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Products Liability—Drugs aud Cosmetics

*Page Keeton**

I. INTRODUCTION

Much has been written by judges and scholars about abrogation of both the requirement of privity for recovery on warranty theories and the prerequisite of a finding of negligence for recovery on a tort theory against manufacturers and other sellers of all kinds of products.[1] As a consequence of this abrogation, the courts in some states have completed the change-over from a fault to a strict liability theory of recovery for harm resulting from unintended and latent dangerous conditions of products.[2] Moreover, removal of initial restrictions limiting strict liability to users and consumers is proceeding apace, and the logical extension of strict liability to bystanders has already been accomplished in several jurisdictions.[3] Confusion and uncertainty remain, however, as to what actual impact these assaults on fault have had with reference to the legal remedies for physical harm caused by inherent risks attendant upon the use of products, such as drugs and cosmetics, that are constructed as they were intended to be.

To date, it has been erroneously assumed that theories of strict liability have materially altered a maker's or seller's liability for physical harm resulting from a dangerous condition characteristic of the product causing injury as well as all others of like kind. If there is to be any kind of liability without fault, based on the capacity of an enterprise to bear

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1. *E.g.*, James, *The Untoward Effects of Cigarettes and Drugs; Some Reflections on Enterprise Liability*, 54 CALIF. L. REV. 1550 (1966); Keeton, *Products Liability—Liability Without Fault and the Requirement of a Defect*, 41 TEXAS L. REV. 855 (1963); Noel, *Products Defective Because of Inadequate Directions Or Warnings*, 23 SW. L.J. 256 (1969); Prosser, *The Fall of the Citadel (Strict Liability to the Consumer)*, 50 MINN. L. REV. 791 (1966); Wade, *Strict Tort Liability of Manufacturers*, 19 Sw. L.J. 5 (1965).

2. *See* Putman v. Erie City Mfg. Co., 338 F.2d 911 (5th Cir. 1964); Gottsdanker v. Cutter Laboratories, 6 Cal. Rptr. 320 (Ct. App. 1960); Henningsen v. Bloomfield Motors, Inc., 32 N.J. 358, 161 A.2d 69 (1960); Goldberg v. Kollsman Instrument Corp., 12 N.Y.2d 432, 191 N.E.2d 81, 240 N.Y.S.2d 592 (1963).

3. *See* Caruth v. Mariani, 11 Ariz. App. 188, 463 P.2d 83 (1970); Elmore v. American Motors Corp., 70 Cal. 2d 578, 451 P.2d 84, 75 Cal. Rptr. 652 (1969); Darryl v. Ford Motor Co., 440 S.W.2d 630 (Tex. 1969); Noel, *Products Liability: Bystanders, Contributory Fault and Unusual Uses*, in *Proceedings of the Judicial Conference of the Sixth Judicial Circuit of the United States*, 50 F.R.D. 321 (1970).

and shift losses, it clearly should apply to a manufacturing enterprise's failure to achieve intended results. On the other hand, recognition of the socially desirable principle that the risk of miscarriages in the manufacturing process should be allocated to the manufacturer on the assumption that losses will be shifted to consumers by charging higher prices for the products, does not logically require the abandonment of fault as a basis for shifting losses resulting from hazards inherent in the product as designed. Great practical difficulties are involved in the description and allocation of these risks to the manufacturer, and there is wide disagreement about the theoretical justification and economic consequences of so doing. These analytical problems are particularly apparent in the case of drugs and cosmetics because in the process of their manufacture, distribution, and use, the resulting benefits to the many[4] have come at a high cost to the few.[5] In order to assess the possible applicability of strict liability for harmful effects caused by products made in the manner intended, three principal categories are suggested as a convenient format for discussion: (1) products with side effects that are apparent at the time of sale; (2) beneficial products whose harmful side effects are preliminarily unknowable; and (3) products whose harmful side effects outweigh their beneficial properties.

Drugs and other products that pose a known or knowable hazard to some at the time of sale constitute the first category. Assuming reasonable care is exercised in the marketing of the product, including the giving of warnings and instructions, are there situations involving this type of product when the manufacturer should be subject to liability without proof of negligence? If not, and if negligence in the manner of marketing the product is a prerequisite to recovery, should the same defenses be available to the defendant as when a claimant seeks recovery on the basis of a breach of the duty of ordinary care, or should only those defenses that may be used by a manufacturer when the basis for recovery is strict tort liability be permitted?

