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GENERIC PRODUCT RISKS: THE CASE AGAINST COMMENT K AND FOR STRICT TORT LIABILITY

JOSEPH A. PAGE*

Professor Page considers whether strict liability should be imposed for injuries caused by products that pose generic risks—risks that do not derive from flaws in the manufacturing process but from product design or from the very nature of the product. He reviews the ALI debate that preceded adoption of section 402A of the Restatement (Second) of Torts and finds the ambiguous meaning of comment k, which deals with “unavoidably unsafe” products, of little use in determining whether section 402A applies to generic product risks. After examining the policy justifications for imposing strict liability in cases involving design defects and construction defects, Professor Page concludes that, at least in cases involving generic product risks that were unknown at the time of sale, strict liability should be imposed as a modest incentive to manufacturers to improve product safety and as a means of satisfying justifiable consumer expectations.

INTRODUCTION

Recent litigation involving asbestos¹ and DES² has attracted widespread interest, not only because of the staggering numbers of claimants alleging serious harm from these products³ and the filing of a bankruptcy petition by the nation's largest asbestos manufacturer,⁴ but also because of the complexity of the issues that the cases involve.

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¹ Asbestos has been implicated as a cause of asbestosis, lung cancer, mesothelioma (a cancer of the chest or abdominal lining), and various forms of gastrointestinal cancers. See Hazards of Asbestos Exposure: Hearings Before the Subcomm. on Commerce, Transportation, and Tourism of the House Comm. on Energy and Commerce, 97th Cong., 2d Sess. 2-11 (1982) (testimony of Dr. Irving Selikoff, Environmental Science Laboratory, Mt. Sinai Medical Center) [hereinafter Asbestos Hearings].

² DES, or diethylstilbestrol, is a synthetic estrogen that was prescribed routinely to pregnant women to prevent miscarriages. The Food and Drug Administration approved DES in 1947. In 1971 the drug was linked to a form of vaginal cancer in the daughters of women to whom it was administered. For a discussion of this history, see generally Payton v. Abbott Labs., 512 F. Supp. 1031, 1032-34 (D. Mass. 1981); Comment, DES and a Proposed Theory of Enterprise Liability, 46 Fordham L. Rev. 963, 963-68 (1978).

³ It has been estimated that nine million American workers were exposed to asbestos during the 1940's and 1950's. See Asbestos Hearings, supra note 1, at 3 (testimony of Dr. Irving Selikoff). Estimates of the number of women who ingested DES range from three to four million. See Note, Market Share Liability: An Answer to the DES Causation Problem, 94 Harv. L. Rev. 668, 668 n.7 (1981).

⁴ On August 26, 1982, Manville Corporation, the largest producer of asbestos in the western world, filed a petition for reorganization under the federal bankruptcy code. The company cited the projected cost of mounting asbestos litigation as the major reason for its filing a bankruptcy petition. See N.Y. Times, Aug. 27, 1982, at A1, col. 6; Wall St. J., Aug. 27, 1982, at 1, col. 6.

For example, many DES claimants, daughters of women who took the drug during pregnancy, are unable to identify the maker of the particular pills consumed by their mothers. The courts have had to decide whether to depart from traditional causation rules that would require directed verdicts for defendants, and if so, what new rules to adopt.⁵ In the asbestos cases, courts have had to determine the obligations of successive insurers to indemnify asbestos manufacturers against claims made by persons who allegedly contracted respiratory diseases from continuous exposure to asbestos over many years.⁶ In addition to these problems, an array of legal theories asserted against an array of defendants who do not manufacture asbestos or DES has emerged in these cases.⁷

The few courts reaching the merits of claims made by asbestos and DES victims have, for the most part, refused to venture beyond the familiar confines of negligence law. Giving dispositive weight to

⁵ Courts have reached opposite conclusions about whether plaintiffs who cannot identify the specific manufacturer of the drug to which they were exposed may recover. Compare *Sindell v. Abbott Labs.*, 26 Cal. 3d 588, 610-13, 607 P.2d 924, 936-38, 163 Cal. Rptr. 132, 144-46 (recovery allowed under theory of market share liability), cert. denied, 449 U.S. 912 (1980); *Ferrigno v. Eli Lilly & Co.*, 175 N.J. Super. 551, 567-69, 420 A.2d 1305, 1314-16 (Law Div. 1980) (recovery allowed under "alternative liability" theory); *Bichler v. Eli Lilly & Co.*, 55 N.Y.2d 571, 584-85, 436 N.E.2d 182, 188-89, 450 N.Y.S.2d 776, 782-83 (1982) (recovery allowed under "concert of action" theory) with *Morton v. Abbott Labs.*, 538 F. Supp. 593, 596-600 (M.D. Fla. 1982) (recovery denied); *Mizell v. Eli Lilly & Co.*, 526 F. Supp. 589, 596-97 (D.S.C. 1981) (same); *Payton v. Abbott Labs.*, 512 F. Supp. 1031, 1039-40 (D. Mass. 1981) (same). Since federal courts hear product liability cases only under diversity jurisdiction, each of the above district courts applied the appropriate state law. For a state court refusing to relax the traditional requirement that a plaintiff identify the defendant who actually caused the harm, see *Payton v. Abbot Labs.*, 437 N.E.2d 171, 188-90 (Mass. 1982).

⁶ Some courts have adopted a theory under which all companies that insured an asbestos firm during the period a claimant was exposed would contribute to the defense of the suit and to the satisfaction of an adverse judgment. See *Keene Corp. v. Insurance Co. of N. Am.*, 667 F.2d 1034, 1050 (D.C. Cir. 1981) (adopting "exposure" theory of liability), cert. denied, 455 U.S. 1007 (1982); *Porter v. American Optical Corp.*, 641 F.2d 1128, 1145 (5th Cir.) (same), cert. denied, 454 U.S. 1109 (1981); *Insurance Co. of N. Am. v. Forty-Eight Insulations, Inc.*, 633 F.2d 1212, 1224-25 (6th Cir. 1980) (same), cert. denied, 454 U.S. 1109 (1981). For a decision requiring defense and indemnification only from the insurance company that covered the asbestos firm at the time the claimant's disease manifested itself, see *Eagle-Picher Indus., Inc. v. Liberty Mut. Ins. Co.*, 523 F. Supp. 110, 115-17 (D. Mass. 1981) (adopting "manifestation" theory of liability), modified, 682 F.2d 12 (1st Cir. 1982).

⁷ See, e.g., *Porter v. American Optical Corp.*, 641 F.2d 1128 (5th Cir.) (action against manufacturer of respirator that failed to prevent asbestos-related disease), cert. denied, 454 U.S. 1109 (1981); *Glover v. Johns-Manville Corp.*, 525 F. Supp. 894 (E.D. Va. 1979) (indemnity action by asbestos manufacturer against the United States as third-party defendant in suit by injured worker), aff'd in part, vacated and remanded in part, 662 F.2d 225 (4th Cir. 1981); *Mink v. University of Chicago*, 460 F. Supp. 713 (N.D. Ill. 1978) (battery action against hospital for experimental use of DES).

section 402A of the Restatement (Second) of Torts, which imposes strict liability for “any product in a defective condition unreasonably dangerous to the user,”⁸ and to comment k of section 402A, which recognizes an exception to strict liability for products deemed “unavoidably unsafe,”⁹ these courts in effect have required plaintiffs to establish that defendants engaged in unreasonable conduct. Under this analysis, if the benefits of a product outweigh its known risks, and if the manufacturer has provided suitable warnings and directions for use, the defendant’s product will be deemed reasonably safe, and the plaintiff will not recover.¹⁰ Similarly, if the manufacturer has placed

* Restatement (Second) of Torts § 402A (1965) provides in full:

Special Liability of Seller of Product for Physical Harm to User or Consumer

- (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.

⁹ Restatement (Second) of Torts § 402A comment k (1965) provides in full:

Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

(emphasis in original).

¹⁰ See, e.g., *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1091 (5th Cir. 1973) (“ . . . even when such a balancing leads to the conclusion that marketing is justified, the seller still has a responsibility to inform the user or consumer of the risk. The failure to give adequate warnings in such circumstances can render the product unreasonably dangerous.” (citing comment k)), cert. denied, 419 U.S. 869 (1974); *Ferrigno v. Eli Lilly & Co.*, 175 N.J. Super. 551, 576, 420 A.2d 1305, 1318 (Law Div. 1980) (comment k rules “are not strict liability rules at all. They are merely rules of negligence embodying the long-standing concepts of a lack of due care and foreseeability of the risk.”).

the product into the stream of commerce without knowledge of the dangers associated with its use or consumption, courts typically have refused to impose liability unless the exercise of reasonable care would have uncovered the hazards.¹¹ One notable exception to this trend is a recent decision by the New Jersey Supreme Court, holding that an asbestos producer might be strictly liable in tort for injuries caused by risks that were unknown despite reasonable investigation at the time of sale.¹²

The reluctance of courts to impose strict liability in toxic-product cases corresponds to a trend, reflected in scholarly musings¹³ and adopted in recent congressional reform efforts,¹⁴ to limit strict liability to product defects attributable to the construction or manufacturing process. With respect to claims alleging inadequate product design, warnings, or instructions for use, the proponents of this limitation would apply a negligence test, either expressly or in a disguised form.

