

Strict Liability in Tort: Its Applicability to Manufacturers of Prescription Drugs

I. INTRODUCTION

It is well known that each year tens of millions of Americans receive prescriptions for pharmaceuticals.¹ It is less well known that more than a million times a year the recipients of the prescriptions suffer adverse reactions so severe that hospitalization is required.² A conservative estimate is that about ninety-one Americans die each day as the result of adverse reactions to prescription drugs.³

¹In 1971, 1,113,811,000 prescriptions, of which 559,492,000 were refills, were filled by drug stores in the United States, accounting for \$4,367,381,000 in sales. Kushner, *New Facts About The Third-Party Phenomenon*, AMERICAN DRUGGIST, Apr. 3, 1972, at 17, 60.

²Statistics on adverse drug reactions are scarce. All available statistics concern drugs in general rather than prescription drugs only. Because prescription drugs are by definition so dangerous that their use is prohibited without the approval of a physician, there is no doubt that the vast majority of adverse drug reactions are caused by prescription, rather than over-the-counter, drugs. A Food and Drug Administration physician, who requested that his name not be disclosed, estimated that adverse reactions from prescription drugs comprise ninety-five per cent of all adverse drug reactions reported to the FDA. Personal communication, Apr. 12, 1974. According to Senator Edward Kennedy, the Department of Health, Education and Welfare's National Health Services Research Center has estimated that 1.5 million hospital admissions per year, costing \$1.1 to 2.1 billion, are due to adverse drug reactions. PHARMACEUTICAL MANUFACTURERS ASS'N NEWSLETTER, Dec. 21, 1972, at 3.

See Medical Tribune, June 13, 1971, at 3, col. 1.

Because, for the reason stated *supra*, the vast majority of adverse drug reactions are caused by prescription drugs and because the FDA physician cited *supra* estimated adverse prescription drug reactions at ninety-five per cent of all adverse drug reactions reported to the FDA, it is reasonable to infer from the figure of 1.5 million hospital admissions due to adverse reactions to all drugs that more than a million hospital admissions each year are caused by reactions to prescription, rather than over-the-counter, drugs.

Of related interest is Ralph Nader's assertion that institutional care necessitated by adverse drug reactions costs Americans an estimated \$3 billion per year. Statement of Ralph Nader, *Hearings on Government Regulation of the Pharmaceutical Industry Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare*, 93d Cong., 1st & 2d Sess. ____ (1974).

³The conservative estimate of ninety-one deaths per day caused by adverse reactions to prescription drugs is based on a conservative estimate of ninety-six

Drug-induced injuries and fatalities have given rise to substantial litigation, and recently plaintiffs have begun to employ the theory of strict liability in tort. The widespread adoption of this doctrine by American jurisdictions has been acclaimed as a radical victory for consumers by many authorities, including the late Dean Prosser. As will be demonstrated, however, the theory has heretofore been applied in surprisingly few cases against prescription drug manufacturers.

Nevertheless, as a theory which has experienced frequent use only in recent years, strict liability in tort does not yet have well-settled boundaries of applicability. It remains possible that it will eventually furnish a cause of action to many drug victims who without it would be unable to state a claim. Dean Page Keeton, whose views will be discussed, has proposed a specific formula under which the applicability of the theory to prescription drug manufacturers would be substantially expanded. This article will present a proposal for still stricter liability.

In concentrating on the theory of strict liability in tort, this article will discuss the history of its development, several areas of uncertain-

deaths per day caused by adverse reactions to all drugs, including prescription and over-the-counter drugs. Because, for the reason stated *supra* note 2, the vast majority of adverse drug reactions are caused by prescription drugs and because the FDA physician cited *supra* note 2 estimated adverse prescription drug reactions at ninety-five per cent of all adverse drug reactions reported to the FDA, it is reasonable to conservatively estimate that ninety-one deaths per day (ninety-five per cent of ninety-six) are caused by adverse reactions to prescription, rather than over-the-counter, drugs.

The conservative estimate of ninety-six deaths per day caused by adverse reactions to all drugs is derived from the only comprehensive published study on the fatality rate from adverse drug reactions, Shapiro *et al.*, *Fatal Drug Reactions Among Medical Inpatients*, 216 J.A.M.A. 467 (1971). This study found twenty-two deaths in non-terminal patients in a survey of 6199 hospitalized patients, a rate of 3.5 per thousand. Applying this rate to the 30,142,000 patients annually admitted to short term hospitals in the United States (U.S. DEP'T OF COMMERCE, STATISTICAL ABSTRACT OF THE UNITED STATES, 1973 at 76 (1973)) would yield an estimate of 105,497 deaths per year. The Shapiro study, however, surveyed only patients admitted to the medical services of hospitals, as opposed to specialty services such as surgical, obstetric, or pediatric services. Because medical services patients comprise only about a third of all patients admitted to short term hospitals, the rate of 3.5 per thousand should be applied to only about a third of all admissions. Applying the rate of 3.5 per thousand to the approximately 10,047,333 annual medical services admissions yields an estimate of 35,166 deaths per year caused by adverse drug reactions, the equivalent of ninety-six per day. This is a conservative estimate because only medical services patients are included: thus all deaths of hospital patients who accounted for the other two-thirds of hospital admissions and all deaths of persons who were never admitted to hospitals are not included in the figure of ninety-six per day. The formula used in the calculation of this figure derives from the statement of Dr. Sidney M. Wolfe, *Hearings on Government Regulation of the Pharmaceutical Industry Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare*, 93d Cong., 1st & 2d Sess. — (1974). It is unclear whether some of the twenty-two deaths in the Shapiro study were caused by negligent administration of a drug rather than by a defect in the drug itself.

ty, and the possibility of broader future applicability. The law of California will be emphasized.

II. ALTERNATIVE THEORIES OF LIABILITY

While there are some notable differences, the course of the law relating to injuries from drugs has for the most part followed the course of the law relating to injuries from products in general.⁴ In particular, the same four theories — negligence, express warranty, implied warranty, and strict liability in tort — predominate; and the same single theory — strict liability in tort — has been growing in application and has been the primary focus of recent scholarly attention.⁵

Although the emphasis of this article is on strict liability in tort, it will be useful, for purposes of comparison, to review the other theories which with it dominate the law of products liability. After these theories are briefly reviewed, strict liability in tort will be considered in detail.

A. THE THEORY OF NEGLIGENCE⁶

A manufacturer has a duty to use due care in producing drugs,⁷ and breach of this duty gives rise to liability if there is proximate cause and if there is no adequate defense such as contributory negligence or assumption of the risk.⁸ The exact degree of care required has to some extent varied with jurisdictions and cases, but has often

⁴For a brief hornbook approach to products liability, see W. PROSSER, *HANDBOOK OF THE LAW OF TORTS* 641-82 (4th ed. 1971) [hereinafter cited as W. PROSSER]. The only prominent casebook in the area is P. KEETON & M. SHAPO, *PRODUCTS AND THE CONSUMER: DEFECTIVE AND DANGEROUS PRODUCTS* (1970) [hereinafter cited as P. KEETON & M. SHAPO].

⁵See especially Keeton, *Products Liability — Drugs and Cosmetics*, 25 VAND. L. REV. 131 (1972) [hereinafter cited as Keeton (Vanderbilt)]; Keeton, *Some Observations About the Strict Liability of the Maker of Prescription Drugs: The Aftermath of MER/29*, 56 CALIF. L. REV. 149 (1968) [hereinafter cited as Keeton (California)]; Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1 (1973) [hereinafter cited as Merrill].

⁶Products liability is one of the most rapidly changing areas of the law. All the leading cases are from the current century. *MacPherson v. Buick Motor Co.*, 217 N.Y. 382, 111 N.E. 1050 (1916), is the leading products liability case grounded on the theory of negligence. In it, Judge Cardozo, in perhaps his most famous opinion, held that if the nature of a product is such that it is reasonably certain to imperil life and limb when negligently made and if the manufacturer knows that it will be used by persons other than the buyer without new tests of the product, then, irrespective of privity of contract, the manufacturer is under a duty to make the product carefully.

