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CLOSE YOUR EYES AND SWALLOW

The FDA deals a severe blow to patients' rights to drug information.

Barbra A. Kavanaugh

In 1972, a baby girl was born with “severe and irreparable brain damage and partial paralysis” after her mother was given an oral anti-coagulant which was “widely accepted in the medical community” as being capable of crossing the placental barrier. Her doctor was not aware of the risk, because he did not read the physician’s package insert that warned of the danger and because the manufacturer had withdrawn the drug from the Physician’s Desk Reference (PDR). The doctor had done no reading on his own on the drug for five years and had assumed it to be safe, as it has been originally marketed without the warning (Baker v. St. Agnes Hospital, 70 A.D. 2d 400 [1979]). On the other hand, the patient package insert for Warfarin, an oral anti-coagulant with the same capability, contains a warning in bold print to pregnant women. If Ms. Baker had received such an insert, she might have questioned her doctor and avoided a tragedy.

Studies show that Ms. Baker’s tragedy is not an isolated incident. Recent studies estimate that reactions to new drugs, about which doctors and patients are poorly informed, have doubled the average duration of hospitalization at the cost of approximately $3 billion per year.

According to attorney Richard O'Meara:

Physicians now have pharmaceutical and biological agents that can be used to destroy bacteria, thwart viruses, imitate glands, change blood pressure, provoke diuresis (produce urine), alter heartbeat, retard cancer, affect emotions, and perform many other therapeutic acts that were previously impossible. This powerful and specific technology creates the unprecedented capacity to help and to harm.

There is a constant tension between our need and desire to cure and treat diseases and the costs of a rapidly increasing technology to meet those needs and desires. We may choose not to impose strict liability on drug manufacturers because it will adversely effect incentive to develop and market new drugs; yet we want to protect ourselves from the risk of harm presented by these new and powerful drugs.

A system has developed to help us at least make informed and responsible decisions about the risks we are willing to take in order to be “well.” Yet this system is inadequate because of its ignorance of actual medical practices and its dependence on a historical, but unjustified, view of the physician’s role in sharing drug information.

One way to repair the system would be to make information directly available to the ultimate consumer/patient. Such a program has been developing over the past twelve years. Patient package inserts are brochures or pamphlets included in the prescription drug package. They list, in plain English, the major side effects, risks, and indications for the drug.

The Food and Drug Administration (FDA) has required patient package inserts (PPIs) for certain drugs since 1968. In 1980, the FDA issued a regulation that required inserts for all prescription drugs, but initially implemented a pilot program for only ten drugs. However, despite indications that PPIs did in fact increase patient awareness, compliance, and participation in their own treatment, Health and Human Services Secretary Richard Schweiker issued a statement on December 23, 1981, that the FDA intended to withdraw the PPI regulation.

The final requirements for the preparation and distribution of patient package inserts (PPIs) were adopted by the Food and Drug Administration (FDA) on September 12, 1980. Although the regulations applied to all prescription drugs and drug classes, the program was initially implemented for only ten drugs. The ten drugs included widely used antibiotics, tranquilizers, and pain-killers, as well as an oral anti-coagulant and a high-blood pressure medication. All of the drugs in the pilot program can cause serious reactions or have an addictive potential and require the patient to participate in reporting symptoms of either to the prescribing physician. The FDA intended to evaluate the limited implementation program in deciding whether to extend, revise, or defer these requirements.

The program followed more than ten years of FDA experience with PPIs. As early as June 1968, the FDA required that inhalation products for asthma sufferers bear a...
two-sentence warning to the patient. Soon after that, the
FDA issued regulations requiring that certain information
be made available to patients about the use of oral contra-
ceptives, intrauterine devices (IUD) and all estrogen-based
drug products.

FDA requirements for PPIs had centered on largely
elective prescription drug products which presented signifi-
cant risks to patients. Following the development of patient
labeling requirements for oral contraceptives in 1970, the
FDA began evaluating the usefulness of PPIs for prescrip-
tion drug products generally and studied alternative means
of presenting information to patients. The process gained
momentum in 1974 when the FDA, responding to sugges-
tions from the National Food and Drug Advisory Commit-
tee, began a Pilot Prescription Drug Labeling Project to
investigate whether the FDA's PPI program should be ex-
panded to apply to a variety of prescription drug products.
In March 1975, the Project received a petition from the
Center for Law and Social Policy on behalf of numerous
consumer and women's health organizations, suggesting the
use of written warnings to guide and benefit the patient
and recommending that such information be attached to the
prescription container. The FDA responded by soliciting
opinions from the public on issues extending beyond the
scope of the petition, including not only the advantages and
disadvantages of such regulations but also the scope, detail,
style, and method of distribution of such patient warnings.