Although the desirability of imposing strict liability upon the pharmaceutical industry for adverse drug reactions has been debated,¹⁵ the larger issue of whether all manufacturers should be held liable without fault for other types of toxic adverse effects of their products largely has escaped scrutiny. Since courts in a number of jurisdictions may soon be addressing the merits of asbestos and DES cases, a fresh look at the subject seems in order.

The central focus of this Article is whether all "generic product risks" should be treated alike. The Article first will discuss the various types of generic risks—avoidable and unavoidable, known and unknown—including those risks associated with toxic products like as-

¹¹ See, e.g., *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1090 (5th Cir. 1973) ("A product must not be made available to the public without disclosure of those dangers that the application of reasonable foresight would reveal."), cert. denied, 419 U.S. 869 (1974); Henderson, *Coping With the Time Dimension in Products Liability*, 69 Calif. L. Rev. 919, 924 (1981).

¹² See *Beshada v. Johns-Manville Prods. Corp.*, 90 N.J. 191, 209, 447 A.2d 539, 546 (1982).

¹³ See Birnbaum, *Unmasking the Test for Design Defect: From Negligence to Warranty to Strict Liability to Negligence*, 33 Vand. L. Rev. 593 (1980); Powers, *The Persistence of Fault in Products Liability*, 61 Tex. L. Rev. 777 (1983).

¹⁴ See S. 44, 98th Cong., 1st Sess. §§ 5, 6, 129 Cong. Rec. S285 (daily ed. Jan. 26, 1983) (strict liability for unreasonably dangerous construction or manufacture; fault-based liability for unreasonably dangerous design or failure to provide adequate warnings or instructions); S. 2631, 97th Cong., 2d Sess., 128 Cong. Rec. S6846 (daily ed. June 16, 1982) (virtually identical predecessor version of S. 44).

¹⁵ See generally McClellan, *Tate & Eaton, Strict Liability for Prescription Drug Injuries: The Improper Marketing Theory*, 26 St. Louis U.L.J. 1 (1981); Merrill, *Compensation for Prescription Drug Injuries*, 59 Va. L. Rev. 1 (1973); Pratt & Parron, *Diagnosis of a Legal Headache: Liability for Unforeseeable Defects in Drugs*, 53 St. John's L. Rev. 517 (1979); Note, *The Liability of Pharmaceutical Manufacturers for Unforeseen Adverse Drug Reactions*, 48 Fordham L. Rev. 735 (1980).

bestos and DES.¹⁶ It will then argue that section 402A of the Restatement and its comments provide little guidance in deciding cases that involve generic risks, and should not be accorded dispositive weight in product liability suits. The Article will then examine and evaluate the policy justifications for adopting a rule of strict tort liability in cases involving generic risks. Ultimately, the Article will conclude that a persuasive case can be made for imposing strict liability on manufacturers whose products contain unknown generic risks.

I

THE NATURE OF PRODUCT RISKS

Risks attributable to flaws or impurities caused by the manufacturing process usually are present only in a small percentage of the units of a particular product and do not endanger every consumer of the product. Such product risks are nongeneric in nature. The presence of a foreign substance in a jar of mayonnaise and a malfunction in a television set due to poor workmanship exemplify this category of hazards. In contrast, asbestos and DES share a common characteristic: the capacity to create risks that endanger, but do not necessarily harm, every user or consumer of the product. Such product risks are generic in nature.

This Article will focus on generic product risks, of which there are two main types. One includes design risks, or risks that can be eliminated or at least reduced by changing the design of the product. For instance, the interior of an automobile can be made more crashworthy so that the occupant is more likely to survive a collision. Some design risks, however, may be impossible to eliminate or to reduce without frustrating the purpose for which the product is marketed. The sharpness of a knife, the heat of a stove, and the physical force generated by an automobile are examples of this type of risk. These hazards enable the products to do what they were meant to do; they are essential to the function of the product and cannot be designed away.

The hazards associated with toxic products like asbestos and DES represent the second main type of generic risk. The manufacturers of asbestos products and DES have no desire to create the hazards associated with their products because these hazards serve no useful purpose. Unlike the capacity of a knife to cut, which is essential to its intended use, the capacity of DES to cause cancer in the daughters of

¹⁶ Although generic risks associated with toxic products like asbestos and DES are but one type of generic risk, these products represent a particularly important type of generic risk.

mothers who used the drug is irrelevant to the effectiveness of the drug; while the cutler consciously designs the cutting edge of a knife, the pharmaceutical company does not intentionally create the risk of cervical cancer. Toxic product risks are inherent in the nature of the product,¹⁷ regardless of its design, and cannot be eliminated, at least given the current state of scientific knowledge, by any means short of withdrawing the product from the market.¹⁸

Other examples of generic, nondesign risks abound: adverse reactions to drugs and exposure to harmful chemicals;¹⁹ the risk of cancer from smoking cigarettes;²⁰ the risk of "toxic shock" from using tampons;²¹ and the possibly deleterious effects of consuming food and beverages containing saccharin²² and caffeine,²³ if these substances were someday linked conclusively to diseases in humans.

As the saccharin and caffeine examples suggest, different types of generic risks, whether designed into a product or inherent in its nature, may also be distinguished by the degree of existing knowledge about them. Some generic risks, such as the risk of cancer from smoking cigarettes, are well known to manufacturers and consumers alike. Other generic risks, such as the carcinogenic effects of DES, were unknown when the consumer was exposed to them. Still others, such as the possible side effects of caffeine, remain unknown today.

¹⁷ Nongeneric risks may also be inherent in a component part of a product. Indeed, it was a flawed wooden spoke on the wheel of a 1910 Buick that gave birth to modern product liability law. See *MacPherson v. Buick Motor Co.*, 217 N.Y. 382, 111 N.E. 1060 (1916) (Cardozo, J.).

¹⁸ In some instances, manufacturers can minimize the generic risks associated with their toxic products by providing consumers and users with warnings and instructions. For example, drug producers can warn users who might suffer allergic reactions, and asbestos producers can instruct users to use protective masks when installing asbestos insulation. Warnings and instructions can be used effectively, of course, only with respect to hazards that are known to exist.

¹⁹ Representative recent cases involving these risks include *Stiles v. Union Carbide Corp.*, 520 F. Supp. 865 (S.D. Tex. 1981) (vinyl chloride); *Gutowski v. M & R Plastics & Coatings, Inc.*, 60 Mich. App. 499, 231 N.W.2d 456 (1975) (tolylenede-isocyanates); *Peterson v. Bendix Home Sys., Inc.*, 318 N.W.2d 50 (Minn. 1982) (formaldehyde).

²⁰ Representative cigarette-cancer cases include *Green v. American Tobacco Co.*, 391 F.2d 97 (5th Cir. 1968), cert. denied, 397 U.S. 911 (1970) (prior appeals reported in 325 F.2d 673 (5th Cir. 1963); 304 F.2d 70 (5th Cir. 1962)); *Pritchard v. Liggett & Myers Tobacco Co.*, 350 F.2d 479 (3d Cir. 1965), cert. denied, 382 U.S. 987 (1966) (prior appeal reported in 295 F.2d 292 (3d Cir. 1961)); *Lartique v. R.J. Reynolds Tobacco Co.*, 317 F.2d 19 (5th Cir.), cert. denied, 375 U.S. 865 (1963).

²¹ See *Lampshire v. Proctor & Gamble Co.*, 94 F.R.D. 58 (N.D. Ga. 1982). For a description of toxic-shock syndrome, see Robertson, *Toxic Shock*, N.Y. Times, Sept. 19, 1982, § 6 (Magazine), at 30.

²² For a discussion of the dangers of saccharin use, see, e.g., *The Banning of Saccharin*, 1977: Hearing Before the Subcomm. on Health and Scientific Research of the Senate Comm. on Human Resources, 95th Cong., 1st Sess. 91-97 (1977) (testimony of Donald S. Fredrickson, Director, National Institutes of Health).

²³ For a discussion of the possible dangers of caffeine use, see N.Y. Times, Apr. 21, 1982, at C1, col. 1.

This Article discusses whether or not these various generic product risks—designed-in and inherent, known and unknown—should be treated alike for purposes of applying strict liability. Should the rights of a plaintiff whose hand is burned by a hot stove or whose eye is injured because a machine tool lacks a safety device be determined by the same theory of liability that determines the rights of a plaintiff disabled by exposure to toxic asbestos fibres or DES? Should the claim of a patient harmed by an adverse side effect known to be associated with a drug be governed by the same theory of liability as is the claim of a patient injured by an adverse side effect that was unknown at the time the drug was administered? The light shed on these questions by the Restatement (Second) of Torts, which has greatly influenced the development of product liability doctrine, is an appropriate starting point.