⁷*Thomason v. Ballard & Ballard Co.*, 208 N.C. 1, 179 S.E. 30 (1935); *Hampton v. Thomasville Coca-Cola Bottling Co.*, 208 N.C. 331, 180 S.E. 584 (1935).

⁸Whether certain damages are recoverable depends in some jurisdictions on whether they are held to have been foreseeable. This is the issue which divided Judges Andrews and Cardozo in the familiar case of *Palsgraf v. Long Island R.R. Co.*, 248 N.Y. 339, 162 N.E. 99 (1928).

been determined to be "high"⁹ or "as high as practically possible."¹⁰ Some courts have held that the degree of care required depends on the harm which may arise from negligence.¹¹

A critical area of negligence theory related to drugs is the issue of warning. The manufacturer has a duty to warn of the dangers which use of its product entails,¹² even if the percentage of users who will be injured is not large.¹³ The manufacturer will be held to this obligation, however, only as to known side effects or those which should have become known through reasonable skill and foresight.¹⁴

The duty to warn requires notification, through labels, advertising, or otherwise, both of how the product should be used¹⁵ and of side effects which may accompany its use. The manufacturer must promptly warn of dangers attending use of the drug.¹⁶

In *Love v. Wolf*,¹⁷ a case involving the deadly antibiotic Chloromycetin,¹⁸ however, the California District Court of Appeal held in 1964 that overpromotion of the drug cancelled the effect of a warning about its dangerous side effects. In *Stevens v. Parke, Davis & Co.*,

⁹*Crigger v. Coca-Cola Bottling Co.*, 132 Tenn. 545, 179 S.W. 155 (1915); *Henderson v. National Drug Co.*, 343 Pa. 601, 23 A.2d 743 (1942).

¹⁰*Peters v. Johnson*, 50 W. Va. 644, 41 S.E. 190 (1902); *Corona Coal Co. v. Sexton*, 21 Ala. App. 51, 105 So. 716 (1925), *cert. denied* 213 Ala. 554, 105 So. 718 (1925).

¹¹*Henderson v. National Drug Co.*, 343 Pa. 601, 23 A.2d 743 (1942).

¹²*Halloran v. Parke, Davis & Co.*, 245 App. Div. 727, 280 N.Y.S. 58 (1935); *Carmen v. Eli Lilly & Co.*, 109 Ind. App. 76, 32 N.E.2d 720 (1941); *Martin v. Bengue, Inc.*, 25 N.J. 359, 136 A.2d 626 (1957).

¹³*Love v. Wolf*, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964).

¹⁴*Christofferson v. Kaiser Foundation Hospitals*, 15 Cal. App. 3d 75, 92 Cal. Rptr. 825 (1971).

¹⁵*Bish v. Employers Liability Assurance Corp.*, 236 F.2d 62 (5th Cir. 1956).

¹⁶*Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143 (Mo. 1967).

¹⁷226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964).

¹⁸Chloromycetin, an antibiotic generically known as chloramphenicol, has been marketed by Parke, Davis & Co. since 1949. By 1960 injuries from it had resulted in twenty-five damage suits. In its first eleven years on the market doctors prescribed it for forty million people, and in 1963 it accounted for \$59 million in sales, 31 per cent of the Parke, Davis total. It was such a popular and trusted drug that it was prescribed not only for severe infections but also for acne, infected mosquito bite, cold, sty, and warts. Chloromycetin was first associated with blood discrasias, namely aplastic anemia, in 1952. In 1962 the California State Department of Public Health reported, after a twenty-two month study, that positive and statistically significant correlations had been found between rates of chloramphenicol sales and rates of aplastic anemia deaths. The Department conservatively estimated the aplastic anemia fatality rate at one in 60,000 Chloromycetin users. When this statistic is combined with the figure of forty million users, it indicates that at least 666 people using the drug in the years 1949-60 died due to Chloromycetin. There were a number of deaths in patients who received Chloromycetin for symptoms such as sore throat, cold, and a sore gum following a tooth extraction. A California urologist, whose own daughter had died from Chloromycetin at the age of five, testified before a State Legislature committee, "I know of no more torturous death, especially in children." Merrill, *supra* note 5, at 46-49; M. MINTZ, BY PRESCRIPTION ONLY 7-14 (rev. ed. 1967) [hereinafter cited as M. MINTZ]; *Love v. Wolf*, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964).

a 1973 case, the California Supreme Court reached the same result.¹⁹

The manufacturer must also keep abreast of scientific developments relating to the drug and must notify physicians of new side effects which are discovered.²⁰ In all but very exceptional cases, however, courts have held that manufacturers need warn only physicians and need not directly warn consumers.²¹

Privity of contract was originally required before a duty of care obtained in products liability cases.²² The rule, however, has lost vitality regarding products in general, and drugs have usually been excepted from the privity requirement as "inherently dangerous" or "imminently dangerous" products,²³ or as products intended for human consumption.²⁴

As will be discussed, the requirements for recovery under the theories of negligence and strict liability in tort, as they are presently applied by the courts, are substantially similar.

B. THE THEORY OF EXPRESS WARRANTY²⁵

Express warranty, while providing grounds for liability in many other products liability cases, including ones involving over-the-

¹⁹9 Cal. 3d 51, 107 Cal. Rptr. 45, 507 P.2d 653 (1973).

²⁰Schenbeck v. Sterling Drug, Inc., 423 F.2d 919 (8th Cir. 1970).

²¹Magee v. Wyeth Laboratories, Inc., 214 Cal. App. 2d 340, 29 Cal. Rptr. 322 (1963); Love v. Wolf, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964); Carmichael v. Reitz, 17 Cal. App. 3d 958, 95 Cal. Rptr. 381 (1971). Because pharmacists virtually always remove warning documents from drugs before sale to the consumer and virtually never warn orally of side effects, if the consumer is not warned orally by the physician he is not warned at all. Because physicians often do not warn patients of possible side effects, courts and legislatures should require that consumers be directly warned, in simple language, of at least all common, serious side effects. The warning should be made by means of printed statements provided by manufacturers and inserted by pharmacists with each prescription drug sold.

²²The foundation of this rule is in dictum of the English case of *Winterbottom v. Wright*, 10 Mees & W. 109, 152 Eng. Rep. 402 (Ex. 1842). Among the American cases in accord are *Dundee Mortgage & Trust Investment Co. v. Hughes*, 20 F. 39 (C.C.D. Ore. 1884); *Cliff v. California Spray Chemical Co.*, 83 Cal. App. 424, 257 P. 99 (1927).

²³The landmark "inherently dangerous" case, *Thomas v. Winchester*, 6 N.Y. 397 (1852), was a drug case. See *MacPherson v. Buick Motor Co.*, 217 N.Y. 382, 111 N.E. 1050 (1916).

²⁴*Ketterer v. Armour & Co.*, 200 F. 322 (S.D.N.Y. 1912); *Buckley v. Gray*, 110 Cal. 339, 42 P. 900 (1895).

²⁵See RESTATEMENT (SECOND) OF TORTS § 402B (1965); UNIFORM COMMERCIAL CODE §§ 2-316, 2-317, 2-318 (1972). § 2-318 has not been adopted in California. The leading express warranty products liability case is *Baxter v. Ford Motor Co.*, 169 Wash. 456, 12 P.2d 409 (1932). In that case a manufacturer was held liable to a person with whom there was no privity of contract for the breach of a printed representation of the degree of safety of the manufacturer's product, where the facts represented were susceptible of knowledge and where the plaintiff relied on the representation to his injury.

counter drugs, has little present relevance to prescription drug cases, since in the usual case no express warranty is made to consumers. Manufacturers communicate information to physicians, not patients.²⁶ Express warranty will become a fertile area, however, if courts or legislatures begin to require that prescription drug manufacturers must ordinarily communicate information directly to consumers. Still, a few cases have already been litigated using a theory of express warranty.²⁷

C. THE THEORY OF IMPLIED WARRANTY²⁸

The drug manufacturer is held to implied warranties that its product is fit for the purpose for which it is sold²⁹ and that the drug is merchantable.³⁰ If either of these warranties is breached, the manufacturer is liable for proximately-caused damage.