Between September 1974 and June 1975, FDA officials
met individually with organizations representing doctors,
pharmacists, and the pharmaceutical industry and, in July
1975, met with consumer representatives to discuss the
general concept of PPIs. The FDA also hosted a series of
meetings in May and June 1976 in which officials met with
consumer advocates and representatives from the pharmace-
autical industry, pharmacy associations, and allied health
professions. Later in 1976, the FDA invited the Drug Infor-
mation Association, an independent nonprofit professional
group interested in drug information, to arrange a sympos-
um on PPIs, which was attended by over seven hundred
health professionals, consumer representatives, and mem-
ers of the press. The FDA continued to solicit public opin-
ion and comment, and, in February 1979, the Institute of
Medicine of the National Academy of Sciences, under con-
tract to the FDA, sponsored a public hearing, soliciting comments on how PPIs should be objectively evaluated
once used on a widespread basis.

In addition to ten years of public and private meetings,
the FDA reviewed literature and studies which indicated
that the distribution of printed drug information to patients
improves patient compliance. It appeared that information
which increased the patient's knowledge of side effects and
contraindications helped the patient in taking drugs proper-
ly and improving decisions the patient made in monitoring
the course of treatment. These results are consistent with
the FDA's intent in requiring PPIs for prescription drugs,
which was to provide patients with information about pre-
scription drug products that will promote their safe and ef-
efective uses and to provide patients with adequate and
meaningful information sufficient for them to participate in
evaluating the benefits, risks, and proper use of prescription
drug products.

The FDA's purpose in requiring PPIs was misinter-
preted by Vice-President George Bush in a press release
issued on August 12, 1980. He questioned the utility of
PPIs in light of the fact that the decision to use a prescrip-
tion drug is made before purchasing the drug, which is
when the patient would receive any information from the
PPI. The given purpose of the PPI program is not to influ-
ence consumer buying habits but to increase patient/
consumer knowledge of and participation in their own
treatment.

The Vice-President's press release, which slated the
PPI program for review, was followed by unofficial notifica-
tion on February 20, 1981, to the drug and pharmaceutical
industries that the FDA would indefinitely stay the effect-
date of the final PPI regulation. This indefinite stay
was imposed a little more than a year from the date that the
regulation was first issued.

After the unofficial notification to the drug industry,
three consumer and health organizations filed a suit against
the Department of Health and Human Services on April 8,
1981, seeking to compel implementation of the PPI program
according to the schedule established by the regulation.
The suit, filed by Public Citizen, the National Women's
Health Network and the National Council of Senior Citi-
zens, charged that the Reagan Administration had failed to
comply with the Administrative Procedure Act by sus-
pending the program indefinitely without public notice or
hearings.

In a memorandum opinion, the District Court for the
District of Columbia felt it necessary to "rely in the de-
fendant's integrity and accept defendant's statement that
nothing more than a 'temporary stay' was contemplated,
rather than an 'indefinite suspension' as argued by the
plaintiffs." Accordingly, the court allowed the Administra-
tion to continue the stay, but limited it to six months. The
court agreed to entertain a motion to reopen the case in the
even that the stay extended beyond that time.

The court also noted that "it is probable that, when
the review has been completed, the current administration
will endorse the views of its predecessors and issue the regulations at issue without change." Former FDA Commissioner Jere E. Goyan was quoted by the court as saying that "...they'll [the new administration's personnel] realize that it is a logical and sensible approach, and they'll allow it to go forward. After all, the PPI program is an experiment; the results should be evaluated before the program is abandoned."

On November 30, 1981, the United States Court of Appeals for the District of Columbia issued an order requiring the Secretary of HHS, Richard Schweiker, to decide the fate of the PPI program by December 3 of that year. Secretary Schweiker responded with a statement on December 23 that the FDA intended to withdraw the PPI regulation.

POSSIBLE REASONS FOR WITHDRAWAL OF THE REGULATION

The Secretary's statement was no doubt prompted by the hearings in September 1981, which were held by the FDA as part of their review of the PPI program. The hearings were attended by representatives of the American Medical Association, the drug industry, and pharmacists' associations. These groups had been fairly acquiescent to the PPI program in recent years, perhaps accepting the PPI program as inevitable. However, they showed new strength in opposing the program at the September hearings, perhaps partially in response to the new Administration's weakened commitment to the program.

