Volume 2 | Issue 1 Article 9

12-15-1974

A Prescription Warning

Carlton Lee Harpst

Case Notes

A Prescription Warning

Introduction

The majority of the medical profession practicing the diagnosis and management of illness and trauma do not really understand how specific medications function upon human physiology and more importantly with what results. Ultimately they depend upon the tests and representations of the manufacturer, whose profit motives are inherently adverse to total candor regarding the drug's suspected faults. Examples are found not only in the horrible results of Thalidomide and MER/29, but also in ASA (simple store-bought aspirin), which was sold for years without anyone being able to effectively explain how or why it achieves its panacea effect upon simple pain, fever and colds. The mystique of medical cures and the general dependence of the American Public upon "pills" coupled with the inherent biological diversity among individuals have traditionally constrained the courts from extending strict liability to personal injuries due to unavoidable proclivities of a *perfectly* manufactured prescription drug. The drug companies enjoyed this special privilege over other manufacturers because the defect is really in the user, not the product. As an alternative to strict liability, the courts, attempting to strike a balance between the therapeutic value of the drug and the deleterious side effects, have allowed plaintiffs to recover on the basis of the manufacturer's failure to provide adequate information.

A Duty to Warn[1]

The inquiry of this paper is into the nature of this duty and the discharge of its associated standard of care.

1. This paper is limited to medications which are totally without manufacturing defects such as impurities. Those interested in specific drug problems are directed to:
   a) FDA reports, which in many instances vary substantially from the standard sources of the medical profession.
   b) U.S. Department of Health, Education and Welfare, Task Force on Prescription Drugs.
   c) Armed forces Institute of Pathology, U.S.A.H., Walter Reed Hospital, Washington, D.C.

Nature of the Duty

The creation of this duty is based on the balancing and fault aspects of negligence theory. Potential side effects are weighed against potential therapeutic value, with the balance generally struck in favor of marketing drugs of proven merit. An excellent example is the Pasteur[2] rabies treatment which commonly has very serious and damaging side-effects, but is indicated because the disease invariably leads to a dreadful death. The duty to warn arises only when the manufacturer knew or in the exercise of reasonable care should have known of the danger. As the frequency and/or seriousness of these side effects increases, the duty to warn may become so pressing that it amounts to a duty to warn against any use at all.

The touchstone of all the cases which have considered this problem is found in Restatement (Second) of Torts § 402A, comment k[3]; this section is a statement of a product's recovery theory grounded in strict liability. The court's approach has been to use this duty to warn as an exception to strict liability in drug cases, rather than as a separate theory of recovery.[4] As an exception to a theory of strict liability, it would seem logical that recovery should be predicated upon showing that the defendant was capable of a slight degree of fault or, in other words, should be held to a high standard of care. This is the position taken by many courts; note the Pennsylvania court which said in *Henderson v. National Drug Co.*: ". . . public interest requires the holding of companies which make and sell drugs and medicines for the use in the human body to a high degree of responsibility. . . ."[5]

---

2. This is the traditional argument put forth by defense counsel in this type of case; therefore, only brief reference to it will be made here.

3. "*Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment for rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians or under the prescription of a physician . . . . 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. . . ."

4. E.g. Stevens v. Parke-Davis & Co., 9 Cal. 3d 51, 597 P.2d 653, 107 Cal. Rptr. 45 (1973); Love v. Wolf, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964); Sterling Drug, Inc. v. Yarrow, 408 F.2d 978 (8th Cir. 1969).

5. Henderson v. National Drug Co., 343 Pa. 601, 610, 23 A.2d 743, 748 (1942).

Discharge of the Standard

The courts have considered the drug manufacturer's conduct with respect to the duty to warn in two major areas: 1) the substantive sufficiency of the warning and 2) the mode of communication utilized. The key to both requirements is that the manufacturer must provide adequate information in both method and manner to allow the plaintiff's doctor to effectively exercise sound and *independent* medical judgment.

