commissioner Arthur Hayes expressed cautious approval so long as the advertisements were truthful,\footnote{Buc, supra note 175, at 407.} the FDA currently is
evaluating its position on the issue.\textsuperscript{177} Although prescription drug advertising is not illegal, the FDA called a moratorium on it in 1983 in order to collect more information on the subject.\textsuperscript{178}

IV. ADDITIONAL METHODS FOR PROVIDING PRESCRIPTION DRUG INFORMATION TO CONSUMERS

An administratively mandated program designed to ensure consumer-directed information is the preferred method of improving the single-source system. The information provided would be accurate and the distribution of information uniform.\textsuperscript{179} Perhaps due to the lack of an administrative mandate, however, other methods exist that haphazardly provide information to the public in response to specific situations. For example, at least one prescription drug manufacturer, Eli Lilly and Company, has developed Patient Information Sheets for certain prescription drugs.\textsuperscript{180} Physicians may obtain the Patient Information Sheets, along with illustrations of dosage forms and prescription vial stickers, from the manufacturer for use as an adjunct to physician teaching.\textsuperscript{181}

In addition, the FDA has published consumer-directed warnings, as in a poem designed to warn consumers about drug-induced sensitivity to sunshine.\textsuperscript{182} The poem was part of a public service campaign designed to increase consumer awareness about prescription drugs and to encourage consumers to question their physicians about them.

\textsuperscript{177} A moratorium on direct-to-consumer advertising for prescription drugs was requested by former Commissioner Arthur Hull Hayes, M.D. in February, 1983. The purpose of this voluntary moratorium was to allow the FDA to conduct public forums and sponsor research to obtain the public's view of prescription drug advertising. Address by Arthur Hull Hayes, Jr., M.D., Pharmaceutical Advertising Council Annual Meeting (Feb. 17, 1983).

\textsuperscript{178} Id.

\textsuperscript{179} See, e.g., supra note 102 and accompanying text.

\textsuperscript{180} Patient Information Sheets containing detailed consumer information are available for "Darvon",\textsuperscript{181} PHYSICIAN'S DESK REFERENCE 1125 (38th ed. 1984), and "Humulin", human insulin. Id. at 1135-38.

\textsuperscript{181} PHYSICIAN'S DESK REFERENCE at 1125.

\textsuperscript{182} 18 FDA Cons. 48-49 (June, 1984). The poem appeared as part of a layout in FDA Consumer, which included the picture of a sunburned man. The text read:

HE GOT THE PRESCRIPTION,
THEN HE GOT A BAD SUNBURN
THE TWO WERE CONNECTED.
This is the tale of a man who loved fun.
He took tetracycline, then lay in the sun.
But to his dismay it was then he did learn
That some drugs plus sunshine can lead to a burn.

Many people are not aware that some prescription drugs make them especially sensitive to the ultraviolet rays from the sun and sunlamps. This reaction is called "photosensitivity". Such a reaction is known as a side effect, or adverse reaction.
Another possible source of drug information is prescription drug advertising to the consumer. Prescription drug advertising is a controversial subject and its effects on the public and the drug industry are currently being studied by the FDA and other interested parties. Whether such advertising would provide truthful, reliable information to consumers may depend upon the extent of both FDA regulation and manufacturer responsibility.

Private publications present another source for the communication of drug information to consumers. Publications currently exist for both prescription and non-prescription drugs which discuss directions for use, side effects, and warnings. This source of information requires a high level of consumer motivation. It would be effective only for those consumers who bought and read the book.

V. CONCLUSION

A multi source system for the communication of prescription drug information to consumers is necessary and desirable to promote the safe use of prescription drugs. The content and manner in which the information is communicated should be regulated by the FDA, due to the greater uniformity, certainty, and full evaluation prior to rulemaking that this approach would provide. Although the need for multiple sources of consumer infor-

Prescription drugs can often cause unwanted side effects (nonprescription drugs can, too).

The widely used antibiotic tetracycline is just one of the drugs that can contribute to an unexpected sunburn. Some high blood pressure drugs and some tranquilizers can do the same thing. When you get any prescription, be sure you know—

The name of the drug
Its purpose—what conditions does it treat?
How and when to take the drug—and when to stop taking it
What food, drinks and other drugs to avoid while taking it
What side effects may result—are they serious, short-term, long-term, etc.?

If you have questions about your prescription, ask your doctor or pharmacist.

18 FDA Cons. 49 (June 1984).

183. The CBS STUDY, supra note 107, was undertaken in order to provide concrete information to the prescription drug advertising debates.

184. Currently there are numerous publications on the market that contain consumer information about prescription drugs. Written by physicians, laypersons, and the government, these publications range from the very detailed and scientific to subjective consideration of the topic. For information on prescription drugs, see R. Burack, THE NEW HANDBOOK OF PRESCRIPTION DRUGS (1980); D. Mason, PHARMACEUTICAL DICTIONARY AND REFERENCE FOR PRESCRIPTION DRUGS (1981); E. Stern, PRESCRIPTION DRUGS AND THEIR SIDE EFFECTS (4th ed. 1983); S. Wolfe, PILLS THAT DON'T WORK (1980). For information on non-prescription drugs, see R. Benowicz, NON-PRESCRIPTION DRUGS AND THEIR SIDE EFFECTS (1982); M. Rubinstein, A DOCTOR'S GUIDE TO NON-PRESCRIPTION DRUGS, (1977).
mation has been articulated in Congress, by the FDA and by consumers, no alternative system is in place today to supplement information consumers receive from their physicians. Political opposition has hampered the efforts of the legislature and the FDA. Judicial action regarding the problem has only provided solutions on a case-by-case basis. Sources of prescription drug information are available to the public, but they are sporadic in nature and do not insure that the necessary information is consistently available. The safe and effective use of prescription drugs will be compromised until an organized multi-source drug information system is established.

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