The Board of Directors of the American Medical Association, which had issued a statement in favor of the program, was pressured by its membership to retract its endorsement. Unfortunately, the membership based its opposition on erroneous assumptions about the program. Many doctors believe that the inserts will be merely copies of the highly technical and sophisticated physicians' inserts. This is simply untrue. PPIs have been written specifically for each drug, taking into account the individual problems of the drug. For example, it is very important to finish a prescription for antibiotics in order to avoid recurring infections. The PPIs for antibiotics stress this point. On the other hand, a patient who is taking an oral anti-coagulant must be aware of the increased risk of bleeding episodes. The PPI for Narfarin, an oral anti-coagulant, encourages the patient to report any unusual bleeding or bruising to their physician. Yet most doctors do not realize how simple and direct the PPIs are. This is an unfortunate consequence of their experiences with the earlier PPIs for oral contraceptives, which were highly technical and did in fact cause problems with patient noncompliance and imagined side effects. It is also a problem that is easily solved by increasing the physicians' awareness of the nature of the modern PPI.

The drug industry takes no single position on the PPI issue. Views differ from manufacturer to manufacturer and drug to drug. Generally, manufacturers are less reluctant to provide an insert with a drug which may cause major side effects, yet is widely used, than a drug with relatively fewer serious side effects or one which is marketed to a small population. However, manufacturers also realize that, although it is unlikely that a PPI requirement would substantially alter the manufacturer's liability by enabling them to use an "assumption of risk" defense, it is very likely that, by increasing patient awareness and compliance, that the number of drug therapy injuries and related claims would be decreased. In fact, G. D. Searle and Company, a leading birth control device and drug manufacturer, has consistently written its own PPIs so that they go beyond the information required by the FDA, as an attempt to limit injury and liability.

The pharmacists have been the most resistant to the PPI program. Their arguments are primarily based on the high costs of implementing the program, citing the costs of storage and hours lost to labeling packages and explaining the inserts. However, it is widely believed in the industry that their position would change if the program would increase their status as members of the professional health team—a status which they have been seeking for many years. Professional status would be contingent upon the professional health team members' acceptance of the pharmacist as the patient's primary source of drug information. As the patient would receive the insert from the pharmacist when he or she dispenses the drug, it would be the pharmacist's responsibility to explain the insert and answer any questions.
“Historically, the doctor-patient relationship has been based on a model of patient helplessness. . . .”

The FDA hearings this past September were followed by Secretary Schweiker’s withdrawal of FDA support from the PPI program, despite the fact that, at the same hearings, Ms. Belita Cowan, Executive Director of the National Women’s Health Network, cited a three-year, $525,000 study which had been completed in August 1981 by the Rand Corporation, under contract to the FDA. The study involved 1,821 patients filling prescriptions at sixty-nine pharmacies in Los Angeles, California. The Rand Corporation divided the patients into a control group which did not receive PPIs and a test group which received PPIs for erythromycin (an antibiotic), fluzepam (a sleeping pill), and currently mandated PPIs for menopausal symptoms. The study showed that the great majority of study participants read and understood the information contained in the PPIs. Moreover, Representative Doug Walgren (D-Pennsylvania, Eighteenth District) said that the study showed that the longer and more detailed the information given, the more useful the PPI was to the patient.

Although there are criticisms of the study, most notably that the participants were aware of their part in the study and that they were paid $2.50 for responding to the questionnaires about the PPIs, it remains the most authoritative study on the subject and is still cited with approval by the FDA. In fact, the criticisms undermine at least one complaint made by physicians about the PPI program. Physicians are saying that, when this type of information is given to patients, it will frighten them away from the drug or cause imagined side effects, thereby decreasing patient compliance. Yet, even though the design of the Rand study may have induced patients to read the PPIs when they normally would not have done so, there was no increase in complaints, nor was there any increase in the number of prescriptions returned to the pharmacy. Patients in the test group were actually more likely to actively participate in and comply with their own treatment.

By ignoring the results of its own study, and seeming to respond only to economic, cost-benefit-type arguments in withdrawing FDA support from the PPI program, the new Administration is lending sad and disturbing credence to the statement by Dr. Sidney Wolfe of the Health Research Group that “the Department of Health and Human Services is more responsive to the interests of the drug industry than to the health needs of the American public.”