Whether a manufacturer is released from the obligations of an implied warranty by means of an express warranty denying an implied warranty or by a disclaimer of implied warranties depends on the individual case.³¹

Uniform Commercial Code section 2-318 (1972), in the form adopted by at least thirty states, asserts that a seller's implied and express warranties extend only to his buyer, people in the buyer's

²⁶Advertising of prescription drugs is confined almost solely to medical journals and advertising mailed or personally distributed to doctors. The theory of express warranty of course has greater applicability to over-the-counter, rather than prescription, drugs, since the packaging of over-the-counter drugs often includes assurances of safety.

²⁷*Basko v. Sterling Drug, Inc.*, 416 F.2d 417 (2d Cir. 1969); *Jorgensen v. Meade Johnson Laboratories, Inc.*, 336 F. Supp. 961 (D.C. Okla. 1972), *vacated*, 483 F.2d 237 (10th Cir. 1973); *Whittington v. Eli Lilly & Co.*, 333 F. Supp. 98 (D.C. W. Va. 1971).

²⁸See UNIFORM COMMERCIAL CODE §§ 2-314, 2-315, 2-316, 2-317, 2-318 (1972). § 2-318 has not been adopted in California. *Henningsen v. Bloomfield Motors, Inc.*, 32 N.J. 358, 161 A.2d 69 (1960), is the leading implied warranty products liability case. There it was held that when a producer puts a new product into the stream of trade and promotes its purchase by the public, an implied warranty of suitability for use as such a product accompanies it to the ultimate consumer.

²⁹UNIFORM COMMERCIAL CODE § 2-315 (1972); *Gottsdanker v. Cutter Laboratories*, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960); *Magee v. Wyeth Laboratories*, 214 Cal. App. 2d 340, 29 Cal. Rptr. 322 (1963).

³⁰UNIFORM COMMERCIAL CODE § 2-314 (1972); *Gottsdanker v. Cutter Laboratories*, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960). "Merchantable" is defined by BLACK'S LAW DICTIONARY at 1139 (rev. 4th ed. 1966) as "salable and fit for the market; sound and undamaged; such as is generally sold in the market; vendable in the market," *citing* *Nettles v. Lichtman*, 228 Ala. 52, 152 So. 450, 453 (1934). See also the definition in UNIFORM COMMERCIAL CODE § 2-314 (1972).

³¹See *Gottsdanker v. Cutter Laboratories*, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960); *Henningsen v. Bloomfield Motors*, 32 N.J. 358, 161 A.2d 69 (1960), which held a disclaimer of an implied warranty of merchantability void as against public policy.

family or household, and guests in the buyer's home. This provision denies drug victims a warranty cause of action against manufacturers, who sell to other sellers rather than directly to consumers. Twelve states, however, have adopted forms of section 2-318 which extend warranties to all people who may reasonably be expected to use or be affected by the product.³² In many jurisdictions, lack of privity also bars certain injured parties from implied and express warranty actions under the common law.³³ A number of jurisdictions generally requiring privity, however, have repudiated the requirement in food and drug cases. More specifically, privity has been held not to be required in cases involving drugs "intended for intimate bodily use,"³⁴ in a case based on the manufacturer's breach of an implied warranty of fitness for human consumption,³⁵ and in a case involving an oral polio vaccine which was dispensed to all comers without individual balancing of benefits and risks by a physician.³⁶

*Gottsdanker v. Cutter Laboratories*³⁷ is the leading California case in implied warranty for impure drugs. In this action, two children contracted poliomyelitis shortly after being inoculated with Salk

³²The UNIFORM COMMERCIAL CODE § 2-318 (1972) provides three alternate privity requirements. Alternative A, adopted by thirty states, the District of Columbia, and the Virgin Islands, states:

A seller's warranty whether express or implied extends to any natural person who is in the family or household of his buyer or who is a guest in his home if it is reasonable to expect that such person may use, consume or be affected by the goods and who is injured in person by breach of the warranty. A seller may not exclude or limit the operation of this section.

Four states have adopted "an expansive hybrid" of alternative A.

Alternative B, adopted by four states, asserts:

A seller's warranty whether express or implied extends to any natural person who may reasonably be expected to use, consume or be affected by the goods and who is injured in person by breach of the warranty. A seller may not exclude or limit the operation of this section.

Alternative C, adopted by eight states, provides:

A seller's warranty whether express or implied extends to any person who may reasonably be expected to use, consume or be affected by the goods and who is injured by breach of the warranty. A seller may not exclude or limit the operation of this section with respect to injury to the person of an individual to whom the warranty extends. As amended 1966.

The count of jurisdictions derives from J. WHITE & R. SUMMERS, HANDBOOK OF THE LAW UNDER THE UNIFORM COMMERCIAL CODE at 331 (1972). § 2-318 has not been adopted in any form by California.

³³*Cadillac Motor Car Co. v. Johnson*, 221 F. 801 (2d Cir. 1915) (express warranty); *Lewis v. Terry*, 111 Cal. 39, 43 P. 398 (1896) (express warranty); *J. Aron & Co. v. Sills*, 211 App. Div. 21, 206 N.Y.S. 695, *aff'd* 240 N.Y. 588, 148 N.E. 717 (1924) (implied warranty).

³⁴*Cudmore v. Richardson-Merrell, Inc.*, 398 S.W.2d 640, 644 (Tex. Civ. App. 1965), *cert. denied*, 385 U.S. 1003 (1967).

³⁵*Oresman v. G.D. Searle & Co.*, 321 F. Supp. 449 (D.R.I. 1971).

³⁶*Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968).

³⁷182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960).

polio vaccine manufactured by defendant Cutter Laboratories. There was substantial evidence that the vaccine, contrary to its proper formulation, contained live poliomyelitis virus, and that the vaccine caused the disease in both children.³⁸ The trial court absolved Cutter of negligence but held it liable on theories of fitness for the intended purpose and implied warranty of merchantability.³⁹

The appellate court rejected the requirement of privity of contract and upheld the application of the doctrine of implied warranties, using food cases as precedents for both holdings.⁴⁰ The court stated that while implied warranties are enforceable only against a seller, the consumer need not be a purchaser under a contract of sale. The initial sale from the manufacturer to the distributor or retailer was held sufficient to invoke the implied warranties.⁴¹

III. THE THEORY OF STRICT LIABILITY IN TORT

Strict liability in tort superficially appears to be the consumer's ultimate weapon in litigation against prescription drug manufacturers. The doctrine is devoid of many of the pitfalls of negligence theory, where it is often difficult to prove want of due care. In addition, it removes from the consumer's neck the warranty theory albatrosses of privity, disclaimer, reliance,⁴² and notice.⁴³

A. HISTORICAL DEVELOPMENT

The history of strict liability in tort in the United States and the history of the theory in California are largely coextensive. In 1944, then-Justice Traynor of the California Supreme Court, in a concurring opinion in *Escola v. Coca-Cola Bottling Co.*,⁴⁴ foreshadowed the Court's later adoption of the doctrine of strict liability in tort. He stated:

[I]t should now be recognized that a manufacturer incurs an absolute liability when an article that he has placed on the market, knowing that it is to be used without inspection, proves to have a defect that causes injury to human beings. . . . Even if there is no negligence . . . public policy demands that responsibility be fixed

³⁸ 182 Cal. App. 2d at 605, 6 Cal. Rptr. at 322 (1960).