II

GENERIC PRODUCT RISKS AND THE RESTATEMENT

Section 402A of the Restatement (Second) of Torts²⁴ gave impetus to a profound and far-reaching change in the law of product liability. It subjected sellers, including manufacturers, of all products to strict liability and grounded the cause of action in tort rather than warranty.²⁵ This change was important because a warranty cause of action was contractual in nature and was being preempted by the Uniform Commercial Code.²⁶ More importantly, this change relieved plaintiffs of the need to establish a privity-of-contract relationship with defendants. This so-called "citadel of privity," preventing plaintiffs from asserting breach of warranty against defendants with whom they were not in privity, already had almost totally collapsed in warranty cases involving products for internal human consumption, and was crumbling under the onslaught of plaintiffs injured by manufactured goods.²⁷ The widespread judicial adoption of section 402A

²⁴ See note 8 *supra*.

²⁵ See Restatement (Second) of Torts § 402A comment m (1965).

²⁶ The Uniform Commercial Code recognizes an implied warranty of merchantability running with the sale of goods, under which the goods must be fit for the ordinary purposes for which they are sold. See U.C.C. § 2-314 (1978). By 1965, the Uniform Commercial Code had been adopted in over 40 jurisdictions. See J. White & R. Summers, *Uniform Commercial Code* 5 (1972).

²⁷ The classic articles on the demise of the privity requirement were both written by Dean Prosser. He first wrote Prosser, *The Assault upon the Citadel (Strict Liability to the Consumer)*, 69 *Yale L.J.* 1099 (1960). Several years later, he finished the story. See Prosser, *The Fall of the Citadel (Strict Liability to the Consumer)*, 50 *Minn. L. Rev.* 791 (1966) [hereinafter Prosser II].

completed the demolition²⁸ and seemed at the time to be the most dramatic aspect of the new rule.

This doctrinal revolution was remarkably swift. What began in 1958 as a modest proposal for strict tort liability for the sale of food "in a condition dangerous to the consumer,"²⁹ was extended three years later to cover "other products for intimate bodily use" in a "defective condition unreasonably dangerous to the consumer."³⁰ By 1964, the final form of section 402A applied to "any product."³¹ This expansion of the strict liability rule, however, was not accompanied by a thorough analysis of the implications of bringing new classes of products within the sweep of section 402A. As a result, the Restatement does not adequately address the issues raised by generic risks.

A. *The Restatement Generally*

When the drafters of the Restatement broadened the scope of section 402A to cover all manufactured goods, they apparently assumed that the doctrine and explanatory comments, which had been developed for food and other products "for intimate bodily use," would apply equally well to all manufactured goods. The final version of the section and its comments, therefore, remained virtually intact.³²

In retrospect, the most significant impact of this rush to strict liability was the confusion and uncertainty that subsequently plagued product-design litigation. Although the concept of design defectiveness was not unknown in 1964,³³ the proponents of section 402A saw no need to adjust the rules to determine explicitly when the new doctrine would impose strict liability for design defects. They retained the terms "defective" and "unreasonably dangerous"³⁴ and added the requirement that the product "must be dangerous to an extent beyond

²⁸ Forty-four states have adopted some form of strict liability based upon § 402A. See J. Beasley, *Products Liability and the Unreasonably Dangerous Requirement* xii-xiii, 97-100 (1981).

²⁹ Restatement (Second) of Torts § 402A (Tent. Draft No. 6, 1961).

³⁰ Restatement (Second) of Torts § 402A (Tent. Draft No. 7, 1962).

³¹ Restatement (Second) of Torts § 402A (Tent. Draft No. 10, 1964). This version was finally enacted. For other reviews of this evolution, see J. Beasley, *supra* note 28, at 21-23; Wade, *On the Nature of Strict Tort Liability for Products*, 44 *Miss. L.J.* 825, 830-31 (1973).

³² Compare Restatement (Second) of Torts § 402A comments a-m (Tent. Draft No. 7, 1962) (coverage limited to food and products for intimate bodily use) with Restatement (Second) of Torts § 402A comments a-m (Tent. Draft No. 10, 1964) (coverage extended to all products, with virtually no change in wording of comments).

³³ For an early recognition of this concept, see Noel, *Manufacturer's Negligence of Design or Directions for Use of a Product*, 71 *Yale L.J.* 816 (1962).

³⁴ Restatement (Second) of Torts § 402A (1965).

that which would be contemplated by the ordinary consumer.”³⁵ In subsequent years, courts and commentators alike have found this formulation inadequate and have struggled in vain to fashion an acceptable test for strict liability in product-design cases.³⁶

Although the issue of design defectiveness was not recognized as a problem during the evolutionary stages of section 402A, certain other generic risks did occupy the attention of Dean William E. Prosser (the Reporter of the Restatement (Second) of Torts), his advisers (the American Law Institute Council), and the American Law Institute (“ALI”) membership. In working out the new rule of strict liability, they were cognizant of the controversy over the causal relationship between cigarette smoking and cancer, as well as of the incidence of serious harm attributed to certain drugs and vaccines,³⁷ and considered whether the tobacco and pharmaceutical industries should be subject to strict liability.³⁸ In their floor debates, Dean Prosser and members of the ALI also considered how whiskey would fit into their scheme of liability.³⁹

With respect to cigarette-cancer litigation, the Restatement came out unequivocally on the side of the tobacco companies. During a 1961 floor debate on section 402A, a motion was made to delete the word “defective” on the ground that the “unreasonably dangerous” requirement was an adequate test for determining when strict liability should apply and that therefore the term “defective condition” constituted excess baggage.⁴⁰ In response to this motion, Dean Prosser pointed out that the ALI Council wanted to retain the element of defectiveness in order to insulate from liability the sellers of dangerous products, such as whiskey, cigarettes, and certain drugs, which are

³⁵ Restatement (Second) of Torts § 402A comment i (1965).

³⁶ Citations to the extensive literature and to a sampling of judicial decisions dealing with the test for liability in design-defect cases may be found in Twerski, *Seizing the Middle Ground Between Rules and Standards in Design Defect Litigation: Advancing Directed Verdict Practice in the Law of Torts*, 57 N.Y.U. L. Rev. 521, 521 n.1 (1982).

³⁷ These products are mentioned specifically in the Restatement (Second) of Torts § 402A comments i, k (1965). See also text accompanying notes 40-44, 54-61 *infra*. Indeed, appellate opinions involving these products already had appeared. See, e.g., *Pritchard v. Liggett & Myers Tobacco Co.*, 295 F.2d 292 (3d Cir. 1961) (cigarettes); *Gottsdanker v. Cutter Labs.*, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960) (polio vaccine).

³⁸ See text accompanying notes 40-43 *infra*. When the ALI was making this decision, early drafts of § 402A applied only to food and to products for intimate bodily use. See Restatement (Second) of Torts § 402A (Tent. Draft No. 7, 1962). Although it is impossible to know for certain, the fact that manufactured goods were excluded from the sweep of § 402A may have affected the drafters' thinking about generic hazards.

³⁹ American Law Institute, 38th Annual Meeting: Proceedings 87-88 (1962) [hereinafter ALI Proceedings].

⁴⁰ *Id.* at 87. The motion was made by Professor Reed Dickerson.

inherently dangerous even though there is nothing "wrong" with them.⁴¹ The specter of alcoholics bringing a barrage of suits against distillers apparently haunted the drafters of section 402A.⁴² After a very brief discussion, the motion was defeated by a voice vote, and the "defective condition" standard remained a part of section 402A.⁴³

The notion that section 402A would apply only to defective products—products that have something wrong with them other than their inherent danger—would seem to exclude most generic risks. It is not clear, however, that this interpretation is what the majority of the ALI had in mind. During the 1961 debate, Dean Prosser agreed with other members that the "unreasonably dangerous" standard was sufficient to protect sellers of products such as cigarettes and whiskey.⁴⁴ In

⁴¹ *Id.* at 87-88.

⁴² As Dean Prosser noted during the 1961 floor debate, "'Defective' was put in to head off liability on the part of the seller of whiskey, on the part of the man who consumes it and gets delirium tremens, even though the jury might find that all whiskey is unreasonably dangerous to the consumer." *Id.* at 88. What the drafters never realized, however, was that the cure, retaining the requirement of a defect, ultimately would prove worse than the disease.

Judge Goodrich, in his concurring opinion in *Pritchard v. Liggett & Myers Tobacco Co.*, 295 F.2d 292, 301 (3d Cir. 1961), was the first to link cigarettes and whiskey. This linkage is more lyric than logical. This imagery suggests a no-liability conclusion in search of a rationale rather than a result dictated either by doctrine or principle. An apparent zeal to exonerate the tobacco industry from strict liability produced the following giddy pronouncement: "Good tobacco is not unreasonably dangerous merely because the effects of smoking may be harmful; but tobacco containing something like marijuana may be unreasonably dangerous." *Restatement (Second) of Torts* § 402A comment i (1965).