4. "Barely a generation ago, a doctor's little black bag contained only a small number of effective drugs . . . . But after the discovery of the first sulfa drug in the Thirties, a doctor's medical kit became a treasury of new drugs that helped to heal, cure and to save lives. With this discovery, the world entered the age of chemotherapy—the treatment of disease with chemical agents." National Observer, May 3, 1965, at 19, col. 1.

5. Whitmore, *Allergies and Other Reactions Due to Drugs and Cosmetics*, 19 Sw. L.J. 76 (1965).

In the second category are drugs or other products that, after a period of use, cause some users to have an adverse reaction which was scientifically unknowable at the time of sale or even at the time of injury; nevertheless, it appears that marketing can be conducted in such a way as to justify its continued use. When the risk is discovered, potential users normally would be given both notice of the risk and instructions about how to avoid serious injury. Before the manufacturer discovers the harmful side effects, however, some persons may be seriously injured by the drug as a result of lack of notice. A drug called Aralen has been productive of litigation in this category.[6]

The third category would include a drug or other product that, after a protracted period of use, proves to be more harmful in its side effects than the benefits to be gained from its use will justify. Within the scope of this category are products that either the judiciary or legislature has found to be defective and, therefore, unmarketable. The drug MER/29 and the vaccine Quadrigen are products that have produced litigation in this area.[7] Many similarly dangerous products are withdrawn from the market, either voluntarily or under coercion of some administrative agency, before a final determination of their defective nature is made. Prior to their withdrawal, however, some persons have been tragically and permanently disabled. Some birth control pills, for example, recently have been withdrawn from the market and claims involving their debilitating effects are now being processed.[8] When a drug proves to be bad, negligence in its development and sale may be easily provable. In other situations, however, this is not an easy task due to the enormous discovery burdens of proving negligence. Yet, in any case arising in this category, the issue must be faced of whether the manufacturer should be held liable for injuries caused by a product before the existence of a risk is established as a scientifically knowable fact.

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6. Basko v. Sterling Drug. Inc., 416 F.2d 417 (2d Cir. 1969); Sterling Drug, Inc. v. Yarrow, 408 F.2d 978 (8th Cir. 1969); Cochran v. Brooke, 243 Ore. 89, 409 P.2d 904 (1966).

7. For a discussion of MER/29 see Rheingold, *The MER/29 Story—An Instance of Successful Mass Disaster Litigation*, 56 CALIF. L. REV. 116 (1968); Keeton, *Some Observations About the Strict Liability of the Maker of Prescription Drugs: The Aftermath of MER/29*, 56 CALIF. L. REV. 149 (1968). *See also* Roginsky v. Richardson-Merrell, Inc., 378 F.2d 832 (2d Cir. 1967); Blum v. Richardson-Merrell, Inc., 268 F. Supp. 906 (D. Md. 1965); Bennett v. Richardson-Merrell, Inc., 231 F. Supp. 150 (E.D. Ill. 1964); Toole v. Richardson-Merrell, Inc., 251 Cal. App. 2d 689, 60 Cal. Rptr. 398 (1967); McLeod v. W. S. Merrell Co., 174 So. 2d 736 (Fla. 1965); Lewis v. Baker, 243 Ore. 317, 413 P.2d 400 (1966); Cudmore v. Richardson-Merrell, Inc., 398 S.W.2d 640 (Tex. Civ. App. 1965). For a discussion of Quadrigen see Parke, Davis & Co. v. Stromsodt, 411 F.2d 1390 (8th Cir. 1969); Tinnerholm v. Parke, Davis & Co., 411 F.2d 48 (2d Cir. 1969).

8. Two claims involving oral contraceptives are reported to have been settled, one in the amount of $85,000 and another for $215,000. 14 PERSONAL INJURY NEWSLETTER 286, 287 (1971).

