The Drug Manufacturer's Duty to Warn -- To Whom Does it Extend?

Donald E. Thompson, II
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DONALD E. THOMPSON II

I. Introduction

A is the manufacturer of a prescription drug \( D \), which has proven effective in the treatment of rheumatoid arthritis. The drug has certain known risks which appear in a small percentage of the consumers who take the drug. One of these risks is chloroquine retinopathy—a degeneration of certain cells in the retina of the eye which results in irreversible blindness. As a method of warning about this risk, \( A \) places an advertisement in the Physician’s Desk Reference and, as is required by federal law, encloses a “package insert” with each shipment of the drug to pharmacists. The insert is “theoretically available” to a prescribing physician upon request. But as is customary and permitted by federal law, the pharmacist removes and discards the package insert before dispensing the drug to consumers. \( B \), a physician, diagnoses rheumatoid arthritis in his patient, \( P \). \( B \) chooses the drug \( D \) from the array of available treatments and prescribes it for \( P \)’s condition. \( P \) takes the drug over a period of several years and goes blind. \( P \) never received a warning about the risk of blindness attending the use of \( D \). Assuming that \( P \) would have chosen another form of treatment had she known about the risk, who, if anyone, should be liable for the failure to warn and the consequent injury?¹

Pharmaceutical drugs present a vast array of legal, moral, and ethical considerations in their development, distribution, and application. As part of the larger category of “unavoidably unsafe” products, pharmaceutical drugs and especially prescription drugs are prime examples of the conflict between products which, given the present state of human skills and knowledge, cannot be made entirely safe, but which nonetheless have substantial beneficial qualities. An important question raised by every such product is whether it should be marketed at all. This is generally a matter of balancing the probability and gravity of the risk of harm against the social utility of the product. For pharmaceutical drugs in this country, the balance is struck in favor of the utility of the drug

¹ This hypothetical involves the actual indications of the drug “Aralen” manufactured by Sterling Drug, Inc. The cases involving Sterling Drug at infra notes 12, 13, and 15 concern litigation regarding this drug.
when it obtains approval by the Food and Drug Administration (FDA). This article presumes that such a balance was correctly struck.

A correct decision to market a prescription drug does not resolve the question of risk allocation. The judicial response to this question regarding other products with known, latent risks has been to impose upon the manufacturer a duty to warn foreseeable users of the product of such risks. This view is consistent with section 388 of the Restatement (Second) of Torts, which imposes liability on suppliers of products known to be dangerous for their 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.3

Pharmaceutical drugs fulfill the prerequisites of subsections 388(a) and (b). Thus, one would expect that a “duty to inform” the patient would arise on the part of the drug manufacturer. Indeed, this is the position which is followed for nonprescription, “over-the-counter” drugs.4 The courts, however, have created an excep-

3. Restatement (Second) of Torts § 388 (1965).

For an interesting extension of the “over-the-counter” rationale to certain immunizations, see Givens v. Lederle, 556 F.2d 1341, 1345 (5th Cir. 1977) (polio vaccine was administered in a manner more like that of a county health clinic than by prescription after consultation with a physician); Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. 1968) (while polio vaccine was a prescription drug, it was not dispensed as such; rather, “[i]t was dispensed to all comers at mass clinics without an individualized balancing by a physician of
tion to the duty to warn for the manufacturers of prescription drugs. The prescription drug manufacturer's duty to warn does not extend to the foreseeable user of the product (the patient), but rather to the medical community (generally the prescribing physician) which acts as "learned intermediary." As one court put it, "the duty to warn the patient, if one exists, lies with the physician and not with the drug manufacturer." It is the thesis of this Comment that the time has come to reevaluate and abandon this judicially-created exception as contrary to both contemporary social policy and the practical realities of the medical profession. 

II. Development and Current Scope of the Drug Manufacturer's Duty to Warn

Until recently, the law was harsh to an injured patient who brought suit against a manufacturer of prescription drugs for failure to provide a warning either to himself or his prescribing physician. Not only did the courts deny that there was a duty to warn the patient, they frequently imposed only the most rudimentary duty to warn the prescribing physician. Marcus v. Specific Pharmaceuticals, Inc. is an example of this extreme position. Marcus involved the death of a thirteen-month-old child from an overdose of suppositories administered at the prescription of a physician. The defendant, Specific Pharmaceuticals, manufactured the suppositories in two sizes, one for children, one for adults. The only information provided by the manufacturer about the product was by advertisements in medical journals. In these advertise-
ments, information concerning dosage was either omitted or given with insufficient emphasis or clarity. Furthermore, no warning was given regarding overdosage. After first finding no duty to warn the patient, the court completely discredited the claim of "negligent failure to give adequate information." The court, seeming content that the manufacturer had not engaged in misrepresentation, reasoned that "[t]here is no reason to believe that a physician would care to disregard his own knowledge of the effects of drugs and hence of the quantity to be administered, and substitute for his own judgment that of a drug manufacturer." Unfortunately, the court failed to consider that without adequate guidance from the drug manufacturer, the only method for the physician to obtain "knowledge of the effects" of the drug is to experiment on his patients—a procedure which proved fatal in the instant case.