In arguing that the manufacturer of cigarettes that cause cancer should not be liable for breach of implied warranty (absent some representation that the product is harmless), Judge Goodrich invoked the whiskey analogy and noted that "[e]verybody knows that the consumption of intoxicating beverages may cause several different types of physical harm." 295 F.2d at 302. He went on to assert that there would be no liability for over-consumption of whiskey "unless (1) the manufacturer tells the customer the whiskey will not hurt him or (2) the whiskey is adulterated whiskey." *Id.* The analogy does not really apply. Plaintiffs in cigarette-cancer cases do not seek damages for harm resulting from excessive or abusive smoking but rather from ordinary smoking over a prolonged period of time. This is the very type of consumption sought by the tobacco companies. Sellers of whiskey, on the other hand, do not overtly encourage the type of over-consumption that causes the harm to which Judge Goodrich adverted.

In addition, Judge Goodrich stated that "[i]f the defendant here takes the position that nobody knows whether cigarettes cause cancer or not but at the same time asserts to buyers that . . . cigarettes do not cause cancer, it is in difficulty if a customer shows that the use of these cigarettes caused cancer in him." *Id.* The problem he never addresses is whether liability should attach when the seller of cigarettes says nothing to the buyer about the risk of cancer, which is unknown to both buyer and seller, and the risk later materializes. Reference to the over-consumption of whiskey obscures rather than informs his analysis.

In 1961 Judge Goodrich was the Executive Director of the ALI and had participated in the Council discussion to which Dean Prosser referred. See text accompanying note 41 *supra*; Wade, *supra* note 31, at 830 n.23.

⁴³ See ALI Proceedings, *supra* note 39, at 89.

⁴⁴ *Id.* ("I thought 'unreasonably dangerous' . . . carried every meaning that was necessary . . .").

drafting comment i to section 402A, he pointed out that many products, including food and drugs, involve "some risk of harm, if only from over-consumption," but this risk did not render such products "unreasonably dangerous." Dean Prosser concluded that the proper test was whether the product was "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."⁴⁵ Thus defined, the requirement of unreasonable danger would not be met in cases involving whiskey, the hazards of which are known universally, but might be met in cigarette cases, depending upon the court's determination of what the ordinary consumer knew about the risks of smoking at the time of marketing.⁴⁶ Toxic risks are not necessarily excluded, therefore, from section 402A.

Another way to approach the scope of section 402A is to ask whether a product with any kind of generic risk, which was found to be unreasonably dangerous, would meet the separate requirement of defectiveness. The comments to section 402A do not answer this question. Comment i presents examples that shed little light upon the problem. The examples contrast generic risks that are not considered unreasonable ("good" whiskey that makes some people drunk, "good" tobacco that causes harm, "good" butter that deposits cholesterol in the blood and leads eventually to heart attacks) with those that do present unreasonable dangers attributable to defects in the same products (whiskey contaminated with a dangerous amount of fusel oil, tobacco with marijuana, butter with poisonous fish oil).⁴⁷ The former pose dangers widely known to the ordinary consumer;⁴⁸ the latter present clear instances of something "wrong" with the product. Neither group of examples presents a product, not otherwise defective, with such unreasonable risks that strict liability ought to apply.

Comment g, elaborating upon the concept of "defective condition," is similarly unhelpful. It limits strict liability to situations where "the product is, at the time it leaves the seller's hands, in a *condition* not contemplated by the ultimate consumer, which will be unreasonably dangerous to him."⁴⁹ The word "condition," like the contami-

⁴⁵ Restatement (Second) of Torts § 402A comment i (1965).

⁴⁶ Studies linking smoking and cancer began emerging in the 1940's. See *Pritchard v. Liggett & Myers Tobacco Co.*, 295 F.2d 292, 300 (3d Cir. 1961). Modern consumers, therefore, know a great deal more about the risks of smoking than did previous generations. The hazards might well now be considered "universally known."

⁴⁷ Restatement (Second) of Torts § 402A comment i (1965).

⁴⁸ This conclusion is based, of course, on a factual finding that cigarettes and butter are harmful.

⁴⁹ Restatement (Second) of Torts § 402A comment g (1965) (emphasis added).

nated product examples, seems to suggest that there must be something "wrong" with the product beyond any inherent capacity to cause harm.

Yet Dean Prosser and the ALI did not intend to exclude from section 402A all products creating generic risks. Comment j states that warnings may be required for "poisonous drugs or those unduly dangerous for other reasons"⁵⁰ (categories broad enough to embrace medicines triggering deleterious reactions), a proposition compelling the conclusion that the failure to include such warnings might subject the manufacturer to strict liability. While the comment specifies that the absence of directions or warnings may render the product unreasonably dangerous, it does not explain whether unreasonably dangerous also means that the drug is in a "defective condition."⁵¹ Does comment k shed any light on the meaning of "defective"?

B. *The Meaning of Comment k*

Comment k, dealing with so-called "unavoidably unsafe products," is more expansive than these other comments. It declares that a drug with proper directions and warnings would be neither defective nor unreasonably dangerous,⁵² thus suggesting that the same characteristic (mislabeling) that made the drug unreasonably dangerous might also make it defective. This wording blurs the distinction between the two elements, and the requirement of a defect thus becomes superfluous.⁵³

The genesis of comment k may help explain this blurring and comment k's other mysteries. Dean Prosser drafted the comment in response to a proposal at the 1961 ALI meeting that prescription drugs

⁵⁰ *Id.* comment j.

⁵¹ *Id.* In an article written after he drafted this comment, Dean Prosser indicated that a drug marketed without warnings of dangers, which consumers would not already know about, would be regarded as "defective." See Prosser II, *supra* note 27, at 801.

⁵² See Restatement (Second) of Torts § 402A comment k (1965). The text of comment k, which emphasizes the word "unreasonably," is reprinted in note 9 *supra*.

⁵³ See Nader & Page, *Automobile Design and the Judicial Process*, 55 *Calif. L. Rev.* 645, 649-50 (1967). For judicial recognition of this point, see *Ross v. Up-Right, Inc.*, 402 F.2d 943, 947 (5th Cir. 1968) ("When . . . the product is [manufactured] exactly as intended by the manufacturer, to speak in terms of a 'defect' only causes confusion. . . . The key . . . is whether the product is 'unreasonably dangerous.' "); *Hamilton v. Motor Coach Indus.*, 569 S.W.2d 571, 577 (Tex. Civ. App. 1978) ("one who sells a nondefective unreasonably dangerous product without communicating the dangerousness of the product . . . is liable for the injuries inflicted by the unreasonably dangerous item"); *Little v. PPG Indus.*, 92 Wash. 2d 118, 121, 594 P.2d 911, 913 (1979) ("[I]t is inaccurate to speak of a properly manufactured but necessarily dangerous product as being in a 'defective' condition. . . . [I]t is more appropriate to describe an article bearing an inadequate warning as 'unreasonably dangerous' than as 'defective.' ").

be specifically excluded from section 402A.⁵⁴ The arguments and the discussion that followed were notably unfocused. The motion under consideration failed to distinguish between harm from adverse reactions and other kinds of drug-induced harm, such as that caused by improper formulation or toxic ingredients.⁵⁵ Since no one could argue seriously that the latter risks should escape strict liability, the failure to separate the two categories muddled the debate. Moreover, neither Dean Prosser nor the ALI member who made the proposal indicated how he thought section 402A would apply to prescription drugs in the absence of an explicit exemption. A solution was being offered for a problem that never had been clearly defined. Nor were adverse reactions about which warnings had been issued at the time of marketing distinguished from other harmful effects not discovered until later.

There was also disagreement over the scope of the proposed exemption. The motion proposed to insulate all prescription drugs from strict tort liability.⁵⁶ Dean Prosser suggested that a better case could be made for excluding "relatively new, experimental, and uncertain drugs, of which there are a great many on the market, and justifiably so."⁵⁷ He defined the term "experimental drug" to include virtually all prescription drugs and even some over-the-counter medicines.⁵⁸ Dean Prosser's use of the adjective "experimental" went far beyond clinical testing, an initial stage of the Food and Drug Administration ("FDA") approval process, and covered drugs that had completed the entire approval process and had been marketed to consumers.⁵⁹ Thus, he was suggesting an exemption even broader than that proposed by the motion.⁶⁰ The motion to include an exemption

⁵⁴ See ALI Proceedings, *supra* note 39, at 90-92. Harold B. Gross of New York City made the motion.

⁵⁵ Dean Prosser, criticizing the motion, observed that a pharmacist who supplies poisoned epsom salts clearly should be liable to the injured consumer. *Id.* at 92.

⁵⁶ *Id.* at 90, 97.

⁵⁷ *Id.* at 93. Dean Prosser's assertion that a great many experimental and uncertain drugs were justifiably on the market, offered *ex cathedra* and without documentation, was a debatable one at best. See generally M. Mintz, *The Therapeutic Nightmare* (1965); M. Shapo, *A Nation of Guinea Pigs: The Unknown Risks of Chemical Technology* (1979). If the assertion stands as a basis for comment k, it demonstrates strikingly the weakness of the Restatement drafting process as a mechanism for resolving policy issues.