II. LIABILITY FOR KNOWN OR KNOWABLE RISKS

It can be confidently said at the outset that no jurisdiction has imposed liability on a manufacturer simply because his product caused harm when it was used as intended. The mere fact that when marketing the product the manufacturer knew, or should have known, that some persons would suffer an idiosyncratic, allergic, or other adverse reaction is an insufficient basis for recovery. In *Davis v. Wyeth Laboratories, Inc.*,[9] for example, it was contended on behalf of the plaintiff, who had contracted polio after receiving a dose of Sabin oral polio vaccine, that the manufacturer should be regarded as guaranteeing to each and every user that the drug was fit and safe for his individual use, rather than merely that it was reasonably fit and safe for public consumption. This contention, had it been accepted, would have made a manufacturer liable to anyone victimized in the course of proper and reasonable use of his product. The court in *Davis*, however, held that it was unwilling to make such a far-reaching change in the law. On the other hand, several dissenting judges on the Fifth Circuit Court of Appeals, in a case involving lung cancer caused by cigarette smoking, were willing to adopt that rule for products with an unknown risk.[10] Their view was that once the jury found both that the deceased used the product as intended and that death resulted from lung cancer which developed as a consequence, no further issue remained to be decided before damages could be assessed.

While it is clear that a manufacturer is not an insurer against harm that may result from even known or knowable risks, it is often asserted and assumed that recovery is sometimes obtainable on a strict liability theory as well as the traditional negligence theory.[11] If this is true, it must be because it is thought that even a nonnegligent manufacturer should be held liable under certain circumstances for harm resulting to a user, either notwithstanding the user's awareness of the risk or because the user, for some reason, was unaware of the risk.

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9. 399 F.2d 121 (9th Cir. 1968).

10. Green v. American Tobacco Co., 409 F.2d 1166, 1168 (5th Cir. 1969) (Brown, Coleman, and Godbold, J.J. dissenting). Judge Brown, in his dissenting opinion, said, "I reject the idea that the enlightened Supreme Court of Florida will tolerate a commercial system that sells with impunity ostensibly innocuous products, but which in fact have lethal consequences." *Id.* at 1170. In the course of its tortuous litigation, this case produced 3 other appellate opinions reported as follows: 391 F.2d 97 (5th Cir. 1968); 325 F.2d 673 (5th Cir. 1963); 304 F.2d 70 (5th Cir. 1962).

11. *See* Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. 1969); Crotty v. Shartenberg's-New Haven, Inc., 147 Conn. 460, 162 A.2d 513 (1960); Bianchi v. Denholm & McKay Co., 302 Mass. 469, 19 N.E.2d 697 (1939); RESTATEMENT (SECOND) OF TORTS § 402A, comment *j* at 354 (1965); Noel, *Products Defective Because of Inadequate Directions or Warnings*, 23 SW L.J. 256, 267 (1969); Traynor, *The Ways and Meanings of Defective Products and Strict Liability*, 32 TENN. L. REV. 363, 373 (1965).

A. The Knowledgeable User

There is much support for the general proposition that the consumer's ignorance constitutes the basis for imposing liability on the manufacturer. The consumer has a right to know or be informed about a product's dangerous characteristics against which he must be protected. Yet, unless the manufacturer fails, especially in the provision of safety features, to conform to the normal and reasonable expectations of those for whose use the product is intended,[12] it cannot be held liable on either a negligence or strict liability theory. Moreover, as a matter of public policy, it can be reasonably argued that economic efficiency in the satisfaction of consumer demands would be best promoted by allocating losses for injuries resulting from the use of products to the consumer, so long as he is adequately informed about the risks involved and the incidence of harm from these risks.[13] Under this rationale a consumer would have no right, as against the manufacturer, to be secure from harm caused by dangerous products except the right to be informed.[14] If this theory were adopted, safety legislation that requires the elimination of an open and obvious danger and that interferes with voluntary market arrangements would necessarily be suspect.

No one would deny that the user's knowledge of the risks involved in the use of a product is relevant to the issue of the manufacturer's liability. The question, however, is whether it should in all circumstances be conclusive. The utility of a product can be outweighed by the magnitude of the danger related to its use even when utmost care is exercised by all concerned. Thus, a drug or cosmetic might justifiably be regarded as a bad product by a jury, or by those who have legislative powers in

12. Schemel v. General Motors Corp., 384 F.2d 802 (7th Cir. 1967) (car designed so it could be driven at a speed of 115 miles per hour is not unreasonably dangerous since the danger is neither latent nor concealed); Bollmeier v. Ford Motor Co., 265 N.E.2d 212 (Ill. App. 1970) (although the definitions of the term "defect" in the context of products liability law use varying language, they all rest upon the common premise that those products are defective which are dangerous because they fail to perform in the manner reasonably to be expected); Murphy v. Cory Pump & Supply Co., 47 Ill. App. 2d 382, 197 N.E.2d 849 (1964) (no guard in front of rotary lawnmower blade, but court concluded that no one was misled by it). The RESTATEMENT (SECOND) OF TORTS § 402A, comment *i* at 352 (1965) provides in part that in order to find an article 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."