Under the modern rule, which emerged in the late 1960s, the manufacturer of prescription drugs has the duty to make timely and adequate warnings to the medical profession of any dangerous side effects produced by the drug which it knows of or should know of, and is directly liable to the patient for a breach of that duty.

Similarly, courts have expanded the scope of the duty to warn to require disclosure of adverse effects "even though the adverse effect[s] involve only a statistically small percentage of those upon whom [the drug is] used." Moreover, decisions have made it clear that the manufacturer's duty to warn is to the medical community as a whole, and not to a particular prescribing physician with which the drug company has had formal contact. These decisions can be commended for their practical realizations that the patient may not return to the original prescribing physician when problems with the treatment occur.

9. Id.
10. Id.
11. Id. at 509-10.
14. Parke-Davis & Co. v. Stromsoe, 411 F.2d 1390, 1400 (8th Cir. 1969) (citing Sterling Drug, Inc. v. Cornish, 370 F.2d 82 (8th Cir. 1966)).
Courts have recognized that even where an adequate warning is originally given by the drug manufacturer, this adequate warning may nonetheless be nullified by subsequent advertising and promotional activities which downplay the risks of the drug or which encourage its application to ailments for which the drug is unsuited. *Love v. Wolf* is the leading case for this proposition. *Love* involved the drug chloromycetin, manufactured by Parke-Davis. The drug was effective in the treatment of certain infections. Due to its association with certain serious risks, such as various blood disorders, administration was indicated only for the treatment of serious diseases, such as typhoid and Rocky Mountain spotted fever. Mrs. Love took the drug initially for the treatment of a sore gum, and later for the treatment of bronchitis. She subsequently developed aplastic anemia, a condition characterized by destruction of the blood-forming elements in the bone marrow. Though Parke-Davis adequately warned of the drug's risks in its medical advertisements, it engaged in a number of activities which considerably diminished the perceived dangers of the drug. The company made statements extolling the "very minimal untoward side effects" of the drug in its advertising. Likewise, the company president made representations to the "detail men" selling the product that "Chloromycetin has been officially cleared by the FDA and the National Research Council with no restrictions on the number or range of diseases for which Chloromycetin may be administered" and that there was "no valid scientific proof that aplastic anemia resulted from chloromycetin." The court concluded that Parke-Davis' overpromotion may well have induced the doctor to disregard the warnings previously given.
While the courts have shown marked improvement in their interpretation of the duty to warn the medical community, no corresponding advancement has been made regarding a duty of the drug manufacturer to warn the consumer. Rather, the courts have steadfastly adhered to the view that where a duty to warn the consumer exists, it is the duty of the prescribing physician and not the drug manufacturer. The rationale for this "no duty" rule was eloquently stated by the court in *Reyes v. Wyeth Laboratories*:

This special standard for prescription drugs is an understandable exception to the Restatement's general rule that one who markets goods must warn foreseeable ultimate users of dangers inherent in his products. Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between the manufacturer and consumer.

In *Buckner v. Allergan Pharmaceuticals Inc.* Florida's Fifth District Court of Appeal recently broadened this rule such that even if the manufacturer is aware that the medical community is not warning the patient of known harmful risks attending the use of a drug, the manufacturer still has no duty to warn the patient. The plaintiff in *Buckner* was prescribed corticosteroids for an eye

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29. For cases discussing a duty of the physician to warn the patient regarding drugs he is prescribing, see Koury v. Follo, 158 S.E.2d 548 (N.C. 1968); Sharpe v. Pugh, 155 S.E.2d 108 (N.C. 1967).

30. 498 F.2d 1264, 1276 (5th Cir.) (citation omitted) (footnote omitted), cert. denied, 419 U.S. 1096 (1974).

31. 400 So. 2d 820 (Fla. 5th DCA), petition for review denied, 407 So. 2d 1102 (Fla. 1981).

32. Id. at 823-24.
disorder. She subsequently developed one of the known side effects of the drug—aseptic necrosis of her femoral heads\textsuperscript{33} (cell death within part of the femur bone in the thigh). She was not warned of this risk.\textsuperscript{34} In dismissing the claim against the manufacturer, the court reasoned that "[s]ince physicians do not have an absolute duty to inform patients of all possible side effects in every instance, failure to do so in a particular instance should not give rise to a duty in the manufacturer."\textsuperscript{35}

An issue not addressed in Buckner was whether, in light of the allegation of known disregard of the warnings by the medical profession, the manufacturer's warnings to the medical profession were adequate. The court in Incollingo v. Ewing\textsuperscript{36} noted that "[w]hen a required warning is retained unchanged in the face of being widely disregarded, and the supplier knows or has reason to know of such wide disregard, a jury may be permitted to find the warning insufficient."\textsuperscript{37} Thus, the disregard of the manufacturer's warnings in Buckner could have been used to demonstrate the need for more explicit and prominent warnings from the manufacturer.