³⁹ 182 Cal. App. 2d at 605, 6 Cal. Rptr. at 322 (1960).

⁴⁰ 182 Cal. App. 2d at 606-07, 6 Cal. Rptr. at 322-23 (1960).

⁴¹ 182 Cal. App. 2d at 608-09, 6 Cal. Rptr. at 324 (1960).

⁴² A plaintiff can recover on an express warranty theory only if he learns of the warranty and his injury results from his reliance on it. *Dobbins v. Pacific Coast Coal Co.*, 25 Wash. 2d 190, 170 P.2d 642 (1946); *Randall v. Goodrich-Gamble Co.*, 238 Minn. 10, 54 N.W.2d 769 (1952).

⁴³ UNIFORM COMMERCIAL CODE § 2-607 (1972) precludes a buyer from recovery on a warranty theory if he does not notify the seller within a reasonable time after he knows or should know of the breach. Nevertheless, there are frequent exceptions to this rule. See W. PROSSER, *supra* note 4, at 655-56.

⁴⁴ 24 Cal. 2d 453, 150 P.2d 436 (1944).

wherever it will most effectively reduce the hazard to life and health inherent in defective products that reach the market.⁴⁵

It was Justice Traynor again who nineteen years later wrote the California Court's majority opinion in *Greenman v. Yuba Power Products, Inc.*,⁴⁶ the leading American case in strict liability in tort. Traynor declared: "A manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being."⁴⁷ Traynor stated that the purpose of strict liability is to impose the cost of injuries on manufacturers who market the product rather than on "injured persons who are powerless to protect themselves."⁴⁸

Section 402A of the Restatement (Second) of Torts was tentatively adopted by the American Law Institute in its original form in 1961 and was adopted in its present form in May, 1964, sixteen months after *Greenman*.⁴⁹ The section, published in 1965, states:

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property if
 - (a) the seller is engaged in the business of selling such a product and
 - (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
- (2) The rule stated in subsection (1) applies although
 - (a) the seller has exercised all possible care in the preparation and sale of his product, and
 - (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

⁴⁵24 Cal. 2d at 461-62, 150 P.2d at 440 (1944).

⁴⁶59 Cal. 2d 57, 27 Cal. Rptr. 697, 377 P.2d 897 (1963).

⁴⁷59 Cal. 2d at 62, 27 Cal. Rptr. at 700, 377 P.2d at 900 (1963). Traynor continued:

Recognized first in the case of unwholesome food products, such liability has now been extended to a great variety of other products that create as great or other hazards if defective.

... Although in these cases strict liability has usually been based on a theory of an express or implied warranty running from the manufacturer to the plaintiff the abandonment of the requirement of a contract between them, the recognition that the liability is not assumed by agreement but imposed by law ... and the refusal to permit the manufacturer to define the scope of its own responsibility for defective products ... make clear that the liability is not one governed by the law of contract warranties but by the law of strict liability in tort.

(59 Cal. 2d at 62-63, 27 Cal. Rptr. at 701-72, 377 P.2d at 901-02 (1963).)

⁴⁸59 Cal. 2d at 63, 27 Cal. Rptr. at 701, 377 P.2d at 901 (1963).

⁴⁹See 38TH ANNUAL MEETING, THE AMERICAN LAW INSTITUTE, PROCEEDINGS, 1961 at 50-107 (1962); 39TH ANNUAL MEETING, THE AMERICAN LAW INSTITUTE, PROCEEDINGS, 1962 at 227-44 (1963); 41ST ANNUAL MEETING, THE AMERICAN LAW INSTITUTE, PROCEEDINGS, 1964 at 349-75 (1965).

Regarding this section, Dean Prosser, the Reporter for the Restatement, said, "With the exception of the change in the law with respect of prenatal injuries, this is the most radical and spectacular development in tort law during this century."⁵⁰

B. STRICT LIABILITY IN TORT COMPARED TO NEGLIGENCE

Despite the proclamation that the adoption of section 402A was a revolutionary event, Prosser and other notable commentators were soon to write that, with respect to manufacturers, the section did not provide nearly the radical modification that the plaintiffs' bar had hoped.⁵¹ In particular, it readily became apparent that the official comments to the Restatement reduced the vaunted new section's applicability to virtually the same cases where negligence theory would also result in liability.

Since the vast majority of drugs which have generated litigation have not been impure, the "defect" most likely to be attributed to a drug will be found in the warning issued about it. That is, if the manufacturer fails to adequately warn of the dangers of using the drug, the drug is deemed defective. This is apparent from comment *h*, which states that where a defendant has "reason to anticipate that danger may result from a particular use" of its product and fails to provide adequate warning of the hazard "a product sold without such warning is defective."

If the manufacturer adequately warned of the drug's side effects, the drug, according to comments *j* and *k*, would not be "unreasonably dangerous," and therefore would not subject the manufacturer to liability under section 402A. Relatedly, comment *j* includes the element of foreseeability, requiring a warning only when the manufacturer "has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge," of the presence in the drug of "an ingredient to which a substantial number of the population are allergic." The requirement of "unreasonably dangerous" and the limitation to *foreseeable* users ring of negligence. (Emphasis added.)

In addition, comment *j* leaves the consumer without a remedy when he does not receive the warning which the manufacturer issues: "Where warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it

⁵⁰Quoted in P. KEETON & M. SHAPO, *supra* note 4, at 759.

⁵¹The dramatic impact of strict liability in tort was against middlemen and retailers, rather than manufacturers, since it made all sellers, from the manufacturer to the retailer, liable to the consumer. Against sellers other than the manufacturer, there is generally no cause of action under the theory of negligence. See W. PROSSER, *supra* note 4, at 659 nn. 72-73.

unreasonably dangerous.”⁵²

Comment *k* further limits the liability of manufacturers, stating that strict liability should not apply in cases where the product is “unavoidably unsafe.” Such a product, the comment says, “if properly prepared and accompanied by proper directions and warning, is not defective nor is it *unreasonably* dangerous.” (Emphasis in original.) The comment gives as examples (1) drugs and drug therapy such as the Pasteur rabies treatment, whose use is fully justified notwithstanding a high risk of harm, because the disease which it prevents is almost invariably fatal; and (2) new or experimental drugs as to which there can be no assurance of safety or perhaps even of purity of ingredients, where such experience as there is justifies the marketing and use of the drug notwithstanding a known risk.

Many commentators have noted the similarities between negligence and strict liability in tort. Professor Richard Merrill has stated that the theories are “functionally interchangeable in most drug injury cases.”⁵³ Dean Prosser wrote that when the issue in a products case is whether reasonable warning was given “the liability is not distinguishable from negligence.”⁵⁴ Dean Page Keeton, an Advisor to the Reporter for the Restatement, has said:

[W]hile strict liability obviates the necessity for convincing the jury as to the existence of negligence, it does not alter in any substantial way the plaintiff's proof problems, and the satisfaction of plaintiff's proof requirements for strict liability will generally result also in a finding of negligence In a products case the primary task of the plaintiff's lawyer is establishing that the damaging event which occurred in the course of the use of the product was the result of a defect not due to some other cause such as misuse.⁵⁵

C. AREAS OF CONFUSION AND UNCERTAINTY

The Restatement and its comments have given rise to substantial confusion and uncertainty. Among the subjects which have caused the greatest concern have been the meaning of “defective,” problems relating to warning, liability for injuries to allergic consumers, and liability for the unknowable risk.

1. THE MEANING OF “DEFECTIVE” UNDER SECTION 402A

Section 402A describes circumstances under which one who sells a product “in a defective condition unreasonably dangerous to the user

⁵²But see *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968) for an exception to this rule.

⁵³Merrill, *supra* note 5, at 31.

⁵⁴W. PROSSER & J. WADE, *CASES AND MATERIALS ON TORTS* 727 n. 2 (5th ed. 1971).