13. *See* Calabresi, *Transaction Costs, Resource Allocation and Liability Rules—A Comment*, 11 J. LAW & ECON. 67 (1968); Coase, *The Problem of Social Cost*, 3 J. LAW & ECON. 1 (1960).

14. For further comments on this issue see Keeton, *Product Liability—Inadequacy of Information*, 48 TEXAS L. REV. 398, 399 (1970).

the matter, even though its dangers are obvious or have been brought to the consumer's attention.

Although there seems to be very little authority that would support recovery by a consumer-user who was made aware, not only of the risk itself, but also of the best means known for avoiding it; I would argue that the law remains unsettled. The obvious nature of a particular danger in a mechanical product, for example, does not necessarily preclude a finding that it is either unfit for its intended purpose or unreasonably dangerous, nor does it prevent a finding of negligence on the part of the manufacturer.[15] Therefore, it is submitted that a user's awareness of the risk involved should not preclude his recovery if, notwithstanding his awareness of the risk, a fact-finder can reasonably conclude that the product should not have been marketed. This does not mean that negligence could not serve as the basis for recovery, but it does mean that assumed risk should not necessarily be a defense and that a doctor's knowledge of the risks involved in the use of a prescription drug ought not to preclude recovery.[16]

It is often assumed that a product is neither unfit nor unreasonably dangerous if the normal person would not have any adverse reaction to it.[17] This assumption has been rejected by some courts in cosmetic cases holding that an allergic victim can recover on proof that he is a member of an appreciable class of persons who are sensitive to some ingredient in the product,[18] provided this fact was scientifically verifiable at the time

15. Wright v. Massey-Harris, Inc., 68 Ill. App. 2d 70, 215 N.E.2d 465 (1966) (self-propelled corn-picker regarded as unreasonably dangerous even though it was clearly no more dangerous than it appeared to be); Palmer v. Massey-Ferguson, Inc., 476 P.2d 713, 719 (Wash. Ct. App. 1970): "[A] rule which excludes the manufacturer from liability if the defect in the design of his product is patent but applies the duty if such a defect is latent is somewhat anomalous . . . . The law, we think ought to discourage misdesign rather than encouraging it in its obvious form."

16. This is contrary to the position taken in the RESTATEMENT (SECOND) OF TORTS § 402A, comment *n* at 356 (1965), which provides: "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 risk, is a defense under this section as in other cases of strict liability."

17. Scientific Supply Co. v. Zelinger, 139 Colo. 568, 341 P.2d 897 (1959); Jacquot v. Wm. Filene's Sons Co., 337 Mass. 312, 149 N.E.2d 635 (1958); Zampino v. Colgate-Palmolive Co., 10 Misc. 2d 686, 173 N.Y.S.2d 117 (Sup. Ct. 1958), *rev'd*, 8 App. Div. 2d 304, 187 N.Y.S.2d 25 (1959); Barrett v. Kresge Co., 144 Pa. Super. 516, 19 A.2d 502 (1941). In *Jacquot* the court said, "For a plaintiff to recover for breach of an implied warranty of fitness of a garment, a cosmetic, or comparable product [there must be proof] that the article was unfit to be worn or used by a normal person." 337 Mass. at 315, 149 N.E. 2d at 638.

18. Gober v. Revlon, Inc., 317 F.2d 47 (4th Cir. 1963) (nail polish); Reynolds v. Sun Ray Drug Co., 135 N.J.L. 475, 52 A.2d 666 (Ct. Err. & App. 1947) (lipstick); Esborg v. Bailey Drug Co., 61 Wash. 2d 347, 378 P.2d 298 (1963) (hair tint). *See generally* Noel, *supra* note 11, at 295; Dickerson, *Products Liability: How Good Does a Product Have To Be?*, 42 IND. L.J. 301, 330 (1967).

of sale. Both the assumption that only a user who suffers a normal reaction can recover and the requirement that an allergic user be a member of an appreciable class are unsound. The typical consumer never expects to be in the sensitive group and, therefore, can be expected to take a chance.[19] Moreover, if other products would serve the same purpose and cause fewer or less serious adverse reactions, the mere fact that neither the "normal" person nor an appreciable class of users would suffer an adverse reaction should not prevent either a finding impugning the product or a finding of negligence against the maker. This is especially true when the adverse reaction is disastrous[20] since a reasonable person could well conclude that the harm caused by the product outweighed its utility. Furthermore, if there is any appreciable risk of serious harm to some persons, whether or not the reactions are designated as allergic or idiosyncratic, it would be feasible to allocate these losses to the manufacturer.