⁵⁸ ALI Proceedings, *supra* note 39, at 96. Dean Prosser also saw a need to treat "experimental foods" in a similar fashion. *Id.* at 94. For an argument against exempting new and experimental foods from strict liability, see Comment, *Cigarettes and Vaccine: Unforeseeable Risks in Manufacturers' Liability Under Implied Warranty*, 63 Colum. L. Rev. 515, 533 (1963).

⁵⁹ Clinical testing is a prerequisite for FDA approval of a new drug. For a description of the process by which the FDA approves new drugs, see generally 1 J. O'Reilly, *Food and Drug Administration* ch. 13 (1982). This approval process helps to insure that information about some risks associated with the approved drugs becomes known after widespread and long-term use.

⁶⁰ The only other member to speak on the issue besides Dean Prosser, Donald J. Farage of Philadelphia, opposed any exemption. See ALI Proceedings, *supra* note 39, at 97.

for prescription drugs in section 402A ultimately was defeated,⁶¹ as was a subsequent motion to insert such an exception in the comments.⁶² On its face, this defeat did not seem to reflect a desire by the membership to exclude *more* than prescription drugs from section 402A, but Dean Prosser apparently saw things differently.

Reflecting the murkiness of its origins, the version of comment k that emerged from the Reporter's hand failed to delineate in any meaningful way either the breadth of its coverage or its purpose. The comment first addresses "unavoidably unsafe products," which it defines as "products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use."⁶³ The comment then appears to focus on "the field of drugs," where such products are "especially common," and presents three overlapping categories of unavoidably unsafe products: high-benefit, high-risk drugs, such as the vaccine used for the treatment of rabies; "many other drugs, vaccines, and the like, many of which [because of high risks involved] cannot legally be sold except to physicians, or under the prescription of a physician;" and "many new or experimental drugs."⁶⁴

The comment furnishes no criteria for determining how risky and how beneficial a drug must be in order to qualify under the first category as "unavoidably unsafe." In any event, such a determination would appear to be unnecessary for drugs. The second category may reasonably be read to include all prescription drugs, since federal law mandates that any medicine with toxic effects that render it unsafe as self-medication be sold under prescription⁶⁵—and a high-risk, high-benefit drug surely would be limited to sale by prescription. The sweeping requirement of prescription status also makes the third category superfluous, a fortunate occurrence since the term "new or experimental drugs" is highly ambiguous.⁶⁶

⁶¹ *Id.*

⁶² *Id.* at 98.

⁶³ Restatement (Second) of Torts § 402A comment k (1965). For a detailed analysis of comment k, see Willig, *The Comment k Character: A Conceptual Barrier to Strict Liability*, 29 *Mercer L. Rev.* 545 (1978).

⁶⁴ Restatement (Second) of Torts § 402A comment k (1965).

⁶⁵ See 21 U.S.C. § 353(b)(1)(B) (1976) ("A drug intended for use by man which . . . because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug . . . shall be dispensed only [upon prescription]. . .").

⁶⁶ The adjective "experimental" seems to refer to the clinical-testing phase of the new-drug approval process. For descriptions of this phase of the process, see 1 J. O'Reilly, *supra* note 59, at 13-39 to 13-46; Campbell, *Civil Liability for Investigational Drugs: Part I*, 42 *Temple L.Q.* 99, 106-07 (1969). While the subsequent reference to the "marketing" of such drugs suggests that they are generally available, the distribution of drugs used in clinical trials actually is highly

Thus, if its examples are taken seriously, comment k reasonably could be read as excluding from section 402A only unavoidably unsafe prescription drugs. The comment, however, fails to explain what might render an unavoidably unsafe product "defective" and thus subject to section 402A in the first instance. Instead, it states that if the known benefits of one of these products outweigh its known risks, it would not be considered "unreasonably dangerous," provided that it was prepared properly and bore adequate warnings and directions for use.⁶⁷ The negative implication of this statement radically expands the scope of the exemption. Since injury caused by any product whose risks outweigh its benefits presumably would be actionable under traditional negligence principles,⁶⁸ comment k may be read to remove from the reach of section 402A any product that is unavoidably unsafe as long as the manufacturer will not be subject to liability under a negligence rule for injury caused by the product. Such an exemption includes but is not limited to prescription drugs, an ironic turn in light of the ALI vote rejecting the proposed exemption for prescription drugs alone.⁶⁹

To appreciate the effect of this interpretation of comment k, it is necessary to consider how sellers of unavoidably unsafe products might be held strictly liable in the absence of comment k. The con-

supervised. Coincidental with the evolution of § 402A and its comments was the passage of the Drug Amendments of 1962, which tightened up new drug clearance procedures. See Drug Industry Act of 1962, Pub. L. No. 87-781, § 104, 76 Stat. 780, 784 (amending 21 U.S.C. §§ 331, 348, 355 (1976)).

Moreover, it is not at all clear what the drafters of § 402A meant by a new but nonexperimental drug. The Food, Drug, and Cosmetic Act defines "new drug" as any drug "not generally recognized . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . ." 21 U.S.C. § 321(p)(1) (1976). Dean Prosser's drug terminology, by drawing this distinction between new and experimental drugs, did not seem to conform to the statutory definition.

⁶⁷ Restatement (Second) of Torts § 402A comment k (1965).

⁶⁸ See W. Prosser, *The Law of Torts* 149 (4th ed. 1971) ("It is fundamental that the standard of conduct which is the basis of the law of negligence is determined by balancing the risk, in light of the social value of the interest threatened, and the probability and extent of the harm, against the value of the interest which the actor is seeking to protect, and the expedience of the course pursued.").

Although courts might theoretically find the mere marketing of a dangerous product negligent because the risks outweighed the benefits, they have not yet done so. At least one recent case has asserted this claim against handgun manufacturers. See First Amended Complaint for Damages at 10-11, *Brady v. Hinckley*, No. 82-0549 (D.D.C. Sept. 8, 1982). See generally Note, *Manufacturers' Liability to Victims of Handgun Crime: A Common Law Approach*, 51 *Fordham L. Rev.* 771 (1983); Note, *Manufacturers' Strict Liability for Injuries from a Well-Made Handgun*, 24 *Wm. & Mary L. Rev.* 467 (1983). For the argument against using product liability as a means to achieve gun control, see D. Santarelli & N. Calio, *Turning the Gun on Tort Law: Aiming at Courts to Take Products Liability to the Limit* (1982) (Washington Legal Foundation Monograph).

⁶⁹ See text accompanying notes 61-62 *supra*.

sumer-contemplation test of comment i⁷⁰ seems to preclude liability in cases where the risks generally were known and therefore within the contemplation of the ordinary consumer. Under this test, if a patient suffers harm from a high-risk, high-benefit drug and the harm falls within the scope of the contemplated risk, the drug would not be unreasonably dangerous. Similarly, a warning about an adverse reaction listed on the label of a prescription drug would be considered part of the contemplated risk,⁷¹ as would be true of known risks posed by experimental drugs. Given the broad sweep of comment i, one can salvage independent meaning for comment k only by surmising that, *without* comment k, harm from unknown risks, or harm from known risks which turns out to be much graver than expected, generally would be actionable under theories of strict tort liability. *With* comment k, therefore, one must surmise that a manufacturer of a product posing such risks would escape liability under section 402A if the product were "unavoidably unsafe."

This analysis suggests that the function served by comment k is to exempt unknown risks created by unavoidably unsafe products, since comment i already excludes known risks. Yet this interpretation presents difficulties. The text of comment k is not at all specific on the point, and a matter as important as the treatment of unknown hazards merits direct mention.⁷² Moreover, the comment focuses on *known* risks. Two of the three categories listed in the comment involve products unavoidably unsafe because of known risks,⁷³ such as a rabies

⁷⁰ See text accompanying note 45 *supra*.

⁷¹ In the case of prescription drugs, the manufacturer discloses risks to the prescribing physician. The physician is then under a legal duty to inform patients of material risks associated with drug therapy. See Merrill, *supra* note 15, at 65-67. In rare instances, courts have imposed a duty upon the manufacturer to insure that the patient is aware of these risks. See, e.g., *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276-78 (5th Cir.) (polio vaccine), cert. denied, 419 U.S. 1096 (1974); *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 130-31 (9th Cir. 1968) (same). Thus, as a general proposition, contemplation of risk by the prescribing physician usually would satisfy the requirement of comment i.

⁷² Shortly after § 402A was published in final form, Dean Prosser wrote a law review article in which he noted that "[t]he conclusion would be clearly indicated that, provided that the product, so far as is known at the time of the sale, is reasonably safe for its intended use, there is no liability for unavoidable dangers—if it were not for the state of confusion surrounding the question of lung cancer from smoking cigarettes." Prosser, *Strict Liability to the Consumer in California*, 18 *Hastings L.J.* 9, 26 (1966). He apparently was convinced that strict liability should not extend to unknowable hazards. Why the comments to § 402A did not take a forthright position on the issue is puzzling.