In a limited number of instances, the FDA has mandated that certain warnings be provided directly to the patient by the manufacturer.\textsuperscript{38} The issue arising in such instances is whether a private cause of action by the patient is created when such warnings are not given, in violation of FDA regulations. In responding to this issue, the court in Lukaszewicz v. Ortho Pharmaceutical Corp.\textsuperscript{39} held that a duty to warn the patient was created. The plaintiff in Lukaszewicz suffered a cerebrovascular accident as a result of taking oral contraceptives produced by the defendant.\textsuperscript{40} The FDA had required by regulation that "[i]nformation in lay language concerning effectiveness, contraindication, warnings, precautions, and ad-

\textsuperscript{33} Id. at 821.
\textsuperscript{34} Id.
\textsuperscript{35} Id. at 824.
\textsuperscript{36} 282 A.2d 206 (Pa. 1971).
\textsuperscript{37} Id. at 222; see also Salmon v. Parke, Davis and Co., 520 F.2d 1359, 1362 (4th Cir. 1975).
\textsuperscript{38} There are currently seven prescription drugs for which the FDA requires patient labeling or patient package inserts. All cited sections are to 21 C.F.R. (1984): (1) isoproterenol inhalation drug, § 201.305; (2) oral contraceptives, § 310.501(a); (3) oral postcoital contraceptive ("morning-after" pill), § 310.501(b); (4) medroxyprogesterone acetate injectable contraceptive (Depro-Provera), § 310.501(a); (5) intrauterine devices, § 310.502; (6) estrogenic drugs, § 310.515; and (7) progestational drugs, § 310.516.
\textsuperscript{39} 510 F. Supp 961 (E.D. Wis.), modified, 532 F. Supp. 211 (E.D. Wis. 1981).
\textsuperscript{40} Id. at 962.
verse reactions shall be furnished to each patient receiving oral contraceptives.\textsuperscript{41} The plaintiff received no such information. Applying Wisconsin law as to when a standard of conduct defined by regulation will be adopted,\textsuperscript{42} the court determined that:

"[s]ince [the regulation] was enacted to protect persons like the plaintiff . . . , and since Wisconsin holds that violation of such a regulation by one on whom it imposes a duty resulting in occurrence of the harm which the regulation was designed to prevent constitutes negligence per se, the defendant in this case did have a duty to warn the plaintiff . . . of the possible side effects of [the oral contraceptive]."\textsuperscript{43}

In recent years, the FDA has promulgated rules to require direct manufacturer-to-patient warnings for certain prescription drugs.\textsuperscript{44} The rules, however, were revoked prior to their effective date. The revocation was due in part to representations made by the pharmaceutical industry and medical profession of a commitment to implement their own system of conveying warnings to consumers.\textsuperscript{45} This creates an issue as to how such "voluntary" warnings should be treated. Should they be deemed to create a comprehensive duty to warn the patient similar to the current duty of the manufacturer to the medical community? Or should such warnings only be required to be accurate, though not necessarily complete? This issue was addressed by the Supreme Court of Ohio in Seley v. G.D. Searle & Co.\textsuperscript{46} Seley involved the prescription of the oral contraceptive "Ovulen."\textsuperscript{47} In addition to preparing warnings for dissemination to the medical community, the defendant, Searle, also

\textsuperscript{41} Id. at 963 (quoting 21 C.F.R. § 310.501(a)).
\textsuperscript{42} See generally, \textit{Restatement (Second) of Torts} § 286 (1963), cited in Lukaszewicz, 510 F. Supp. at 964.
\textsuperscript{43} Lukaszewicz, 510 F. Supp. at 965.
\textsuperscript{46} 423 N.E.2d 831 (Ohio 1981).
\textsuperscript{47} Id. at 834.
prepared pamphlets containing warnings and use instructions written in lay language for the ultimate users of the pill.\textsuperscript{48} The supreme court stated that the court of appeals had employed the “voluntary duty doctrine,”\textsuperscript{49} and had held that “having voluntarily undertaken to provide such warnings, Searle could be held liable if the warnings failed to convey a full explanation of the risks associated with use of Ovulen, and if Mrs. Seley relied on those warnings.”\textsuperscript{50} In a five-two decision, the supreme court reversed, holding the voluntary duty doctrine inapplicable to prescription drugs.\textsuperscript{51} The court reasoned that although the pamphlet was intended to benefit the patient, the patient was expected to place primary reliance on the advice of her prescribing physician and not upon the literature provided by the manufacturer.\textsuperscript{52} The manufacturer’s duty to warn was satisfied when the physician was warned. The physician was to act as a “learned intermediary” between the drug manufacturer and patient.\textsuperscript{53} Thus, even where the manufacturer voluntarily undertakes to provide the patient with information, the learned intermediary theory is a hurdle, if not a bar, to the imposition of a direct manufacturer-to-patient duty to warn.