⁵⁵Keeton, *Manufacturer's Liability: The Meaning of "Defect" in the Manufacture and Design of Products*, 20 SYR. L. REV. 559, 563 (1969) [hereinafter cited as Keeton (Syracuse)].

or consumer or to his property" will be liable. This phrasing does not make clear whether "defective" and "unreasonably dangerous" are separate concepts or whether the latter defines the former.

Keeton believes that "unreasonably dangerous" serves only to define "defective."⁵⁶ He also believes that under the Restatement comments, particularly *i*,⁵⁷ "unreasonably dangerous" means "*dangerous to an extent* beyond that which would be reasonably contemplated by intended (and reasonably foreseeable) purchasers."⁵⁸ (Emphasis in original.) But this, he says, is a "nebulous test," because the ordinary consumer does not have expectations regarding the safety of many aspects of "complexly made products" which are purchased.⁵⁹

Contrary to Keeton, however, some courts, including the Ninth Circuit in the 1968 polio vaccine case of *Davis v. Wyeth Laboratories, Inc.*,⁶⁰ have construed "defective condition unreasonably dangerous" as stating two separate requirements for recovery.⁶¹

A recent development has mooted the question of the significance of the phrase "unreasonably dangerous" in California. In *Cronin v. J.B.E. Olson Corp.*,⁶² which involved a delivery truck whose bread racks dislodged and injured the driver, the California Supreme Court in 1972 deleted the requirement of "unreasonably dangerous" from the plaintiff's burden of proof. The court held that although the manufacturer is not an insurer against all injuries resulting from the use of its products, the plaintiff meets his burden by proving that there was a defect in manufacture or design and that the defect proximately caused the injuries.⁶³ The court stated:

The result of [the "unreasonably dangerous" requirement] . . . has not been merely to prevent the seller from becoming an insurer of his products with respect to all harm generated by their use. Rather, it has burdened the injured plaintiff with proof of an element which rings in negligence.⁶⁴

⁵⁶Keeton, *Products Liability and the Meaning of Defect*, 5 ST. MARY'S L.J. 30, 32 (1971) [hereinafter cited as Keeton (St. Mary's)].

⁵⁷Comment *i* states that for an article to be "unreasonably dangerous" it must be "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics."

⁵⁸Keeton (St. Mary's), *supra* note 56, at 37.

⁵⁹*Id.* As examples, Keeton gives "the risk of fire from the way gasoline tanks are designed and installed in cars or the magnitude of the risks of cars overturning and the like." The argument seems equally applicable to drugs.

⁶⁰399 F.2d 121, 128 (9th Cir. 1968).

⁶¹*Downey v. Moore's Time-Saving Equip., Inc.*, 432 F.2d 1088, 1091 (7th Cir. 1970); *La Gorga v. Kroger Co.*, 275 F. Supp. 373, 379 (W.D. Pa. 1967); *Greeno v. Clark Equip. Co.*, 237 F. Supp. 427, 429 (N.D. Ind. 1965); *Suvada v. White Motor Co.*, 32 Ill. 2d 612, 621, 210 N.E.2d 182, 187 (1965); *Wright v. Massey-Harris, Inc.*, 68 Ill. App. 2d 70, 79, 215 N.E. 2d 465, 470 (1966); *Ford Motor Co. v. Lonon*, 217 Tenn. 400, 421-22, 398 S.W.2d 240, 249-50 (1966).

⁶²8 Cal. 3d 121, 104 Cal. Rptr. 433, 501 P.2d 1153 (1972).

⁶³8 Cal. 3d at 133-34, 104 Cal. Rptr. at 442, 501 P.2d at 1162 (1972).

⁶⁴8 Cal. 3d at 132, 104 Cal. Rptr. at 441-42, 501 P.2d at 1161-62 (1972). The

To add to the confusion, there are at least three ways in which a product can be defective: (1) it may be defectively designed: a pure but unjustifiably dangerous drug would be an example; (2) it may be defectively produced: for instance, a drug which is impure because it contains ingredients not in its formula; (3) it may not be the subject of accurate or sufficiently well distributed warnings or directions.⁶⁵

Keeton has proposed that, with respect to drugs which have been approved and not later withdrawn, approval of a product by the Food and Drug Administration should preclude recovery on the theory of strict liability in tort in the absence of defective manufacture or impurities in the drug if appropriate warnings were given.⁶⁶ This test derives from *Lewis v. Baker*, a 1966 Oregon case brought under an implied warranty theory.⁶⁷

To allow the FDA to determine whether drug manufacturers are liable would, however, be unwise. It often has been charged that the FDA favors industry rather than the public interest. The shuttling back and forth of top personnel between FDA posts and executive suites at drug firms has done little to alleviate consumer insecurity.⁶⁸

2. WARNING

Because most drugs are pure, they are likely to be held "defective" only if there is inadequate warning regarding their side effects. The issue of warning therefore is the most important of the several areas of uncertainty.

Three comments to the Restatement are relevant here. Comment *h* states that where a defendant has "reason to anticipate that danger may result from a particular use" of its product and fails to provide adequate warning of the hazard, "a product sold without such warning is in a *defective condition*." (Emphasis supplied.) As stated, com-

"unreasonably dangerous" requirement was also eliminated in *Glass v. Ford Motor Co.*, 123 N.J. Super. 599, 304 A.2d 562 (L.Div. 1973). See Note, *Products Liability: New Jersey Court Eliminates "Unreasonably Dangerous" Requirement in Strict Tort Liability*, 5 SETON HALL L. REV. 152 (1973).

⁶⁵Keeton, *Products Liability*, 50 F.R.D. 338 (1970) [hereinafter cited as Keeton (F.R.D.)]; RESTATEMENT (SECOND) OF TORTS § 402A, comment *h* (1965).

⁶⁶Keeton (California), *supra* note 5, at 158-59.

⁶⁷243 Ore. 317, 413 P.2d 400, 404 (1966).

⁶⁸A study made at the request of then-Congressman Melvin Laird showed that of 813 scientific, medical, and technical employees who left the FDA in 1959-63, at least eighty-three took jobs with FDA-regulated companies. Dr. Joseph Sandusk, Jr., who as Director of the FDA's Bureau of Medicine had taken many actions and made many statements involving Chloromycetin which "were considered perilous to children but advantageous to Parke, Davis and Company," its manufacturer, joined Parke, Davis as a vice-president one year after leaving the FDA. (M. MINTZ & J. COHEN, *AMERICA, INC.* 13, 247 (1971)). Until his appointment as the present FDA General Counsel, Peter Hutt, while a member of a private law firm, served as General Counsel of the Pharmaceutical Manufacturers Association. (M. Green, forthcoming Ralph Nader study group report on Washington law firms.) See J. TURNER, *THE CHEMICAL FEAST* 202-16 (1970).

ment *j* requires a warning when the manufacturer knows or should know that the drug "contains an ingredient to which a substantial number of the population are allergic," and comment *k* asserts that an unavoidably unsafe product is not defective "if properly prepared and accompanied by proper directions and warning."

The question of warning presents several sub-issues. In particular, there is conflict and uncertainty as to what constitutes inadequacy of disclosure and, to a lesser extent, as to whether it is necessary for a causal relationship to exist between inadequacy of disclosure and the alleged injury.⁶⁹

Three cases have produced holdings on the issue of warning which are particularly favorable for future plaintiffs. The California District Court of Appeal, in *Toole v. Richardson-Merrell Inc.*⁷⁰ which involved the infamous drug MER/29,⁷¹ held in 1967 that a warning of all known dangers must be made if a drug is to fall under comment *k*:

There is another reason why the principles expressed in comment (k) . . . do not aid appellant here. There was evidence that its drug was not properly labeled in that it did not give adequate warning of its inherent dangers. Appellant had knowledge, before permission to market its new drug was granted, that use of the drug in test animals caused blood changes and eye opacities. When permission to market the drug was first given, nothing was said in the labeling information about the possibility of eye opacities from its use. . . . There was an abundance of evidence before the jury from which it could reasonably infer that in marketing MER/29 proper warning had not been given of the known consequences of its use.⁷²

The Eighth Circuit, in *Sterling Drug, Inc. v. Yarrow*,⁷³ which involved the notorious drug Aralen,⁷⁴ placed a weighty responsibility

⁶⁹Keeton (Syracuse), *supra* note 55, at 575.