⁷³ See text accompanying notes 64-67 *supra*. This emphasis is especially apparent in the case of a high-risk, high-benefit product, such as a cancer cure known to have fatal consequences for a small percentage of users. Dean Prosser mentioned such a hypothetical drug during the ALI floor debate on § 402A. See ALI Proceedings, *supra* note 39, at 54, 93. In referring to comment k, Dean Prosser stressed that it was designed to protect "the person who is selling a drug which is

vaccine. According to the comment, the manufacturers of these drugs should not be strictly liable for harm from the known risk, a proposition seemingly rendered superfluous by comment i. The third category, "new or experimental drugs," however, does cover products that are unavoidably unsafe because of unknown risks. Indeed, one important purpose of the clinical testing of experimental drugs is to learn more about adverse reactions they might cause. On the other hand, since a patient participating in clinical trials must give an informed consent, which includes an understanding that the harmful effects of the drug are not yet fully known,⁷⁴ any adverse reaction the patient suffers may be said to fall within the range of consumer contemplation.⁷⁵

Comment j, unlike comment k, speaks specifically to product risks unknown at the time of marketing; but comment j raises more questions than it answers and sheds little light on the meaning of comment k. In discussing the duty to give warnings and directions for use, Dean Prosser indicated that the sellers of food need not provide warnings about common allergic reactions to their products, since they might reasonably assume that consumers who suffer from the allergy are aware of it.⁷⁶ This conclusion is consistent with the consumer-contemplation of unreasonable danger test in comment i: to the ordinary consumer with a common allergy, an allergic reaction would be an expected hazard, and hence not unreasonable. The Reporter went on to state, however, that

[w]here . . . the product contains an ingredient to which a substantial number of the population are allergic, and the ingredient is one whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product, the seller is required to give a warning against it, if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ingredient and the danger. Likewise in the case of poisonous drugs, or those

necessarily unsafe, although its utility outweighs the risk." American Law Institute, 41st Annual Meeting: Proceedings 360 (1965). Once again the implication is clear that the risk making the drug necessarily unsafe was known at the time the product was marketed.

⁷⁴ See 21 C.F.R. § 50.25(b)(1) (1983) (human subject of clinical trials must be told that "the particular treatment or procedure may involve risks to the subject . . . which are currently unforeseeable").

⁷⁵ See Campbell, *Civil Liability for Investigational Drugs: Part II*, 42 Temple L.Q. 289, 335-36 (1969).

⁷⁶ "The seller may reasonably assume that those with common allergies, as for example to eggs or strawberries, will be aware of them, and he is not required to warn against them." Restatement (Second) of Torts § 402A comment j (1965).

unduly dangerous for other reasons, warnings as to use may be required.⁷⁷

This language is unclear on a number of points. Why should the duty to warn unwary allergy victims be limited to cases in which a "substantial" segment of the populace is affected? Under ordinary negligence principles, one might find the risk of serious harm or death to a miniscule percentage of individuals, or even a single individual, to be sufficient justification for requiring a warning.⁷⁸ Also, if the risk is undiscoverable in the exercise of due care and hence need not be mentioned in the warnings or instructions for use, does it follow that the manufacturer will not be strictly liable for harm resulting from the risk? This seems to be a fair reading of the text. If so, strict liability will not attach even though the product was dangerous beyond the contemplation of the ordinary consumer.

But what are the reasons for this departure from the comment i test? Does the last sentence of the paragraph indicate merely that drugs fall within the scope of the general duty to give warnings or directions in every case? Or does it mean that allergic reactions to drugs should be governed by the same principles applicable to reactions to food, i.e., that users need not be warned about common risks that are known by both the manufacturer and the consumer? Should it be read even more expansively to preclude liability for harm from all unknowable adverse drug reactions, and, by extension, from all unknowable generic risks? If this gloss on the language of comment j is correct, comment k again would serve no purpose.

Another noteworthy aspect of comment k is its suggestion that strict liability not be imposed on the manufacturers of "new or experimental" drugs containing harmful or impure ingredients that could not be eliminated "because of lack of time and opportunity for sufficient medical experience."⁷⁹ The scope of the "unavoidable product danger" exception would be extended beyond generic risks and would apply to garden variety defects, where something is actually "wrong"

⁷⁷ *Id.*

⁷⁸ See *Wright v. Carter Prods., Inc.*, 244 F.2d 53, 56 (2d Cir. 1957) (allergic reaction to deodorant; duty to warn even though "only a miniscule percentage of potential customers could be endangered"); *Braun v. Roux Distrib. Co.*, 312 S.W.2d 758, 768 (Mo. 1958) (duty to discover and warn of risks of serious allergic reaction; plaintiff was apparently first to suffer reaction from defendant's hair dye); see also Keeton, *Products Liability—Liability Without Fault and the Requirement of a Defect*, 41 *Tex. L. Rev.* 856, 866 (1963). But see *Cudmore v. Richardson-Merrell, Inc.*, 398 S.W.2d 640, 644 (Tex. Civ. App. 1965) (adverse reaction to MER/29; manufacturer liable only if an "appreciable number" of people experience the adverse reaction), cert. denied, 385 U.S. 1003 (1967).

⁷⁹ Restatement (Second) of Torts § 402A comment k (1965).

with some units of the product. Such a view reads into comment k an "impure ingredient" exception.⁸⁰

If the risk of an impure or otherwise deleterious ingredient is known when a drug is marketed, but the manufacturer could not discover which doses contained the substance (as is the case of blood contaminated with serum hepatitis), an adequate warning on the label of the drug would place the defect within the scope of consumer expectations. The product thus would not be unreasonably dangerous under the comment i test.⁸¹ Impure ingredients whose presence is not known when the drug is sold (such as the offending agents in the polio vaccine case) pose a more difficult problem because of their similarity to impurities in food and manufacturing defects in mass-produced goods. The seller may be unaware of these defects and may be unable to discover them by economically feasible methods. But these instances are plainly covered by the strict liability rule of section 402A.⁸²

The comment k "impure ingredient" exemption should not apply to either of these cases. The exception should be narrowly limited to emergencies in which the usual precautions for assuring the purity of ingredients have not been taken, yet there is medical justification for using the drug.⁸³ The appropriate scope of the exception is thus so narrow that the exception would make more sense as an interpretation of the consumer contemplation test of comment i than as an exception to the strict liability rule of section 402A: in this particular context, assuming an adequate warning has been given, the risk of harmful ingredients is within the ambit of consumer contemplation.

In conclusion, the Restatement's treatment of generic risks falls short on several counts. The requirement of a "defect" as a distinct element of strict liability was inserted to serve a function already

⁸⁰ A California decision might well have inspired this "impure-ingredient" exception. See *Gottsdanker v. Cutter Labs.*, 182 Cal. App. 2d 602, 607-08, 6 Cal. Rptr. 320, 323 (Dist. Ct. App. 1960). In *Gottsdanker*, live polio virus constituted the "impure ingredient" in a polio vaccine. The court applied strict liability under a theory of implied warranty from the producer of the vaccine, since the specifications of the vaccine called for only inactive polio virus.

⁸¹ In at least two blood-contamination cases, the labels on the products bore warnings, but the courts chose to ignore comment i, and instead used comment k as a basis for finding for the defendants. See *Brody v. Overlook Hosp.*, 127 N.J. Super. 331, 339-40, 317 A.2d 392, 397 (App. Div. 1974), *aff'd per curiam*, 66 N.J. 448, 332 A.2d 596 (1975); *Hines v. St. Joseph's Hosp.*, 86 N.M. 763, 764-65, 527 P.2d 1075, 1076-77 (Ct. App. 1974).

⁸² The rule of strict liability applies even though "the seller has exercised all possible care in the preparation and sale of his product." Restatement (Second) of Torts § 402A(2)(a) (1965); see also *Wade, Strict Tort Liability of Manufacturers*, 19 Sw. L.J. 5, 13 (1965) ("If the article left the defendant's control in a dangerously unsafe condition . . . the defendant is liable whether or not he was at fault in creating that condition or in failing to discover and eliminate it.").

⁸³ One hypothetical example would be the emergency production of a new vaccine to combat a serious and rapidly spreading epidemic.

adequately addressed by the "unreasonably dangerous" test. The Restatement fails to make a clear distinction between known and unknown hazards, and never takes a forthright position on which of these two types of hazards strict liability should cover: either, neither, or both. This omission is surprising given the evident concern, reflected both in the ALI floor debates and the comments, over the effect of section 402A upon the manufacturers of drugs, vaccines, and cigarettes. Comment k also is vague in that it fails to make clear what kind of special rule it puts in place, what purposes it meets, and to what classes of products it applies. Finally, the ALI's position on generic product risks, uncertain though it may be, reflects policy judgments. While the ALI is a distinguished body, it is a private, nongovernmental entity.⁸⁴ The courts have ultimate responsibility for translating policy into common-law rules, and the matter of liability for generic risks, and for toxic products in particular, requires more comprehensive scrutiny than has been afforded by the Restatement.

III

GENERIC PRODUCT RISKS RECONSIDERED

When the Restatement's commentary on adverse reactions to drugs, food, and tobacco was drafted, the proposed rule of strict liability did not cover all products placed in the stream of commerce.⁸⁵ Thus, there was no need to consider how the full range of generic risks should be integrated into the framework of a strict liability system. Even had the drafters reflected on this issue, their efforts may not have produced an internally consistent doctrine to cover harm from the ill effects of products for human consumption and intimate bodily use, and harm from the designed-in dangers of mass-produced goods, for the problem is not an easy one.