While the \textit{Reyes} theory seems plausible, a closer examination reveals deficiencies. The doctrine substantially overstates the ability and willingness of the medical community to act as a “learned intermediary,” impedes the right of the patient to knowledge of the substances which he places in his body, and ignores the substantial benefits derived from having an informed patient.

\begin{itemize}
\item \textsuperscript{48} Id. at 839. At the time in question, the FDA did not require manufacturers of oral contraceptives to provide warnings directly to the consumer. Id. n.6.
\item \textsuperscript{49} Under the voluntary duty doctrine, one who gratuitously undertakes a voluntary act assumes the duty to complete it with the exercise of due care under the circumstances. See \textit{W. Prosser, Handbook of the Law of Torts} § 56, at 343-48 (4th ed. 1971); \textit{Restatement (Second) of Torts} § 323 (1965), \textit{cited in Seley}, 423 N.E.2d at 839.
\item \textsuperscript{50} \textit{Seley}, 423 N.E.2d at 839 (citing No. 80-336, Ohio Ct. App.) (footnote omitted).
\item \textsuperscript{51} Id.
\item \textsuperscript{52} Id. at 839-40.
\item \textsuperscript{53} Justice Brown, joined by Justice Donofrio, adopted the position of the court of appeals. He noted the possible economic benefit to Searle from the pamphlet as a form of promotional advertising. Similarly, he felt that while “Searle may well have had no duty to warn prospective users by direct communication, but having undertaken to do so voluntarily, Searle must inform prospective users fully in its promotional literature.” \textit{Id.} at 845 (Brown, J., dissenting).
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III. Why Should There Be a Direct Manufacturer-to-Patient Warning?

A. Shortcomings in the Marketing System

Before proceeding to the specific problems with the current warning and advertising system of manufacturers, it is first necessary to have a basic understanding of how that system works. Once the decision is made to warn of certain adverse effects, the drug manufacturer has a number of avenues available to warn the physician. The manufacturer may warn through the package insert, which is a legally required compendium included with each original drug package sent to a pharmacy by the manufacturer;\(^5\) by advertisement in the *Physician's Desk Reference*; by advertisements in medical publications; by direct letters to physicians; or by personal contact with medical personnel in their offices or at conventions, through company representatives known as “detail men.”\(^6\)

Because the patient package insert is not distributed to the physician but to the dispensing agent\(^6\) and because the *Physician's Desk Reference* is published only once a year, the last three advertising methods have the greatest potential for providing up-to-date warnings regarding the risks of the manufacturer's products. Yet these three methods have historically proved to be the most abused and least reliable.\(^5\)

Until recently, there was little regulation regarding the advertising claims of drug manufacturers. Unproven claims of effectiveness and superiority were the rule, rather than the exception.\(^5\) Not until the FDA propounded regulations in the 1960s was some semblance of order imposed.\(^6\) These new regulations required a fair balance in all forms of advertising. Fair balance essentially means that the physician be properly warned about the dangers and side effects of a drug in equal balance to the assertion of the drug's benefits. Likewise, documentation of claims of superiority and effectiveness were required.\(^6\)

While the new regulations have had the effect of making adver-

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54. 21 C.F.R. § 201.100(c) (1984).
55. See 1 M. Dixon, Drug Product Liability § 3.05, at 3-16 (1974).
56. 1 M. Dixon, supra note 55, § 6.10[4][a], at 6-33 (1975).
57. See, e.g., supra notes 16-27 and accompanying text; infra notes 63-66 and accompanying text (discussing overpromotion through such advertising methods).
58. See 1 M. Dixon, supra note 55, § 6.10[1], at 6-23.
Advertisements more reliable, they have not stemmed the great volume of drug literature and advertising that is sent to or directed at physicians. Many have conceded that in light of the constant bombardment with large volumes of rapidly changing drug literature, the physician is "unable to keep up with this ever-changing sea of knowledge." This fact undercuts the theory of the physician as a "learned intermediary" between the drug manufacturer and the patient. The sheer volume of drug literature militates against the physician's being informed of all the hazards of a particular drug—especially those hazards which are discovered after the initial marketing of a drug and about which supplemental warnings have been distributed. Direct warnings accompanying prescriptions to patients would not result in similar inundation, as the patient is not concerned with knowing the risks of a broad spectrum of drugs, but only of the risks of the drug prescribed.

On occasion, the opposite result occurs. A physician who learns the proper warnings regarding a particular drug gets so caught up in the manufacturer's promotional advertising that he "forgets" or is led to disregard the warnings. This phenomenon is generally referred to as "overpromotion." Salmon v. Parke, Davis and Co. involved a prescribing physician who received a calendar advertising chloromycetin, together with a sample package containing a warning about the drug. In recognizing that "a calendar might remain on a physician's desk as a constant reminder to prescribe a drug long after the sample and its warning had been removed," the court concluded that "[a] jury could infer . . . that the absence of a warning on an advertisement [the calendar] . . . was a form of overpromotion which nullified the effect of even a valid warning on the package."

The problem of overpromotion would be unlikely to affect direct warnings to the patient, since prescription drug manufacturers rarely advertise their products to the general public. In summary, many of the difficulties in providing adequate warnings under the current "duty to warn the medical community" standard would not be present in a direct manufacturer-to-patient warning system.