⁷⁰251 Cal. App. 2d 689, 60 Cal. Rptr. 398 (1967).

⁷¹Richardson-Merrell, Inc. marketed MER/29, an anticholesterol drug whose generic name is triparinol, in 1960-62. Prior to the Food and Drug Administration's approval of marketing, the manufacturer failed to disclose to the FDA that its own research indicated that the drug caused severe side effects. During marketing Richardson-Merrell issued only belated and inadequate warnings despite substantial additional data connecting MER/29 with major side effects in humans. When the company finally took the drug off the market, more than 5000 of the drug's 418,000 users had suffered serious side effects. Injuries often came in a combination which became known as the "classical triad": cataracts, usually operable, in both eyes; loss or thinning of hair; and severe skin reactions. About 1500 persons sued Richardson-Merrell as a result of MER/29 injuries. In addition, Richardson-Merrell, the William S. Merrell Co. (a division), and three individuals were the subject of unprecedented criminal convictions. Merrill, *supra* note 5, at 40-43; M. MINTZ, *supra* note 18, at 230-37, 241-47b; Toole v. Richardson-Merrell Inc., 251 Cal. App. 2d 689, 60 Cal. Rptr. 398 (1967); Rheingold, *The MER/29 Story—An Instance of Successful Mass Disaster Litigation*, 56 CALIF. L. REV. 116 (1968).

⁷²251 Cal. App. 2d 689, 709-10, 60 Cal. Rptr. 398, 413 (1967). See also Love v. Wolf, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964).

⁷³408 F.2d 978 (8th Cir. 1969).

⁷⁴Aralen, generically called chlorquine phosphate, is produced by Sterling Drug,

on a manufacturer when, in 1969, it affirmed a district court holding that under the specific circumstances of the case there was a failure to warn because a warning to physicians was not communicated by the company's detail men.⁷⁵ The Circuit Court added that the manufacturer "should have employed all its usual means of communication" to warn physicians.⁷⁶

In *Davis v. Wyeth Laboratories, Inc.*,⁷⁷ a 1968 Ninth Circuit case, plaintiff took Wyeth's Type III Sabin oral polio vaccine at a mass immunization clinic in West Yellowstone, Montana. At the time he was thirty-nine years old and in good health. Within thirty days he suffered paralysis and other symptoms of polio, and he remained paralyzed at the time of trial.⁷⁸

Prior to the organization of the clinic, the Surgeon General of the United States had issued reports recommending "that the use of Type III vaccine in mass campaigns be limited to pre-school and school age children."⁷⁹ Although the Wyeth salesman who made sales to the clinic and assisted in its organization knew of at least one of the Surgeon General's reports, no warning was issued to participants in the clinic, and assurances were made that the vaccine was safe for all. The pharmacist who administered the clinic did not read the package insert, which contained excerpts from one of the Surgeon General's reports, and no effort was made by the salesman to inform him of the risk.⁸⁰

The court said that while the vaccine qualified for inclusion under comment *k* as an unavoidably unsafe product, the manufacturer of such a product is strictly liable unless the sale is accompanied by proper directions and warnings.⁸¹ The court stated that in cases of

Inc. It was first approved for marketing in 1946 as an antimalarial agent and, beginning in 1957, was approved for cases of lupus erythematosus and rheumatoid arthritis as well. Some time prior to July 1959 it was also approved for treatment of extraintestinal amebiasis. After research in 1959-63 indicated that Aralen caused retinal lesions and irreversible corneal changes in humans, Sterling issued new warnings, but the warnings greatly underrepresented the harmfulness of the drug. Substantial litigation arose from Aralen-induced injuries, which included permanent total blindness. Merrill, *supra* note 5, at 43-46; Basko v. Sterling Drug, Inc., 416 F.2d 417 (2d Cir. 1969); Sterling Drug, Inc. v. Yarrow, 408 F.2d 978 (8th Cir. 1969); Sterling Drug, Inc. v. Cornish, 370 F.2d 82 (8th Cir. 1966); Oppenheim v. Sterling Drug, Inc., 7 Ohio App. 2d 103, 219 N.E.2d 54 (1964); Christofferson v. Kaiser Foundation Hospitals, 15 Cal. App. 3d 75, 92 Cal. Rptr. 825 (1971); Cochran v. Brooke, 243 Ore. 89, 409 P.2d 904 (1966).

⁷⁵408 F.2d 978, 991-92 (8th Cir. 1969). A detail man is a salesman who contacts doctors on behalf of a drug manufacturer. He promotes drug sales and usually has some background in chemistry.

⁷⁶*Id.* at 992.

⁷⁷399 F.2d 121 (9th Cir. 1968).

⁷⁸*Id.* at 122.

⁷⁹*Id.* at 124.

⁸⁰*Id.* at 125.

⁸¹*Id.* at 128-29.

drugs whose risk applies in some degree to all, or to a significant portion, of those who take the drug, "its danger is reasonable only if the balance is struck in favor of its use."⁸² Where the risk is not otherwise known to the consumer, the court stated, "the drug can be properly marketed only in such fashion as to permit the striking of the balance; that is, by full disclosure of the existence and extent of the risk involved."⁸³

The court held that although warning to the prescribing physician ordinarily suffices, warning to the consumer himself is required in cases where the drug is dispensed to all comers without an individualized balancing by a physician of the risks involved. The court gave as examples situations where the drug is distributed at a clinic or is sold over the counter.⁸⁴

Because physicians often do not warn patients of possible side effects, courts and legislatures should require that consumers be directly warned, in simple language, of at least all common, serious side effects of all prescription drugs. The warning should be made by means of printed statements provided by manufacturers and inserted by pharmacists with each prescription drug sold.

3. ALLERGIC CONSUMERS

Almost all drugs result in substantial harm to a certain percentage of consumers.⁸⁵ Injuries are incurred by hypersensitive and allergic users despite proper use and adequate instructions and warnings.⁸⁶

Comment *j* to section 402A states that a seller is required to warn about a product containing "an ingredient to which a substantial number of the population are allergic." Consequently, it appears that a manufacturer would not be held strictly liable in tort for injuries to allergic persons who make up a small part of the population, even if no warning was given. This point, however, is not yet settled.⁸⁷

4. LIABILITY FOR THE UNKNOWABLE RISK

In cases where a product is found to be defective due to a risk of harm that was not scientifically knowable or discoverable at the time of sale, the law is unsettled as to whether liability will attach.⁸⁸ The

⁸²*Id.* at 129.

⁸³*Id.*

⁸⁴*Id.* at 130-31.

⁸⁵Keeton (Syracuse), *supra* note 55, at 572.

⁸⁶*Id.*

⁸⁷See also two negligence cases: *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966); *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143 (Mo. 1967). See also Adler, *Strict Products Liability: The Implied Warranty of Safety, and Negligence with Hindsight, as Tests of Defect*, 2 HOFSTRA L. REV. ____ (1974).

⁸⁸Keeton (Syracuse), *supra* note 55, at 569.

problem commonly arises in drug cases, since the full extent of the dangers of a drug often cannot be ascertained until after a period of use by humans.