There are two basic approaches to the issue of liability for the deleterious effects of generic risks. One approach is to focus on strict liability as it has evolved in design-defect and warning cases, and to ask whether the manufacturer's duty to eliminate⁸⁶ or warn of product dangers extends to the particular generic hazard in question. The other approach is to ask whether the policy justifications for imposing

⁸⁴ For a description of the process by which the Restatements are drafted, see Goodrich, *The Story of the American Law Institute*, 1951 Wash. U.L.Q. 283, 287.

⁸⁵ See Restatement (Second) of Torts § 402A (Tent. Draft No. 7, 1962); text accompanying notes 29-31 *supra*. Dean Prosser did not hide his belief, however, that the case law was moving in that direction. See ALI Proceedings, *supra* note 39, at 52-55.

⁸⁶ The manufacturer's duty might also extend to refraining from designing in product dangers.

strict tort liability in cases involving nongeneric risks, i.e., construction defects, where there is general agreement that it should be imposed, support the extension of strict liability to cases involving generic risks. Each of these approaches will be considered in the remainder of this section.

*A. Justifying Strict Liability for Generic Risks: Is the Duty in Design-Defect and Warning Cases Adequate?*⁸⁷

Under well settled principles of negligence law, a manufacturer has a duty to use reasonable care in the design of a product.⁸⁷ This obligation requires the manufacturer to use precautionary measures which are economically and technologically feasible,⁸⁸ and which will eliminate unreasonable risks of harm. The duty extends to risks of which the manufacturer is aware and, in the exercise of due care, should be aware.⁸⁹ If a hazard may be reduced by providing information to the user of a product, the duty of reasonable care may be discharged by providing instructions and warnings.⁹⁰

To have meaning in design cases, the concept of strict liability must make the manufacturer answerable for product-related harm for which negligence theories would provide no remedy. Strict liability potentially might extend to all generic risks, to risks that are designed into a product as well as to those naturally and unavoidably present.⁹¹ The failure to design out or to warn against these risks would render the manufacturer liable, even though the design change or warning might be economically or technologically infeasible, and even though the risk may have been unknown or unknowable at the time of production.

⁸⁷ See I L. Frumer & M. Friedman, *Products Liability* § 7 (1982).

⁸⁸ The duty of reasonable care has been interpreted, within an economically rational (i.e., profit maximizing) framework, as requiring an actor to expend on accident prevention an amount up to the projected cost of accidents that might occur in the absence of such an outlay. See Posner, *A Theory of Negligence*, 1 J. Legal Stud. 29, 32-33 (1972). The duty also obliges manufacturers to keep reasonably "abreast of techniques used by practical men in the industry." Noel, *Recent Trends in Manufacturers' Negligence As to Design, Instructions or Warnings*, 19 Sw. L.J. 43, 51-52 (1965) (citing cases).

⁸⁹ For a discussion of the manufacturer's duty to test, see I L. Frumer & M. Friedman, *supra* note 87, § 6.

⁹⁰ See *id.* § 8.

⁹¹ A rule of absolute liability would hold manufacturers responsible for all harm causally related to a product whether or not the product was defective. A rule of liability for harm from all generic risks associated with a product would be somewhat less than absolute, but nonetheless "ultra-strict." For a discussion of absolute liability in the products context, see Schwartz, *Foreword: Understanding Products Liability*, 67 Calif. L. Rev. 435, 441-48 (1979) (referred to as "genuine strict liability"). For use of the term "ultra-strict liability," see Owen, *Rethinking the Policies of Strict Products Liability*, 33 Vand. L. Rev. 681, 714 (1980).

A theory of "ultra-strict" liability for harm from all generic hazards has found neither judicial nor scholarly acceptance. As Professor Gary Schwartz has argued in a similar context, if loss spreading is our goal, we ought not to adopt a rule that discriminates against the victims of nonproduct-related accidents.⁹² Courts adopting "ultra-strict" product liability would find themselves on the fabled slippery slope and would be unable to offer any logical reason for not extending the doctrine to other contexts in which the public is routinely exposed to the risk of injury, such as the operation of premises held open for business or public purposes⁹³ or leased to tenants.⁹⁴ Such radical changes in the common law surely and properly would encounter judicial hesitation, grounded upon the conviction that it would be more appropriate to leave the difficult policy judgments involved in adopting such an expansive rule to the legislature.⁹⁵

The rejection of "ultra-strict" liability leaves open, however, the theoretical possibility of imposing strict liability for *some* harm caused by generic risks. For example, suppose an automobile manufacturer is deemed not liable for all harm to occupants who collide with the interior of a vehicle. Is there any way to assign responsibility for some but not all injuries attributable to the generic risks of the so-called "second collision"—to assign responsibility in fewer than all cases, as would be done under a rule of ultra-strict liability, yet in more cases than would be done under a rule of negligence? In other words, are there second collisions that the manufacturer could not have avoided by exercising reasonable care but for which the manufacturer should be held liable? This question has provoked considerable academic debate, much of it sharply critical of courts that have answered "yes" and imposed liability for injuries that were not reasonably avoidable

⁹² Schwartz, *supra* note 91, at 445. Professor Schwartz also points out that the rule might not deter certain kinds of accidents, such as those caused by plaintiffs themselves or by other participants in the event, and that it might be difficult to determine which of several manufacturers whose products were involved in the accident ought to be held liable. *Id.* at 441-45. It is questionable whether his analysis, focusing on absolute liability, would apply equally in the context of "ultra-strict" liability for harm from generic risks.

⁹³ See Ursin, *Strict Liability for Defective Business Premises: One Step Beyond Rowland and Greenman*, 22 U.C.L.A. L. Rev. 820 (1975) (case for applying strict liability for harm from dangerously defective business premises).

⁹⁴ See Love, *Landlord's Liability for Defective Premises: Caveat Lessee, Negligence, or Strict Liability?*, 1975 Wis. L. Rev. 19, 134-44 (case for applying strict liability for harm from defective leased premises).

⁹⁵ See Epstein, *Products Liability: The Search for the Middle Ground*, 56 N.C.L. Rev. 643, 660-61 (1978) (legislatures are better suited than courts to consider and resolve issues raised by absolute or ultra-strict product liability); Owen, *supra* note 91, at 705-06 (legislature is more appropriate body to effectuate "distributive justice" via product liability rules).

without articulating a clear, workable standard for deciding when an alleged design flaw is defective or unreasonably dangerous.⁹⁶ The emerging consensus seems to be that design defects are best dealt with under a balancing test,⁹⁷ which is indistinguishable from the negligence standard. Thus, the failure to develop judicially administrable criteria for strict liability has led to the conclusion that product manufacturers, absent negligence, should not be liable for failing to design out functional dangers. Commentators have concluded, in short, that there is no middle ground between negligence and “ultra-strict” liability, at least in cases involving design defects.

The one exception to this proposition, originally articulated by Deans Page Keeton⁹⁸ and John Wade,⁹⁹ and since adopted in several

⁹⁶ Design liability falling between the poles of ultra-strict liability and negligence may be imposed under the consumer-expectation test, which asks what type of design features guarding against the risk of injury an ordinary consumer would have expected. Another compromise approach would use a fault-based standard which lessens the burdens traditionally assigned to plaintiffs in negligence cases. For a decision permitting both approaches, see *Barker v. Lull Eng'g Co.*, 20 Cal. 3d 413, 432, 573 P.2d 443, 455-56, 143 Cal. Rptr. 225, 237-38 (1978) (plaintiff may use either consumer-contemplation test or negligence-type balancing test, in which the burden is on defendant to establish that the design feature in question was not defective).

For criticisms of *Barker*, see, e.g., Birnbaum, *supra* note 13, at 602-18; Epstein, *supra* note 95, at 650-54; Henderson, *Renewed Judicial Controversy Over Defective Product Design: Toward the Preservation of an Emerging Consensus*, 63 *Minn. L. Rev.* 773, 782-97 (1979). For an exhaustive and painstakingly fair-minded discussion of *Barker*, see Schwartz, *supra* note 91, at 464-82.

⁹⁷ For a classic balancing test, see Wade, *supra* note 31, at 837-38 (discussing factors used to weigh the risk of a product against its utility). Such an analysis has been adopted by several courts. See, e.g., *Hagans v. Oliver Mach. Co.*, 576 F.2d 97, 99-100 (5th Cir. 1978); *Bowman v. General Motors Corp.*, 427 F. Supp. 234, 244 (E.D. Pa. 1974). Other scholars have also urged the adoption of balancing tests. See Keeton, *Product Liability and the Meaning of Defect*, 5 *St. Mary's L.J.* 30, 37-38 (1973).

For the emerging consensus, see Birnbaum, *supra* note 13, at 649 (concluding that design defect cases should be decided under a negligence standard); Schwartz, *The Uniform Product Liability Act—A Brief Overview*, 33 *Vand. L. Rev.* 579, 584-87 (1980) (discussing adoption of a negligence test for design and warning cases in the Uniform Product Liability Act).