SUBSTANCE AND FORM

In *Carmichael v. Reitz*[6] the court, while stating the general rule, adopted Rheinold's excellent characterization of the physician's role in drug prescription.

> The doctor is intended to be an intervening party in the full sense of the word. Medical ethics as well as medical practice dictate independent judgement, unaffected by the manufacturer's control, on the part of the doctor . . . it is the prescribing doctor who in reality stands in the shoes of 'the ordinary consumer'.[7]

This court recognized that, despite years of medical training and experience which enable the doctor to adequately and effectively analyze the manufacturer's information, the physician really is in no better position with respect to a manufacturer than any ordinary consumer. The best source of drug information is the manufacturer. The most common drug reference for the practicing physician is the *Physician's Desk Reference* (P.D.R.). Since the P.D.R. is merely a reprint of the manufacturer's drug inserts (which are paid for by the manufacturer), the drug companies are in a practical sense the only source of information for the physician. Dependent upon this information and knowledge, the doctor must make a decision which could potentially involve the life of the patient. Only when the manufacturer provides the *complete* body of *established* knowledge can the doctor exercise sound and *independent* judgment vital to effective treatment and management of the patient.

The court's desire to insure the reliability of the doctor's decision based upon the manufacturer's information has led to an analysis of the content and effects of promotional campaigns and advertising associated with drug sales. The courts will consider

6. 17 Cal. App. 3d 958, 95 Cal. Rptr. 381 (1971).
7. *Id.*, at 978, 95 Cal. Rptr. at 400-01.

the adequacy of a warning in light of the amount and nature of advertising and promotion done by the manufacturer. The leading case in California is *Love v. Wolf*[8] (chloromycetin). At the time the FDA required a warning that the drug should only be given for major infections, for example meningitis, typhoid, etc., and when prolonged or intermittent use was contemplated, it should only be given in conjunction with adequate blood studies because it was suspected of being causally connected with aplastic anemia. Although the manufacturer complied with the FDA requirements, he also made the following representations via detail men and advertising literature:

> 'More than 11,000,000 patients have been treated with this important antibiotic. . . . A review of the literature points up the fact that the great majority of investigators who study this drug clinically report no evidence of untoward reactions. Side effects occur infrequently . . . and . . . are generally unusually mild for this type of therapy.'
>
> 'In no case have we seen any evidence of depression of the hemopoietic system resulting in aplastic anemia or agranulocytosis. We are now certain that chloromycetin is effective with very minimal untoward side effects.'
>
> '. . . the fact that a drug was administered prior to development of aplasia is by no means proof that the drug is the offender. At this time, there are absolutely no cases known to us in which such proof is extant.'
>
> 'Chloromycetin has been officially cleared by the FDA and the National Research Council with no restrictions on the number or the range of diseases for which Chloromycetin may be administered.'[9]

While the *Love v. Wolf* court felt that these statements may have expressed a literal truth, it is clear that the inferences to be drawn from them were far from the complete truth.[10] Although an alternate theory of recovery might have been more akin to common law fraud,[11] the court was content to uphold the plaintiff by ruling ". . . if the over-promotion can reasonably be said to have induced the doctor to disregard the warnings previously given, the warning given is thereby withdrawn or cancelled. . . ."[12] Thus, an otherwise adequate warning will be insufficient if it has been *compromised* by other material.