Although the proposed withdrawal from the PPI program must still go through public hearings before the FDA, it is unlikely that it will survive with the Administration’s support. If that is in fact the case, it will be the responsibility of the courts to safeguard patients’ health and right to drug information in the face of a growing drug technology and actual medical practices. By establishing a rule requiring manufacturers to warn the ultimate consumer/patient in simple and direct language, patients will be able to participate in their own treatment and add an extra layer of information and protection to the present system as well. There is a way in which the courts may provide such protection, and it can be derived from current drug manufacturer’s products liability doctrine.

**DRUG MANUFACTURERS’ LIABILITY**

Generally

The majority of drugs today are purified chemicals, and the amount of litigation resulting from the drug product being unsanitary or contaminated with other chemical products is relatively minimal. Most drug litigation occurs because the product is inherently harmful. Although drugs may be properly manufactured, it is not possible to design an effective but completely safe drug. Almost all drugs have the potential to inflict serious harm; in fact, a degree of toxicity is an essential element of an effective pharmaceutical.

In recognition of this fact, an exception to strict liability was included in the Restatement of Torts 2d, Comment K under §402A of the Restatement admits that “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.” Accordingly,

[c]he seller of such products . . . 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. [emphasis
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Comment K does not free drug manufacturers from all liability but rather applies a “risk/benefit” analysis. Because of the language of Comment K referring to an “apparently reasonable risk,” the protection under Comment K is lost if the drug which causes an injury has no substantial benefit. Yet, the majority of drugs about which litigation has arisen over the years are still marketed, which means that the risk/benefit ratio of these drugs still favors marketing. The defect lies neither in the manufacturing nor in the formulation but in the adequacy of the warning which accompanies the drugs. A drug marketed without warning of known dangers is clearly defective, and the manufacturers will be held strictly liable for any resulting injury.

Duty to Warn the Physician: Although the manufacturers of most consumer goods have a duty to provide users with information necessary for the safe use of the product, the drug manufacturer historically has been required to warn only the prescribing physician as the physician stands as the “learned intermediary” between the manufacturer and the ultimate consumer. The courts continue to support this exception to the strict liability doctrine in drug litigation.

There are only two instances where the ultimate consumer has a right to drug information directly from the manufacturer.

The first is the right created by FDA regulations, which required PPIs for all birth control devices and products. However, the courts have, with very few exceptions, refused to recognize this right to information as a basis for liability. In the area of contraceptives that cause death or injury, the courts have continued to hold that the duty of an adequate warning by the manufacturer is discharged by its warning of the hazards to the prescribing physician and that there is no duty on the part of the manufacturer to warn the patient of the hazards incurred in the use of the products. This is despite the regulations which require PPIs for these drugs. (This rule, however, was not applied in Lukasewicz v. Ortho Pharmaceutical Corp., 510 F. Supp. 961 [1981], in which the oral contraceptive PPI requirement was held to create a duty to warn ultimate consumers.)

The courts have created their own exception to the “adequate warning to physicians” rule. In Reyes v. Wyeth Laboratories, 498 F. 2d 1264 (1974), the court held the drug company strictly liable for having marketed an unavoidably unsafe oral polio vaccine without warning the ultimate consumer of the risks involved. The vaccine was administered through a mass immunization program. The company argued that it had no duty to warn the ultimate consumer of a prescription drug. Although the court agreed that it is generally true that manufacturers of prescription drugs are not required to warn the ultimate consumer, it also recognized that this special standard is an exception to the general rule that one who markets goods must warn the foreseeable user and was made only because a medical expert could be expected to intervene in the choice of a prescription drug. In this case, as in other mass-immunization cases, the drug was not administered by a doctor. The court held that the company had ample reason to foresee the manner in which the drug would be administered and, in the absence of a “learned intermediary,” had a duty to warn the ultimate consumer. The absence of such warning caused the imposition of strict liability on the manufacturer.

Both the general rule (adequate warning to physician discharges the manufacturer’s duty to warn) and the court-created exception (warning must go to the ultimate consumer of the drug product when the manufacturer can reasonably foresee that it will be administered without the intervention of a “learned intermediary”) assume a large role for the prescribing physician. The rules assume that once the physician receives adequate warning, he or she will then inform the patient of any risks so that an optimally safe and effective program of therapy and treatment can be developed.

However, even the best-intentioned doctors would be unable to adequately inform a patient if they do not have sufficient information themselves.