61. See 1 M. Dixon, supra note 55, § 6.10[1], at 6-25; Annot., 94 A.L.R.3d 1080, 1081 (1979); Comment, supra note 24, at 210-211 (quoting a "distinguished" physician).
62. See supra notes 16-27 and accompanying text.
63. 520 F.2d 1359 (4th Cir. 1975).
64. Id. at 1363.
65. Id.
66. Id.
B. Informed Consent—The Patient's Right to be Free of Impediments to Self-Determination

Undoubtedly, the single most important reason for imposing upon the manufacturer of prescription drugs the duty to warn consumers of possible side effects is the notion of informed consent. Historically, the problem of informed consent arose in two situations involving medical operations and treatments. The first situation occurred where the physician exceeded the scope of the patient's consent, as where the physician operated on the wrong ear or otherwise operated on parts of the body to which the patient had not consented. The second situation involved a failure to disclose a particular risk. This situation frequently arises today and involves the physician's duty to advise the patient of the risks inherent in a particular course of treatment and the alternatives available to the patient in lieu of undergoing the suggested treatment.

The second situation, involving the failure to disclose risks, and which heretofore had been limited to disclosure among methods of treatment, now presents a problem in physicians' prescriptions. By placing the warning into the hands of the physician, who is given sole discretion to determine what risk, if any, will be communicated to the patient, the current system of manufacturer warnings perpetuates paternalism and aggravates the problem of informed consent.

The concept of informed consent is inextricably bound with the ideas of active participation in the treatment process and self-determination. It is the belief that it is the ultimate prerogative of the patient to determine where his interests lie—that it is the right of every human being, and thus every patient of adult years and sound mind, to determine what shall be done with his own body. Before such self-determination can be intelligently exercised, however, the patient must have a familiarity with the availability and risks of alternative methods of treatment.


69. A cancer patient, for example, may wish to choose an operation over radiation therapy.

70. Numerous studies have concluded that health care professionals, including both phy-
The extent to which the patient is entitled to knowledge of the risks attending a particular course of treatment and the availability of alternative treatment has been a stumbling block for the courts. In general, the judicial attitude is that "reasonable disclosure" is required of the physician. Just what "reasonable disclosure" means, however, varies widely.

One view, which is consistent with the idea of self-determination, is represented in Canterbury v. Spence. Canterbury involved a young man troubled only by back pain, who submitted to an exploratory and remedial operation on his back. He was not informed of the incidental risk of paralysis. Following the operation, he became partially paralyzed. In reversing a directed verdict for the physician, the court of appeals held that the evidence presented a jury question as to the sufficiency of the surgeon's disclosure regarding whether a one percent possibility of paralysis was peril of sufficient magnitude to require disclosure. The court also found that the duty to inform was independent of a patient's request for disclosure and that the standard for disclosure is not that which is set by custom of physicians practicing in the community. Rather, the court reasoned that "[r]espect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves."
In contrast to this rather broad view of what constitutes "reasonable disclosure" is the view demonstrated by Buckner v. Allergan Pharmaceuticals, Inc.,77 in which the court stated that "[t]he physician decides what facts should be told to the patient . . . [based upon his perception of what is] in the best interest of the patient."78 The court noted that the appropriate standard of review was "whether a reasonable medical practitioner in the community would make the pertinent disclosures under the same or similar circumstance."79 In other words, the duty to disclose is set by physicians' customary practice.80 Obviously, this paternalistic view of the physician is in opposition to the idea of self-determination by the patient in that it gives the medical profession sweeping authority to decide unilaterally what is in the patient's best interest. At best, this view affords the patient only a limited knowledge of the risks attendant with his treatment—at worst, it affords none at all. Indeed, one commentator has noted that courts have found that the current standard of practice for physicians in some communities is to keep the patient completely ignorant of the risks to which he is subject.81 Ironically, Buckner itself substantiates the commentator's fear, as the plaintiff there alleged that her physician and the "medical profession [as a whole were] not adequately relaying . . . warnings to the consuming public."82 The right of the patient to disclosure then, is invariably subject to the "ebb and flow" of the judicial and medical attitude regarding what constitutes "reasonable disclosure." While controversy over the right of disclosure is unavoidable in the context of operations and the choice of method of treatment, the same cannot be said of disclosure of risks regarding prescription drugs. With regard to operations and method of treatment, there is no third party who is qualified to make disclosure. Only the physician is qualified to make disclosure. But in the case of prescription drugs, both the physician and a

77. 400 So. 2d 820 (Fla. 5th DCA 1981).
78. Id. at 823 (quoting Terhune v. A.H. Robbins Co., 577 P.2d 975, 978 (Wash. 1978)).
79. Id. at 824. The willingness of the court to adopt this view was, no doubt, influenced by Fla. Stat. chs. 458, 465, and 500 (1979), which evidence "legislated public policy to rely on physicians . . . to protect the consuming public from injury by product use when the product is a prescription drug." Id. at 822 n.3.
81. See 1 M. Dixon, supra note 56, § 7.23, at 7-110.
82. Buckner, 400 So. 2d at 821.
third party, the drug manufacturer, are qualified to make disclosure. The imposition of a manufacturer’s duty to inform the patient would assure the patient the opportunity to be informed and would not needlessly subject the patient’s right of disclosure to the physician’s or the courts’ discretion.83

Not all of the problems of informed consent would be eliminated by a manufacturer-to-patient duty to warn. Since the patient receives the medication after the physician has already examined him, the physician must necessarily be responsible for some discussion of the attendant risks at the time the prescription is made. But self-determination is only meaningful if based upon full disclosure. Imposition of the proposed duty would insure that the right to full disclosure is honored. The fact that the actual right of self-determination is not exercised until after the prescription is filled should not diminish the importance of its exercise.