B. The Uninformed User

One who is injured by either a prescription drug or an over-the-counter drug or cosmetic may, for one of two reasons, have been unaware at the time of use of the risk involved or the means of avoiding harm. The maker may have made no attempt to communicate his knowledge of the risk, or, notwithstanding his efforts to inform, the user may have never actually become aware of it. Thus, claimants have often asserted the following as separate grounds of recovery: (1) A product made according to the intended design was, nevertheless, "unfit" or "unreasonably dangerous"; and (2) even if the product itself was not defective, adequate information was never received by the consumer about its inherent risks. In the vast majority of these cases, however, the recovery, if any, was obtained on a theory of negligence in failing either to give any warning or to take adequate measures to convey the necessary information.[21]

Assuming that a risk, known or knowable on the part of the maker, is one that no reasonable person would want to be subjected to without

19. Keeton, *supra* note 6.

20. *But see* Cochran v. Brooke, 243 Ore. 89, 409 P.2d 904 (1966).

21. Parke, Davis & Co. v. Stromsodt, 411F.2d 1390 (8th Cir. 1969); Tinnerholm v. Parke, Davis & Co., 411 F.2d 48 (2d Cir. 1969); Sterling Drug, Inc. v. Yarrow, 408 F.2d 978 (8th Cir. 1969); Rumsey v. Freeway Manor Minimax, 423 S.W.2d 387 (Tex. Civ. App. 1968). For a discussion of the subject see Dillard & Hart, *Product Liability: Directions for Use and the Duty to Warn*, 41 VA. L. REV. 145 (1955); Noel, *Manufacturer's Negligence of Design or Directions for Use of a Product*, 71 YALE L.J. 816 (1962); Noel, *supra* note 11.

sufficient information to avoid it if he chooses, should the maker be held strictly liable for causing a victim to be subjected to this risk or should his liability be based on whether he implements reasonable safeguards? Imposition of strict liability on the maker, without regard to the precautions of intermediate sellers, doctors, or the victim himself, would be a far cry from holding a manufacturer responsible for miscarriages in the manufacturing process. Perhaps no liability should be imposed on a manufacturer for miscarriages in the communication process unless he is negligent. If this position is taken, one could argue that the negligence rules of proximate cause and contributory negligence also would be applicable to a products liability case. On the other hand, the basic issue in a products liability case ought to be whether the manufacturer constructed, designed, or marketed the product in a manner that results in an unreasonable risk of harm to those who might be injured in the course of its use. Under this view, contributory negligence should either be a defense in all of these situations or in none of them, the position apparently taken in the *Restatement (Second) of Torts*.[22] Dean Prosser has said that when a products liability case involves the question of reasonable warning, the liability is not distinguishable from that which would be found in an ordinary negligence case.[23] It is distinguishable from negligence liability, however, if the defense of contributory negligence is not regarded as a bar to recovery.

In *Davis v. Wyeth Laboratories, Inc.*,[24] the court, with one judge dissenting, applied a kind of strict liability. The plaintiff had ingested Type III Sabin oral polio vaccine at a mass immunization project. At the time he was 39 years of age. No effort was made by either the manufacturer or those managing the project to provide any warning about the risk of contracting polio from the vaccine. Since the need for polio immunization diminishes with advancing age and because there is a small potential risk, especially to adults, of contracting polio from Sabin oral vaccine, the desirability of using this vaccine to immunize a person 39 years old is questionable. According to the court, the situation necessitated a "true choice judgment, medical or personal," because the "risk of contracting the disease without immunization was about as

22. RESTATEMENT (SECOND) OF TORTS § 402A, comment *j* at 353 (1965).

23. "In occasional cases, such as the principal one [Davis v. Wyeth Laboratories, Inc.,] 399 F.2d 121 (9th Cir. 1968) the liability has been put on the basis of implied warranty, or strict liability in tort, on the ground that a product sold without warning is unsafe or 'defective'. But since the question is one of reasonable warning, the liability is not distinguishable from negligence." W. PROSSER & J. WADE, CASES AND MATERIALS ON TORTS 727 n.2 (5th ed. 1971).