Failures and Weaknesses in the Present System

Informing the Physician: Since 1961, the FDA has required manufacturers to provide information to physicians regard-

“By establishing a rule requiring manufacturers to warn the ultimate consumer/patient in simple and direct language, patients will be able to participate in their own treatment. . . .”
ing various aspects of their drug products. The FDA-approved insert defines indication for drug use, contraindications (circumstances under which the drug should never be used), possible adverse reactions, and the warnings which are necessary for the best and safest use of the drug. This is the only regulated and fully controlled source of information on which the physician can rely, yet it does not normally go to the physician. Although he or she may request a copy of the insert, it usually goes to the pharmacist with a shipment of drugs and is discarded when the medication is dispensed.

Yet the physician package inserts are generally accepted as evidence that a manufacturer has fulfilled its duty to warn both doctors and consumers of potential hazards, despite the fact that physicians rarely read the insert and rely instead on the Physician's Desk Reference (PDR). The PDR is essentially a privately published compilation of official package inserts. Although the inserts contained in the PDR are regulated as labeling, it does not list all of the drugs on the market. In addition, the inserts and PDR entries are often laced with advertisements, emphasis on the positive aspects of the product and de-emphasis, if not deletion, of negative aspects.

The impact of overpromotion and “watered-down warnings” is also seen in another source of information for the doctor: the “detailman.” In practice, the person responsible for most of the doctor’s drug information is the manufacturer’s commission sales representative or “detailman.” The detailman makes the rounds of practitioners’ offices and encourages physicians to use their company’s products, as his or her own income is at least partially dependent upon his or her sales volume. This creates an obvious conflict of interest, and the courts have recognized the impact of overpromotion, imposing liability despite otherwise adequate warnings when overpromotion subconsciously or unconsciously caused the doctor to disregard the warnings. However, a charge of “overpromotion” brings with it serious problems of proof. Also, doctors often do not take the time to meet with and listen to the manufacturer’s representative as they consider it to be a wasteful and unproductive use of otherwise valuable time, but the courts continue to generally accept the sales representative as an adequate means of informing the physician.

Due to the nature of the drug industry, the tremendous rate at which new drug products are being developed, and an apparent lack of extensive pharmacological training in American medical schools, physicians have become increasingly dependent upon drug companies for information about their products. The courts have recognized the failures and weaknesses of this system but continue to support it. The courts also assume that once the doctor receives any drug information he or she will, in turn, inform the ultimate consumer. This is typically not the case.

Historically, the doctor–patient relationship has been based on a model of patient helplessness coupled with a view of the doctor as a possessor of expert knowledge and technical competence, enabling him or her to diagnose and treat ailments about which the patient knows very little. This view of the doctor as a professional has afforded her or him professional autonomy from judicial scrutiny.

When a patient alleges that a lack of information has negated any consent to treatment, the courts usually apply a professional standard in examining the physician’s conduct. The test asks what information the reasonable medical practitioner would give to a patient, as opposed to what information a reasonable person would want to have in order to make an informed decision about his or her own treatment. The professional standard is also used when a doctor claims that disclosure would have increased or created a risk and that he or she exercised a therapeutic privilege in withholding the information.

There is a growing trend toward a “patient perspective” in requiring the disclosure of drug information by physicians. This trend no doubt reflects the efforts of various consumer and patients’ rights organizations, yet it still fails to guarantee that the ultimate consumer will receive adequate warning. A physician cannot be expected to disclose risks of which he or she is unaware.

In sum, the present system of issuing warnings fails to fully inform the ultimate consumers/patients of the risks of drug therapy or to allow them to take an active role in their own treatment. This failure of the drug manufacturers’ liability doctrine can be repaired by, in effect, returning to the reasoning behind the strict products liability doctrine. That is, the party most likely to be aware of the risks involved with the use of each drug should be required to provide that information to the ultimate consumer/patient.

Such a rule is no more than a logical extension of the court-created “mass immunization” exception. The current system’s reliance on a “learned intermediary” is misplaced, in that doctors either may not have the information themselves or may fail to inform the patient. Requiring the manufacturer to directly inform the ultimate consumer/patient would accomplish two objectives. Not only would such a requirement provide an extra “layer” of protection to the patient but it would recognize the basic right of “[e]very human being of adult years and sound mind . . . to determine what shall be done with his [or her] own body” (Schoendorff v. Society of New York Hospital, 211 N.Y. 125, opinion by Justice Cardozo).