83. The FDA has consistently recognized the role of informed consent in promulgating certain manufacturer-to-patient warning requirements. See supra note 38. For example, in response to the mandated patient package insert for the “morning after” pill and Depro-Provera (injectable contraceptive), Dr. Alexander M. Schmidt, the Commissioner of The FDA in 1973, noted:

The consumer . . . would seem to have a right to know the options available and to participate on an informal basis with her physician in the decision making. The prerequisite for an informed consent is obviously an informed patient, and that is the purpose of the patient package insert.

Similar decisions for other classes of drug therapy must also be considered. For example, some drugs are administered over long periods for chronic diseases. These drugs may sometimes make the patient more vulnerable to other medical problems. Here again, the patient has an absolute need, not to say right, to know what these problems might be and if, in fact, he’s willing to accept the risk.

1 M. Dixon, supra note 55, § 6.10[4], at 6-35. Likewise, the Commissioner of the FDA in 1978, Donald Kennedy, commenting on the newly mandated patient labeling for oral contraceptives, noted:

[T]he action represents response to a growing consumer demand for greater knowledge and a greater voice in making personal choices about contraception.

. . . .

[T]oday’s sophisticated consumers are clearly determined to participate in basic decisions affecting their personal health and safety. I applaud this trend. I believe that labeling for patients will make people better patients, better consumers, and better able to take care of themselves.

Beyond this, I believe that consumers have the right to know what chemicals they are taking into their bodies. They are today exercising the right as never before.

In line with this trend, the FDA is committed to doing what it can to provide consumer information not only about birth control pills but about other prescription drugs as well. We want more patients to have more information in plain language about their own therapy.

C. The Benefits Derived from an Informed Patienity

Beyond allowing the patient to exercise her right to self-determination, a direct manufacturer-to-patient warning requirement will serve other useful functions. The benefit derived from having an informed patient is the most important example. A patient who is fully informed of the adverse risks attending a particular drug and the symptoms of an adverse reaction will be better able to recognize those reactions before they fully develop. Moreover, the patient is more likely to be the first observer of the symptoms of adverse drug reaction. Rarely will the physician be present when these initial symptoms are manifested. Unless the patient is educated to watch for danger signals, she will not know the significance of these early warnings of adverse reaction. As one commentator aptly stated:

The average patient does not see a physician when the early danger signs appear, because the significance of the danger is not recognized. . . . In many clinical circumstances, the patient continues . . . taking the drug until serious problems develop which provide the incentive to return to a physician. . . . The time delay [between recognition of an adverse drug reaction by an informed and an uninformed patient] may spell the difference between safety and catastrophe.84

Similarly, increased compliance with the proper use of prescription drug products should result from direct manufacturer-to-patient warnings. Current estimated rates of noncompliance range from fifty to eighty percent for some drug regimens, and thirty to fifty percent for a wide range of drugs.85 Such evidence has prompted the FDA to note that “[t]he patient’s failure to use a prescription drug product properly may be a major cause for the therapeutic failure of the product, or may cause the patient to experience a serious adverse reaction.”86 A direct manufacturer-to-patient warning should explain both the importance of taking the drug product as directed and the risks of taking the drug improperly, and thereby aid in reducing the current level of misuse.

Moreover, the informing of the patient by the physician, while

86. Id.
such activity is to be encouraged, would not necessarily lead to the same benefits. For instance, a warning from the manufacturer would necessarily be in writing. A written warning has the advantage of providing a source of future reference to the patient and almost invariably of providing greater detail than a warning from a physician. Likewise, studies demonstrate that significant proportions of patients do not remember medical information that is presented orally, and that health professionals frequently use language that patients do not understand. Finally, numerous studies have verified that written product information does improve patient knowledge.

In addition to these benefits, studies have shown wide-spread public support for the idea of patient labeling accompanying prescription drugs. One study featured a nationwide survey of adults who were asked whether they believed it was important for printed patient labeling to be provided with prescription drug products. Sixty-four percent responded positively, while thirty-three percent believed current practices to be adequate. This two-to-one preference for patient labeling was consistent among all sex, age, and educational subgroups.

Opposition to the idea of a manufacturer-to-patient duty to warn has emanated almost exclusively from the pharmaceutical and medical industries. The duty, and the methods advocated to implement it, have been attacked as encouraging self-diagnosis and the transfer of prescription drugs between patients, producing adverse reactions through suggestion, adversely affecting the liability of the drug manufacturer, interfering with the patient-physician

87. This article does not propose that a manufacturer-to-patient warning be the sole source of information for patients about prescription drugs. Ideally, a patient warning will merely reemphasize and supplement the information provided by the physician when the drug was prescribed.