24. 399 F.2d 121 (9th Cir. 1968).

great (or small) as [plaintiff's] risk of contracting it from the vaccine."[25] Therefore, even in the absence of a finding of negligence, the court held that the manufacturer was liable to the plaintiff because he received no warning of the material risks involved in taking the vaccine or of the dubious value of the protection thereby provided.

There is not very much difference between requiring disclosure, or an attempt at disclosure, of a risk that would be regarded as material both by a reasonable man in giving or withholding consent to a medical procedure and by a doctor in deciding whether to prescribe a drug for a particular patient, and requiring the same warning only when a reasonable man would give it. The *Wyeth* case, however, illustrates a situation in which one could justifiably conclude, as the trial judge apparently did, that the difficulty of trying to communicate the relative dangers involved to all users precluded a finding of negligence, and yet agree with the court of appeals that a true, choice judgment was involved. It is not at all clear what the court would have done if some measures had been taken to provide notice, such as putting up posters, and the issue before the court had been the sufficiency of these precautions. If the negligence standard for when an effort should be made to communicate a risk is abandoned in this type of case, how can one set up a realistic standard for deciding what the measures to be taken should be? While it can be argued that the plaintiff should recover unless it is found that he either knew or should have known about the risk from the notices that were given, there would appear to be no support for this position.

Another drug case, *Basko v. Sterling Drug, Inc.*,[26] differs from *Wyeth* in that after the danger of possible blindness resulting from the use of its drugs became known, various measures were taken by the manufacturer to warn doctors who might prescribe them. Despite these efforts, however, the plaintiff suffered permanent eye injury. In rejecting the plaintiff's contention that she was entitled to a directed verdict as a matter of law, the court said that with respect to the question of liability for failure to warn, negligence and strict liability concepts are virtually identical. Therefore, it upheld a charge requiring the jury to find as a prerequisite to recovery that reasonable efforts to warn were not made. The court distinguished *Wyeth* by saying that there, the evidence was overwhelming that the manufacturer not only knew that the vaccine was being dispensed without any warning of its deleterious effects, but also attempted to assure all members of the community that they should take it.

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25. *Id.* at 130.
26. 416 F.2d 417 (2d Cir. 1969).

III. THE UNKNOWABLE RISK

One important, fundamental question that has not been finally resolved is whether the manufacturer of a drug or other product intended for intimate bodily use should be liable for a harmful reaction that occurs before the harmful propensities of the product become known. Arguably, the manufacturer's failure to discover the risk could occur in one of three different situations: (1) his lack of knowledge was due to negligence; (2) although the hazard was either scientifically known or knowable, the manufacturer in the exercise of ordinary care failed to discover it; or (3) the risk would not have been a scientifically discoverable fact. Thus, it would seem that in discussing the liability of the manufacturer for unknowable risks, the distinction should be between risks that the manufacturer ought to have discovered in the exercise of ordinary care and risks of which he was justifiably unaware at the time of sale. The issue, then, is simply whether a finding of negligence should be a prerequisite to recovery against a manufacturer for a harmful reaction attributable to an unknown hazard.

The initial holdings on this issue involved the claims of lung cancer victims against cigarette manufacturers. Of the three courts passing on the question, one concluded that the manufacturer could be held liable if the unknowable risk made the product unfit or defective.[27] The two other courts, however, held that in order to recover, the plaintiff must prove that the warranted product contained an element from which, on the basis of existing human knowledge at the time of sale, harm might be expected to flow.[28] Two arguments have been advanced in support of the latter position. First, an unknowable risk ought to be borne by the individual in common with his fellow humans and insured against in the same fashion as death or disease,[29] because, unlike ordinary miscarriages or failures, it is not an inevitable by-product of the manufacturing pro-

27. Green v. American Tobacco Co., 154 So. 2d 169 (Fla. 1963). In its opinion the court said: "No reasonable distinction can, in our opinion, be made between the physical or practical impossibility of obtaining knowledge of a dangerous condition, and scientific inability resulting from a current lack of human knowledge and skill.

. . . .

"The contention that the wholesomeness of a product should be determined on any standard other than its actual safety for human consumption, when supplied for that purpose, is a novel proposition in our law, and one which we are persuaded has no foundation in decided cases." *Id.* at 171, 173.