The California District Court of Appeal in *Christofferson v. Kaiser Foundation Hospitals*, a 1971 case, held that strict liability in tort does not apply to the unforeseeable side effects of a drug. The court reviewed section 402A and decided that it "properly limits the duty to warn to situations in which the manufacturer 'has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge of . . . the danger.'"⁸⁹

D. AFFIRMATIVE DEFENSES

By definition a patient could not be contributorily negligent in using a drug as prescribed by a physician unless, perhaps, the patient had reason to believe the doctor was incompetent. The user could, however, be held to have misused the drug if he did not follow the physician's directions for quantity and frequency of dosage, or could be held to have assumed the risk if he voluntarily used a drug he knew to be defective. If the consumer misused the drug, he would also have difficulty meeting the requirement of strict liability in tort that the injury be caused by a defective product.

Regarding contributory negligence and assumption of the risk, comment *n* to section 402A of the Restatement asserts:

Contributory negligence of the plaintiff is not a defense when such negligence consists merely in a failure to discover the defect in the product, or to guard against the possibility of its existence. On the other hand the form of contributory negligence which consists in voluntarily and unreasonably proceeding to encounter a known danger, and commonly passes under the name of assumption of the risk, is a defense under this Section as in other cases of strict liability.

IV. CONCLUSIONS

A. JURISDICTIONS ADOPTING THE DOCTRINE

A 1974 tally showed that strict liability in tort had been expressly adopted by twenty-three of the fifty states and by the admiralty courts. The states included California, Illinois, New Jersey, Ohio, Pennsylvania, and Texas. The acceptance of the doctrine by ten other states, including Michigan and New York, could be inferred from court decisions. The District of Columbia and nine of the remaining seventeen states reached strict liability through a warranty,

⁸⁹15 Cal. App. 3d 75, 79, 92 Cal. Rptr. 825, 827 (1971). The Texas Court of Civil Appeals in *Cudmore v. Richardson-Merrell, Inc.*, 398 S.W.2d 640 (Tex. Civ. App. 1965), *cert. denied*, 385 U.S. 1003 (1967), which was decided on an implied warranty theory but cited § 402A, reached the same result.

rather than tort, theory. Puerto Rico and eight states, including Massachusetts, had not adopted strict liability on either theory.⁹⁰

B. CASES CITING SECTION 402A

One unfamiliar with the problems of applying strict liability in tort to injuries from prescription drugs would assume that since thirty-three states have accepted the doctrine it must by now have been applied in countless prescription drug injury cases. Such, however, has not been the case.

From its adoption in 1964 until the end of 1971, section 402A was cited in only nineteen reported decisions involving injuries from prescription drugs.⁹¹ Apparently only one additional such case was decided from January 1972 through late 1973.⁹² Strict liability in tort will have major impact on drug injury litigation only if a form of the doctrine which is stricter than section 402A is adopted.

C. TOWARD STRICTER LIABILITY IN TORT

1. DEAN KEETON'S PROPOSAL

Dean Keeton has proposed a substantially stricter form of strict liability in tort than has thus far been applied by the courts. To avoid the problems of defect, warning, and unknowable risk as well as the general confusion generated by the Restatement and its comments, Keeton wrote in 1969:

. . . I am inclined to the view that all risks that result in bad products

⁹⁰CCH PROD. LIAB. REP. ¶ 4060 (updated Mar. 6, 1974).

⁹¹*Oresman v. G.D. Searle & Co.*, 321 F. Supp. 449, 453, 456, 457 (D.R.I. 1971); *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 979, 987-88, 95 Cal. Rptr. 381, 393, 399 (1971); *Christofferson v. Kaiser Foundation Hospitals*, 15 Cal. App. 3d 75, 79, 92 Cal. Rptr. 825, 827 (1971); *Nolan v. Dillon*, 261 Md. 516, 276 A.2d 36, 40 (1971); *Incollingo v. Ewing*, 444 Pa. 263, 299; 282 A.2d 206, 219 (1971); *Abbott Laboratories v. Gravis*, 470 S.W.2d 639, 642 (Tex. 1971); *Gravis v. Abbott Laboratories*, 462 S.W.2d 410, 413, 414 (Tex. Civ. App. 1970), *rev'd in part and aff'd in part*, 470 S.W.2d 639 (Tex. 1971); *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 419, 425-28 (2d Cir. 1969); *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978, 992, 993, 995 (8th Cir. 1969); *Hornung v. Richardson-Merrell, Inc.* [*sic*], 317 F. Supp. 183, 184 (D. Mont. 1970); *Grinnell v. Charles Pfizer & Co.*, 274 Cal. App. 2d 424, 436, 79 Cal. Rptr. 369, 375 (1969); *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 126-29 (9th Cir. 1968); *Tinnerholm v. Parke Davis & Co.*, 286 F. Supp. 432, 444 (S.D.N.Y. 1968), *modified*, 411 F.2d 48 (2d Cir. 1969); *Yarrow v. Sterling Drug, Inc.*, 263 F. Supp. 159, 161 (D.S.D. 1967), *aff'd*, 408 F.2d 978 (8th Cir. 1969); *Toole v. Richardson-Merrell, Inc.*, 251 Cal. App. 2d 689, 708, 709, 60 Cal. Rptr. 398, 412, 413 (1967); *Stromsodt v. Parke-Davis & Co.*, 257 F. Supp. 991, 997 (D.N.D. 1966); *Cochran v. Brooke*, 243 Ore. 89, 409 P.2d 904, 906 (1966); *Lewis v. Baker*, 243 Ore. 317, 413 P.2d 400, 402, 403 (1966); *Cudmore v. Richardson-Merrell, Inc.*, 398 S.W.2d 640, 645 (Tex. Civ. App. 1965), *cert. denied*, 385 U.S. 1003 (1967).

⁹²*Singer v. Sterling Drug, Inc.*, 461 F.2d 288, 290-91 (7th Cir. 1972), *cert. denied* 409 U.S. 878 (1972).

— products that expose users to so much harm as to outweigh the benefits therefrom — should be allocated to the maker.⁹³

Keeton would extend liability to allergic users,⁹⁴ but has at times hesitated to propose the imposition of liability for scientifically unknowable dangers.⁹⁵ In the statement *supra*, however, he implied that liability should be imposed for such dangers, and in 1968, in enunciating a test similar to the one *supra*, stated that no distinction should be made between knowable and unknowable risks. On the contrary, he said, courts should determine liability “only by weighing the risks as found to exist at the time of trial and not the risks as they appeared at any point in the past.”⁹⁶

As a reason for this view, he has written that the fact-finding task in determining whether a risk was knowable is often impossible, especially when drugs are involved. The outcome, he has said, “depends too much on the competency and skill of advocates and investigators.”⁹⁷

2. A PROPOSAL FOR YET STRICTER LIABILITY

Like section 402A, Keeton's proposal does not provide the protection to consumers that one might think. If prescription drug litigation devolves to Keeton's harm against benefit test, many injured users will remain without remedy. This is because many consumers are injured by prescription drugs whose benefits outweigh their harms. Protection should be extended to these consumers.

Manufacturers should be liable for all substantial injuries resulting from the legal use of prescription drugs, where the injury was not due to the ingestion of a dosage substantially dissimilar from that recommended by the manufacturer. A substantial injury might be defined as one requiring medical attention or causing the loss of a day's work. An exception should be made only for drugs falling under a narrowed form of comment *k*'s exception for unavoidably dangerous products. That is, there should be liability unless the drug was very useful and, at the time of prescription, (1) was, according to information available at the time of trial, incapable of being made safer (such as certain anti-cancer drugs and certain digitalis-like drugs used in the treatment of congestive heart failure) or (2) was a new or experimental drug about which there could not yet be an assurance of safety, where available information justified marketing of the

⁹³Keeton (Syracuse), *supra* note 55, at 571. See also Keeton (St. Mary's), *supra* note 56, at 37-38; Keeton (Vanderbilt), *supra* note 5, at 144.

⁹⁴Keeton (Vanderbilt), *supra* note 5, at 136.