Mode of Communication

Most courts that have considered this question have adopted a

8. 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964).
9. *Id.*, at 398-99, 38 Cal. Rptr. at 195.
10. *Id.*,at 399, 38 Cal. Rptr. at 195. At the time the company had approximately 600-700 detail men in the field.
11. Wm. Prosser, Handbook of the Law of Torts, § 106 (4th Ed. West, 1971).
12. 226 Cal. App. 2d 378, 400, 38 Cal. Rptr. 183, 196 (1964).

rule similar to that in the case of *Sterling Drug, Inc. v. Yarrow.*[13] There are four usual methods of communication between the manufacturer and the physicians:

1) by detail men, who are specially trained field representatives engaged in selling and promoting the use of its products by personal calls in which oral presentations are made and literature and samples are delivered,
2) by listings of drugs in an anually published advertising medium known as the Physicians' Desk Reference (sic),
3) by 'product cards' which are mailed and distributed by detail men to physicians and are available at medical conventions and hospital exhibits, and
4) by special letters mailed to physicians.[14]

A finding of fact was made that while methods 2 through 4, inclusive, were used to disseminate the warning, ". . . . detail men who made regular personal calls on prescribing physicians and customers were never, in the relevant period, instructed to invite attention . . . to the reported dangers . . . (of) use of the drug by patients."[15] Although the court felt it unreasonable to require that the manufacturer convey product warnings by the most effective method, such as individual personal messenger, it did rule that:

> . . . it was not unreasonable to find that the appellant (manufacturer) should have employed all its usual means of communication, including detail men, to warn the prescribing physicians of these dangers.[16]

The reasoning of this holding is that any method which provides an effective means of selling in the manufacturer's estimation also provides an effective medium of conveying a warning. Given the potential dangers to the patient and the slight inconvenience to the manufacturer, this is hardly an onerous burden. Thus a warning of substantive sufficiency will fail to exonerate the manufacturer unless all usual or established modes of dissemination are used.

FDA STANDARDS

Although advances have been made in establishing viable case-law standards, most commentators[17] feel that the statutory scheme

13. 408 F.2d 978 (8th Cir. 1969).
14. *Id.*, at 987.
15. *Id.*, at 987.
16. *Id.*, at 992.
17. Lecture and syllabus of California Trial Lawyers Association on

has not been fully explored by plaintiff's counsel. The explanation may rest in the ease with which the manufacturers meet these legislative requirements. Since these standards are the minimum required of drug firms, California courts have readily predicated liability upon non-compliance. In fact, the holding in one California case, *Toole v. Richardson-Merrill*, seems to indicate that the appellate court is willing to utilize *any* violation as a basis for civil liability:

> The act is designed to protect the public as a whole (citation omitted) and to keep dangerous and deleterious products from reaching the uninformed consumer. We see no logical distinction between the labelling provisions of the act on one hand and the reporting provisions on the other, with respect to the class of persons to be protected or the harm to be presented.[18]

Indications are that these minimal standards may soon change. Reports of extensive promotional gifts (all-expense tours, color TV, etc.) and indiscriminate distribution of free samples—many of which are then incorrectly used—have brought Senate Sub-committee investigation to the industry. Current remedial recommendations include pharmaceutical educational standards for detail men and careful monitoring of promotional practices by the HEW. The resultant expense and inconvenience to the industry is clearly out-weighed by the benefit to the public by improving the quality of information that the physician receives by curbing "the hard sell" by some drug firms.

Conclusion

The manufacturer can avoid liability if he can satisfy the following yardstick:

> The manufacturer must utilize all *established* lines of communication between himself and the physician to appraise the latter *completely* and *uncompromisingly* of all *known* facts regarding the dangers and recommended usage such that the risks of its selection and application reflect an exercise of the doctor's *independent* medical judgment.

This yardstick is more an exception to the doctrines of strict liability in products recovery than a standard of care inherent to a negligence analysis. All balances of social policy were struck in its creation; therefore, the courts demand absolute compliance with all the key elements of this exception. Any conduct by the drug industry by whatever means, active or passive, that conceals relevant information will provide a basis for liability under this rule.

CARLTON LEE HARPST

Medical Malpractice, "Manufacturer's Liability for Drugs which Cause Personal Injury," Joseph W. Cotchett, speaker.

18. 251 Cal. App. 2d 689, 707, 60 Cal. Rptr. 398, 409 (1967).