28. Ross v. Phillip Morris & Co., 328 F.2d 3 (8th Cir. 1964); Lartigue v. R.J. Reynolds Tobacco Co., 317 F.2d 19 (5th Cir.), *cert. denied*, 375 U.S. 865 (1963) (applying Louisiana law).

29. Connolly, *The Liability of a Manufacturer for Unknowable Hazards Inherent in his Product*, 32 INS. COUNSEL J. 303 (1965).

cess. Secondly, a risk cannot be spread unless it is known. Since, as Fleming James has observed, the inevitability of allergic, idiosyncratic, and other adverse reactions from elements in drugs and cosmetics is as well known as is the inevitability and certainty of failures in construction,[30] it is difficult to justify a distinction between an unreasonably dangerous condition arising from a miscarriage in the manufacturing process and an unreasonably dangerous condition attributable to society's lack of scientific development. Nevertheless, even though the existence and magnitude of scientifically unknowable risks are as measurable as the likelihood of construction defects, it can reasonably be argued that the activity of manufacturing drugs should not be required to bear accident losses resulting therefrom. Moreover, a number of considerations can be cited in support of this position. It is not the limitations of the enterprise, but the limitations of mankind's technology that account for the manufacturer's ignorance. In addition, the effect that this liability would have on the price of drugs and the development of new products is unclear. Furthermore, if any new products would, in fact, be kept off the market, it might be those most worth the risk.[31]

My position has been and remains that, whatever the reason may be, if the sale of a product exposes the user or others to an unreasonable risk of harm, liability for harm resulting from that risk should follow. Under this rationale, the manufacturer of a product would be liable for all harm resulting from an unknowable risk, (1) if the product proved ultimately to be bad, or (2) if the user of the product was subjected to an unreasonable risk in that he was deprived of the means for avoiding harm from it. Although there is not much judicial authority for either of these assertions, they are desirable from a practical standpoint in light of the plaintiff's difficult burden of proof in a negligence action. The time and expense required to investigate all the procedures of those who make and sell a new drug is enormous, and may prevent an individual litigant from gathering the necessary facts to prove negligence when it does, in fact, occur. Moreover, the economic costs of such an investigation and the administrative difficulties that are involved in the fact-finding and decision-making processes argue eloquently for nonfault and enterprise liability when feasible. The litigation concerning MER/29, an

30. In James, *The Untoward Effects of Cigarettes and Drugs: Some Reflections on Enterprise Liability*, 54 CALIF. L. REV. 1550, 1557 (1966), the author says: "That the specific is unknown and unknowable in advance is not as significant as he (Connolly) seems to think, where the risk is of a *type* which is foreseeable" (emphasis in original).

31. Connolly, *supra* note 29, at 306.

anticholesterol drug that caused cataracts and other serious damage to the eyes of some users, amply illustrates these difficulties.[32]

While very few courts have discussed the problem of liability for harm resulting from good products before the manufacturer knew or should have known of the risk, some of the language in the *Basko* and *Wyeth* cases is instructive. In *Basko* claims were filed against a manufacturer of a drug called Aralen, which is a trade name for chloroquine phosphate. This drug was developed and sold for the treatment of arthritis. It ultimately became known that continued application over a protracted period of time would cause blindness in some users. On the other hand, the onset of any adverse reaction could be detected in time to avoid irreversible damage. In purporting to apply Connecticut law, the Court of Appeals for the Second Circuit said: "Defendant did not warn of the risk of idiosyncratic reaction until 1960. Thus, the only real question with respect to Aralen is whether the risk was either knowable or reasonably foreseeable at a time when the plaintiff was still taking the drug."[33] The opinion in *Wyeth* contains similar language regarding the manufacturer's duty: "[W]hen Type III Sabin vaccine was first licensed by the government in early 1962 and first manufactured and sold by Wyeth, there was no known or foreseeable risk involved in taking it. Thus, *Wyeth* could not initially be expected to warn of unknown dangers."[34] Therefore, both *Basko* and *Wyeth* support the proposition that a manufacturer is not liable for harm resulting from a good product until after the manufacturer knew or should have known of the risk of harm and failed to give adequate warning. There apparently is no judicial authority or language to the contrary, but this could be partially explained by the fact very few courts have discussed the question.