88. Ellis, Hopkin, Leitch, & Crofton, "Doctors' orders": controlled trial of supplementary, written information for patients, 1 BRR. MED. J. 456 (1979) [hereinafter cited as Ellis]; Ley & Morris, supra note 70, at 120 table 2, Recall of Orally Presented Medical Information (fifteen studies reporting a mean percentage forgotten ranging from 37% to 71%).


90. See Ley & Morris, supra note 70, at 125 table 6, Studies Assessing the Effects of Written Information in Patient Populations (31 of 32 studies finding improvement in patient knowledge); Ellis, supra note 88.

91. See Ley & Morris, supra note 70, at 123 table 4, Percent Desiring Written Information in the Form of Patient Package Inserts (twelve studies reporting findings ranging from 38% to 97%).


relationship, and as carrying a heavy economic impact. The first two arguments have been rejected by the FDA and others as unsupported and contrary to available evidence.\textsuperscript{94} Manufacturers might reduce the likelihood of transfer of prescriptions among patients by advising consumers that the drug has been prescribed for the particular individual and should not be given to others.\textsuperscript{95} Rather than interfering with the patient-physician relationship, such a warning is likely to foster the relationship. By allowing the patient to obtain a greater knowledge of the drug product, he is in a better position to intelligently discuss his treatment with the physician. Moreover, to the extent that the manufacturer's warnings to the consumer can track the substance of the warnings provided to the medical community, similar conclusions regarding the adequacy of the warning and culpability of the manufacturer will follow. To the extent that such warnings increase the price of the drug product, consumers have shown a willingness to incur such expense in exchange for drug information.\textsuperscript{96}

A final consideration is whether a patient who receives information regarding the risks of drug therapy will be charged with knowledge of the information and, therefore, be deemed to have assumed the risk of adverse reactions. An FDA attorney has posited that a patient package insert would provide a minimum level of information to a patient and that side effects not covered by the insert would still leave the manufacturer subject to liability.\textsuperscript{97} The attorney also contends that a patient package insert would not absolve a drug manufacturer from the effects of overpromoting a drug or failing to warn the physician. To argue otherwise, this attorney notes, “confuses the patient's right to participate in the decision to assent to drug therapy with the [prescribing physician's] responsibility for choosing the proper drug for his condition.”\textsuperscript{98} The attorney argues that a physician's responsibility depends upon adequate information from the manufacturer, and “the benefit

\textsuperscript{94} Id. at 40,022-23; Ley & Morris, \textit{supra} note 70, at 122. 


\textsuperscript{96} A survey of certain television viewers found that 69% of the noon and 57% of the evening viewers said they were willing to pay an additional thirty cents per prescription to receive patient package inserts. Of those not willing to pay thirty cents, 69% of the noon and 64% of the evening viewers were willing to pay an additional ten cents. 45 Fed. Reg. 60,754, 60,759 (1980).


\textsuperscript{98} Id. at 859-60.
given the patient through such increased knowledge should not be rendered a burden by having it used to reduce manufacturer liability.\footnote{99. \textit{Id. at} 860.} However, where the warning advises of the same risk which the patient subsequently develops, a patient package insert may reduce potential manufacturer liability.

IV. Methods for Implementing the Manufacturer-to-Patient Duty to Warn

Of the current methods of warning utilized by drug manufacturers, the method with the greatest potential for providing a warning to the patient is the drug package insert. The drug package insert is a brochure which contains a summary of a particular drug's indications and adverse reactions. It is included with the drug package or container when shipped to the pharmacist. FDA regulations make the inserts mandatory for every package of a drug which reaches the pharmacist's shelf.\footnote{100. 1 M. Dixon, \textit{supra} note 56, § 6.10[4][a], at 6-33.} The purpose of the insert is to provide current information on the product to the physician. Theoretically, the insert is available to the prescribing physician, though there are no provisions for forwarding such inserts to him. Not surprisingly, the inserts are rarely requested by the physician and are removed and discarded by the pharmacist before the drug is sold to the consumer. FDA regulations are silent on the removal of these package inserts.\footnote{101. \textit{Id.}} Thus, the current practice makes the package insert of minimal value as a tool for transmitting product deficiencies to physicians.

With only a few modifications to the existing drug package insert program, however, warnings about a vast array of prescription medicines can be provided to the consumer.\footnote{102. Under the FDA approach, the drug manufacturer must provide both patient package inserts and physician package inserts.} For drugs which are sent by the manufacturer in prepackaged containers not meant to be subdivided by the pharmacist, the warning may be communicated to the consumer by simply prohibiting the removal of the enclosed drug package insert. For drug products which are distributed in mass quantity containers which the pharmacist subsequently repackages based upon the patient's prescribed dosage, the warning can be provided to the consumer by sending a sufficient quantity of package inserts to the pharmacist to cover the contem-
plated breakdown of the product shipment. Then, the pharmacist could include a package insert with each prescription filled.

Of course, for the package insert to be truly helpful to the patient, its content must be understandable. Much of what is currently contained in the package insert would need to be "rewritten" in language understandable to the lay consumer. Medical terminology within the insert regarding adverse reactions would need to be replaced with simpler language.