⁹⁵Keeton (Syracuse), *supra* note 55, at 571; Keeton (St. Mary's), *supra* note 56, at 39; Keeton (F.R.D.), *supra* note 65, at 347.

⁹⁶Keeton (California), *supra* note 5, at 158-59.

⁹⁷Keeton (Syracuse), *supra* note 55, at 570.

drug. In the case of either type of drug, there should be liability if, according to information available at the time of trial, a similarly effective drug available at the time of prescription would have harmed plaintiff less.

Even if the drug falls within this narrow category of unavoidably dangerous drugs, the only user who should be precluded from recovery should be one who voluntarily took the drug knowing what benefits he was likely to gain and knowing that he would certainly or almost certainly suffer the very side effects which he did incur. That is, users who knew only that there was a risk, rather than a certainty or near-certainty, of harmful side effects, should not be precluded from recovery. Consequently, since very few drugs have certain or near-certain side effects, very few users would be precluded from recovery for injuries.

There are many policy reasons supporting this proposal for stricter liability. Foremost is the reason underlying the adoption by the courts of section 402A:⁹⁸ manufacturers have the ability to distribute, as a cost of doing business, the financial burden of drug injuries.⁹⁹

In addition, because the proposal precludes recovery only where plaintiff knew what harm he would encounter, the adoption of the proposal would encourage direct warning to consumers, as was required under the atypical facts of *Wyeth*.¹⁰⁰ Direct warning would reduce the incidence of injury.

It is also likely that the proposed test would result in greater care by manufacturers. They would be burdened with more lawsuits (though perhaps shorter), more damage payments (though distributed), and more adverse publicity, all of which would tend to encourage greater care.

Additional policy reasons favoring the proposal are that, as between the injured user and the manufacturer, the manufacturer is better able to keep injuries from occurring and is better able to bear the substantial losses which are often occasioned by drug-induced injuries. The manufacturer of drugs is particularly able to sustain losses because drug companies possess massive sales, net income, and assets,¹⁰¹ and because lack of competition in the drug industry makes

⁹⁸ Keeton (F.R.D.), *supra* note 65, at 339.

⁹⁹ For a discussion of the economic complexity of loss distribution, see Morris, *Enterprise Liability and the Actuarial Process — The Insignificance of Foresight*, 70 YALE L.J. 554, especially 583-87, 593-99 (1961).

¹⁰⁰ Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. 1968).

¹⁰¹ See *infra* notes 105-08 and accompanying text. The strong financial condition of drug companies is due in large measure to lack of competition, which is caused particularly by state prohibition of substitution, by pharmacists, of generic for brand name drugs when brand name drugs are prescribed, and by the seventeen year patent provided by 35 U.S.C. §154 (1970). See Statement of

loss distribution particularly feasible.¹⁰²

There are, of course, arguments against the imposition of liability for virtually all injuries from prescription drugs. In particular, there is the possibility that the development of new drugs would be discouraged¹⁰³ and the fact that distribution of increased damage payments would result in higher drug prices.

The development of some new drugs might indeed be discouraged. But, as stated, there would be no liability for injuries from highly useful, unavoidably unsafe drugs for which there were no safer substitutes, when the injured consumer voluntarily encountered a near-certainty or certainty of harm. Thus development of these critical drugs would not be discouraged. As for other drugs, there possibly would be some reduction in development. But in view of the excellent financial condition of drug companies¹⁰⁴ and the availability of loss distribution as a cost of doing business, it seems unlikely that the prospect of increased damage payments would frighten manufacturers to such an extent that they would radically decrease the development of new drugs.

Distribution of losses by definition causes price increases. It seems reasonable, however, to make an addition to the consumer's drug costs, as a built-in premium insuring him against the burden which he would otherwise bear in the event of a drug injury.

Implicit in much of the reasoning behind the proposal for liability for virtually all drug injuries is the fact that drug companies are in excellent financial condition. If this were not true, the companies might have difficulty bearing increased damage payments, even with distribution of losses, and might be unable to risk damage claims by continuing active development of new drugs. But if there is one industry in the United States which is financially strong, it is the drug industry.

Eleven companies whose principal product is prescription drugs¹⁰⁵

Ralph Nader, *Hearings on Government Regulation of the Pharmaceutical Industry Before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare*, 93d Cong., 1st & 2d Sess. — (1974). See also *Hearings on Present Status of Competition in the Pharmaceutical Industry Before the Subcomm. on Monopoly of the Senate Comm. on Small Business*, 91st Cong., 1st Sess. (1969). The seventeen year patent makes the ability to distribute losses particularly great, because the holder of an unexpired patent can raise prices on his patented drug without fear that the consumer might purchase an identical drug made by another manufacturer. Even in the absence of an unexpired patent, the prohibition of generic substitution protects the price-raising manufacturer's brand name drug against competition from identical drugs produced by other companies.

¹⁰² See note 101 *supra*.

¹⁰³ See Willis, *Product Liability without Fault: Some Problems and Proposals*, 15 FOOD DRUG COSM. L.J. 648, 660-63 (1960).

¹⁰⁴ See *infra* notes 105-12 and accompanying text.

¹⁰⁵ That the principal product of each of the companies is prescription drugs is indicated by the listing of products for each company in STANDARD & POOR'S REGISTER OF CORPORATIONS, DIRECTORS AND EXECUTIVES 1974 (1974).

rank among the top five hundred industrial corporations in sales in the United States. These range from number 92, the Warner-Lambert Co., whose 1972 sales were \$1,487,504,000 and whose Parke, Davis & Co. subsidiary manufactures Chloromycetin; to the maker of Aralen, Sterling Drug, Inc., which with sales of \$720,840,000 ranks 191st; to the producer of MER/29, Richardson-Merrell, Inc., number 285 with sales of \$446,478,000; to number 422, C.D. Searle & Co., which had 1972 sales of \$271,878,000.¹⁰⁶

But sales tell only part of the story. Every one of the eleven prescription drug companies in the top five hundred ranks higher in net income than in sales, from Merck & Co. at number 36 with net income of \$147,556,000 to Richardson-Merrell at number 174 with \$36,740,000.¹⁰⁷ Prescription drug companies also rate high in assets.¹⁰⁸

The hefty statistics of individual drug companies add up to extremely impressive figures for the industry as a whole. Of twenty-eight industries ranked by *Fortune* magazine in return on stockholders' equity, the pharmaceuticals industry ranks second at 15.3 per cent, just behind soaps and cosmetics.¹⁰⁹ The average for all industries is 10.3 per cent.¹¹⁰

Among twenty-eight industries ranked in return on sales, the pharmaceuticals industry is again in second place, with 9.1 per cent, this time trailing only the mining industry.¹¹¹ The average of all industries in return on sales is only 4.1 per cent.¹¹²

These statistics show that if ever there were an industry which could easily withstand the impact of liability for virtually all injuries caused by its products, it is the drug industry. Courts and legislatures should consider this and other policy factors when determining just how strict the liability of manufacturers should be for injuries suffered by consumers of prescription drugs.

Craig H. Kubey

¹⁰⁶ FORTUNE, May 1973, at 222-41.

¹⁰⁷ *Id.*

¹⁰⁸ *Id.* Pfizer, Inc. is in 94th place with assets of \$1,267,409,000, and G.D. Searle & Co., which ranks lowest in this category among drug firms in the top five hundred, still counts \$313,824,000 in assets to place 304th.

¹⁰⁹ *Id.* at 244. G.D. Searle & Co. and Merck & Co. place eighth and ninth, respectively, among all of the top five hundred industrial corporations, returning 24.7 and 24.3 per cent, respectively, on stockholders' equity.

¹¹⁰ *Id.*

¹¹¹ *Id.* G.D. Searle & Co., Eli Lilly & Co., and Merck & Co. place fourth, fifth, and sixth, respectively, among all of the top five hundred industrial corporations, each returning 15.4 per cent on sales.

¹¹² *Id.*