If a product is found to be bad after a period of use, there is more uncertainty with respect to the manufacturer's liability to those who were injured prior to knowledge of the risk. Such products are usually withdrawn from the market, as in the case of MER/29 and Quadrigen. Claims resulting from the marketing of MER/29 produced two decisions, one in Oregon[35] and one in Texas,[36] denying liability. The Oregon Supreme Court adopted the proposition that no warranty is applicable

32. Keeton, *supra* note 6; Rheingold, *The MER Story—An Instance of Successful Mass Disaster Litigation*, 56 CALIF. L. REV. 116 (1968).

33. Basko v. Sterling Drug, Inc., 416 F.2d 417, 426 (2d Cir. 1969).

34. Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 129 (9th Cir. 1968).

35. Lewis v. Baker, 243 Ore. 317, 413 P.2d 400 (1966).

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

to the sale of an unadulterated, uncontaminated prescription drug approved by the Federal Drug Administration. In Texas the intermediate appellate court adopted Judge Wisdom's view in one of the cigarette cases,[37] stating that since medical knowledge was not developed sufficiently to enable the defendant to reasonably have discovered that MER/29 caused cataracts, there should be no liability. There is, of course, a fundamental difference between MER/29 and cigarettes, because cigarettes have never been withdrawn from the market nor regarded as bad per se, whereas MER/29 had been banned when the plaintiff's claim was brought.

In contrast to the Aralen cases, the two decisions involving Quadrigen claims, one in the Second Circuit[38] and one in the Eighth Circuit,[39] contain language that could be regarded as indicating that the manufacturer would be liable for an injury that occurred before the risk of harm from Quadrigen was knowable. In both cases the victimized infant was innoculated within four months of the initial commercial distribution in July 1959 and well before the vaccine was withdrawn from the market in 1961 as unsafe. The children contracted an encephalopathy, which left them severely mentally retarded. In each case there were trial court findings of negligence and breach of warranty, and in each the defendant's principal defensive theory was the insufficiency of the evidence to justify a finding of causal connection between the vaccine and the subsequent contraction of encephalopathy. The Second Circut said that it was unnecessary to discuss liability resting on negligence theories since "it cannot be disputed (and appellant does not disagree) that *a drug manufacturer impliedly warrants under New York law that its products will not prove to be unreasonably dangerous . . . .*"[40] The Eighth Circuit concluded that the evidence was sufficient to justify findings of negligence as well as breach of warranty.[41] While the issue of liability for an unknowable risk could hardly be said to have been considered by either court, it does appear that both courts were willing to consider on the issue of warranty liability a great deal of evidence related to the dangerousness of Quadrigen that was not available until after the vaccine had been sold and administered.

37. Lartigue v. R.J. Reynolds Tobacco Co., 317 F.2d 19, 24 (5th Cir. 1963).
38. Tinnerhold v. Parke, Davis & Co., 411 F.2d 48 (2d Cir. 1969).
39. Parke, Davis & Co. v. Stromsodt, 411 F.2d 1390 (8th Cir. 1969).
40. 411 F.2d at 53.
41. 411 F.2d at 1399.

IV. Conclusion

It is suggested that a court should find a drug or cosmetic to be unreasonably dangerous at the time of sale, thereby subjecting the manufacturer to strict liability, if at the time of trial the product is found to be bad in the sense that the possibility of adverse reactions from its proper use outweighs the potential benefits to consumers. A product can be found to be bad either because the political authorities, through legislative or administrative procedures, have reached that conclusion or because a reasonable man would do so. Another suggested basis for regarding a drug or cosmetic as unreasonably dangerous at the time of sale would be a finding at the time of trial that the product's sale without the manufacturer's supplying or attempting to supply additional information about potential hazards would subject those who use, or upon whom the product is used, to an unreasonable risk of harm. If at the time of trial these additional precautionary measures are required by the political authorities or if a reasonable man would conclude that these measures should be taken, a manufacturer who has failed to take them would be held liable for resulting harm to users because he has subjected them to an unreasonable risk.

Perhaps the manufacturer's liability should be further extended in some manner to those who suffer serious and tragic reactions from good drugs properly used and marketed, even when the risk was known to the victim. More often than not, however, the situation would be one in which the drug was used as a last resort to save life or prevent bodily injury, and, therefore, the damages would be speculative. In any event, this liability has not yet been imposed, and it is extremely doubtful that it should be.