The FDA currently employs a similar approach in requiring "patient leaflets and brochures" for oral and injectable contraceptives, the morning-after pill, aerosolized asthma drugs, and the intrauterine device (IUD). In 1979, the FDA proposed to establish a comprehensive patient package insert program which would have extended to most prescription drug products. The following year the FDA adopted a rule establishing an initial implementation period of three years for ten specified drug classes. The agency based its action on the benefits consumers would receive from written information concerning prescription drugs. Under the regulation, patient package inserts (PPIs) written in nontechnical language and adapted from the existing professional labeling for the product would have been required to accompany new prescriptions of drugs from the specified drug classes. The PPI was to include a summary section on information about the drug, and more detailed sections which were to describe the proper uses of the drug, circumstances under which it should not be used, serious adverse reactions, precautions to be observed when using the drug, risks of developing tolerance to or dependence on the drug, proper responses by patients in case of overdosage, and the possible side effects from the use of the drug.

Prior to the effective date of the regulation, however, a temporary stay was issued by the FDA. The temporary stay was fol-

103. See supra note 38.
105. 45 Fed. Reg. 60,754 (1980). The 10 drug classes included were: ampicillins, benzodiazipines, cometidine, clopidate, digoxin, methoxsalen, propoxyphene, phynitron, thiazides, and warfarin. Id. at 60,758.
ollowed by revocation of the patient package insert program in 1982.109 The stay and revocation are easily traceable to a change in political orientation of the executive branch after President Reagan took office in 1981. The temporary stay of the regulation was largely responsive to Executive Order 12,291110 concerning the Presidential Task Force on Regulatory Relief. Section 7 of the Order provided that “agencies shall . . . suspend or postpone the effective dates of all major rules that they have promulgated in final form as of the date of this Order, but that have not yet become effective. . . .”111 The revocation, in turn, followed the appointment of a new FDA Commissioner 112 and the repudiation of many of the principles accepted by the FDA in the preceding years.113 The new FDA position is that private sector initiatives should prove at least as efficient as the FDA-mandated patient warnings.114 Without debating the soundness of such an assumption,115 it is important to note that the FDA still believes that “patients have both a right and a need to know about the drugs they use.”116

Thus, while the FDA has receded from its position of mandating patient package inserts, it has not receded from its position as to the desirability of an informed patient. Rather, the FDA has chosen to rely upon voluntary drug information programs in the private sector. The FDA noted that several comments to the revocation of the PPI program “stated that most voluntary drug information programs have arisen only as a direct result of FDA pressure and argued that if the agency revokes the PPI program, the promise of voluntary alternative programs will fade and the programs will never materialize.”117 Indeed, such voluntary programs are as yet largely unfelt by the majority of drug consumers. Courts, however, could ensure the continued development of the “voluntary warning initiative” by imposing upon the drug manu-

111. Id. at 13,196.
116. Id.
117. Id. at 39,152.
facturer a duty to warn the patient. In imposing such a duty, the courts can be secure in the knowledge that there are realistic, available methods of warning, and that private industry has already represented its ability to implement such warnings.

V. Conclusion

Returning to the introductory hypothetical, the only person having any liability under the current state of the law is the physician. The physician's liability is contingent upon a showing of causation—that "but for" his failure to warn the patient, the patient would not have taken the drug. The manufacturer has no duty to warn the patient of the possible adverse effects.

While the prescribing physician is undoubtedly in the best position to determine whether a patient is an appropriate candidate for a particular drug, the manufacturer is more knowledgeable about the adverse effects and risks of the drug. After all, it is the drug manufacturer who has rigorously tested the drug for such adverse effects before gaining FDA approval to market the drug. Given that the product warning regarding contra-indications is derived from this extensive testing, which, undoubtedly, is meant to inure to the benefit of the patient, the law ought to see that the patient is actually warned. As such, a mandatory duty to inform the consumer of the risk of a drug should be imposed upon the manufacturer, as is the general rule with respect to manufacturers of other products, in lieu of the current discretionary duty by the medical profession.

In order for a product warning to be effective, the following criteria must be met:

1. the warning must be received;
2. the warning must be understood; and
3. the individual must act in accordance with the warning.\(^{118}\)

Leaving the disclosure of warnings to the medical profession frequently results in no warning being received by the patient. Information not received by the patient, of course, cannot be understood. A direct manufacturer-to-patient duty to warn in lay language would ensure receipt of a warning understandable to the consumer.

The only remaining impediment to an effective system of warnings is the extent to which the patient makes use of the warnings.

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Thus, the final utility of the warning information is subject to the patient's self-determination. The patient can familiarize himself with the risks, accept them, and attempt to watch for the early symptoms of an adverse reaction. The patient may reject the risks and decide not to use the drug. Alternatively, the patient may neglect to familiarize himself with the warning (perhaps, thereby, consenting to the treatment). The ultimate choice is left to the patient. This is as it should be.

In the future, courts should not so readily adopt the rationale of the "learned intermediary," but instead examine closely its underlying premise, taking into account the developments in the consumer movement, the substantial benefits derived from informed patients, and the existence of reasonable methods for the pharmaceutical industry to comply with the imposition of a duty to warn the consumer.