⁹⁸ See Keeton, *Products Liability—Adequacy of Information*, 48 *Tex. L. Rev.* 398, 407-08 (1970) (“[T]he fact that the maker was excusably unaware of the extent of the danger and had not committed any negligent act or omission that caused the danger would be entirely irrelevant.”); Keeton, *Some Observations About the Strict Liability of the Maker of Prescription Drugs: The Aftermath of MER/29*, 56 *Calif. L. Rev.* 149, 158 (1968) (“A drug or any other product is unreasonably dangerous, I suggest, if, and only if, a reasonable man, with knowledge of the condition of the product and an appreciation of all the risks as found to exist at the time of the trial, would not now market the product at all or would do so pursuant to a different set of warnings and instructions as to use.”). For the earliest mention of this exception, see Keeton, *Products Liability—Current Development*, 40 *Tex. L. Rev.* 193, 210 (1961) (concluding that “excusable ignorance of a defect or the properties of a product is immaterial as regards warranty liability”).

⁹⁹ See Wade, *supra* note 31, at 834 (“assume that the defendant knew of the dangerous condition of the product and ask whether he was negligent in putting it on the market”); Wade,

jurisdictions,¹⁰⁰ is that knowledge of risks should be imputed to the manufacturer as of the time of production or sale. Thus, in determining whether to impose liability for failure to design out or warn of a danger, a jury might take into account hazards that were unknown, or even unknowable, to the manufacturer when the product was marketed. That the manufacturer could not have discovered these risks in the exercise of reasonable care would be irrelevant; if a hypothetical reasonable manufacturer, aware of these risks, would not have marketed the product or would have warned of the dangers, an injured plaintiff may recover.¹⁰¹

This exception uses hindsight to achieve a genuine strict liability in certain cases of generic risks, such as adverse reactions to drugs, dusts, and chemicals. This hindsight approach, however, has not

supra note 82, at 15 (“[A]ssuming that the defendant had knowledge of the condition of the product, would he then have been acting unreasonably in placing it upon the market?”). Dean Wade has recently stated that he never intended this broad language to apply to unknowable hazards, but only to manufacturing flaws in the condition of the product. See Wade, *On the Effect in Product Liability of Knowledge Unavailable Prior to Marketing*, 58 N.Y.U. L. Rev. 734, 765 (1983). His position has heretofore widely been interpreted as being identical to that of Dean Keeton. See Birnbaum, supra note 13, at 619; Powers, supra note 13, at 791; Veltri, *Products Liability: The Developing Framework for Analysis*, 54 Or. L. Rev. 293, 299 (1975). But see *Phillips v. Kimwood Mach. Co.*, 269 Or. 485, 492 n.6, 525 P.2d 1033, 1036 n.6 (1974) (en banc).

¹⁰⁰ See, e.g., *Olsen v. Royal Metals Corp.*, 392 F.2d 116, 119 (5th Cir. 1968); *Helene Curtis Indus., Inc. v. Pruitt*, 385 F.2d 841, 850 (5th Cir. 1967), cert. denied, 391 U.S. 913 (1968); *Dorsey v. Yoder Co.*, 331 F. Supp. 753, 759-60 (E.D. Pa. 1971), aff’d mem., 474 F.2d 1339 (3d Cir. 1973); *Beshada v. Johns-Manville Prod. Corp.*, 90 N.J. 191, 200, 447 A.2d 539, 544 (1982); *Phillips v. Kimwood Mach. Co.*, 269 Or. 485, 492, 525 P.2d 1033, 1036 (1974) (en banc).

¹⁰¹ If knowledge or risk as of the time of marketing is to be imputed to the manufacturer, it would seem logical also to impute subsequently acquired knowledge of inefficacy. Hence, factors to be weighed in a strict liability action would include newly discovered information about risks and benefits. A New Jersey intermediate appellate court has refused to apply the hindsight approach to either risks or benefits in a DES decision. See *Ferrigno v. Eli Lilly & Co.*, 175 N.J. Super. 551, 576, 420 A.2d 1305, 1318 (Law Div. 1980). The court felt itself bound by comment k in product liability cases and interpreted the comment as mandating a foresight test.

It would also seem logical that, if the product might reasonably have been marketed with knowledge of the risk and with adequate warnings, plaintiffs should have to establish that such warnings would have led them not to use the product. See *Henderson*, supra note 11, at 946-48. In most cases, however, this requirement would hinge resolution of the causation issue upon plaintiffs’ credibility. Alternative approaches have been adopted. See *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1281 (5th Cir.) (presumption, rebuttable by the manufacturer, that warning would have been heeded), cert. denied, 419 U.S. 1096 (1974); *Canterbury v. Spence*, 464 F.2d 772, 791 (D.C. Cir. 1972) (causation to be determined by asking what a reasonable person in plaintiff’s position would have decided if informed of all risks), cert. denied, 409 U.S. 1064 (1974); Model Uniform Product Liability Act § 104(C)(3) (Dep’t of Commerce 1979), 44 Fed. Reg. 62,714, 62,721 (1979) (“claimant must prove by a preponderance of the evidence that if adequate warnings or instructions had been provided, they would have been effective because a reasonably prudent product user would have either declined to use the product or would have used the product in a manner so as to have avoided the harm”).

received much policy-oriented justification either by courts or commentators.¹⁰² The mere fact that it created a well-delineated area of strict liability in design and warning cases seemed to suffice. It was inevitable that a need for a firmer rationale would arise.

The recent decision of the New Jersey Supreme Court in *Beshada v. Johns-Manville Products Corp.*¹⁰³ attempted to provide such a rationale. The court held that asbestos manufacturers might be liable for lung diseases caused by exposure to asbestos dust at a time when the risks were unknown and undiscoverable, offering three reasons to support this extension of strict tort liability: the allocation of the costs of injuries to the parties best able to bear them; the reduction of risks by increasing incentives for safety research; and the elimination of the need for plaintiffs to prove scientific knowability, a factual determination that is too complex and speculative for jury resolution.¹⁰⁴ The potential problems with each of these reasons will be considered in turn.

The first rationale offered, the notion that manufacturers of defective or unreasonably dangerous products are in a superior posi-

¹⁰² The applicability of the hindsight approach to drugs and cigarettes has been criticized. See, e.g., Connolly, *The Liability of a Manufacturer for Unknowable Hazards Inherent in His Product*, 32 *Ins. Couns. J.* 303, 306 (1965); Comment, *supra* note 58, at 530-35. For an effort to meet some of these criticisms, see James, *The Untoward Effects of Cigarettes and Drugs: Some Reflections on Enterprise Liability*, 54 *Calif. L. Rev.* 1550, 1555-58 (1966).

¹⁰³ 90 N.J. 191, 447 A.2d 539 (1982).

¹⁰⁴ See *id.* at 205-08, 447 A.2d at 547-48. The precise issue in *Beshada* was whether the trial judge erred in denying plaintiffs' motion to strike the defendants' assertion that the danger of which they failed to warn was undiscoverable when the products were marketed. The court referred to this assertion as a "state-of-the-art" defense. See *id.* at 196, 447 A.2d at 542. The term would seem to apply more properly and precisely to considerations of practical feasibility, relating to technology that might have been used to reduce a known risk. See W. Keeton, D. Owen & J. Montgomery, *Products Liability and Safety: Cases and Materials* 465 (1980); Model Uniform Product Liability Act § 107(D) and commentary (Dep't of Commerce 1979), 44 *Fed. Reg.* 62,714, 62,728-30 (1979). The term, however, has also been used to encompass both technological feasibility and state of scientific knowledge. See Murray, *The State of the Art Defense in Strict Products Liability*, 57 *Marq. L. Rev.* 649, 651-52 (1974); Spradley, *Defensive Use of State of the Art Evidence in Strict Products Liability*, 67 *Minn. L. Rev.* 343, 344-47 (1982).

Beshada is the first case in which the New Jersey Supreme Court has applied the hindsight approach to the unknowable adverse effects of a toxic product. Prior decisions had approved the test where plaintiffs sought recovery for harm from machinery which allegedly had been designed defectively or from a flammable liquid chemical. See *Freund v. Cellofilm Properties, Inc.*, 87 N.J. 229, 239-41, 432 A.2d 925, 930-31 (1981) (flammable chemical); *Suter v. San Angelo Foundry & Mach. Co.*, 81 N.J. 150, 171-72, 406 A.2d 140, 150-51 (1979) (same); *Cepeda v. Cumberland Eng'g Co.*, 76 N.J. 152, 163-75, 386 A.2d 816, 821-27 (1978) (defectively designed machine), overruled in part, 81 N.J. 150, 177, 406 A.2d 140, 153 (1979). An intermediate appellate court in New Jersey has refused to apply the *Beshada* rule in a drug case. See *Feldman v. Lederle Labs.*, 189 N.J. Super. 424, 432-33, 460 A.2d 203, 207-08 (App. Div. 1983).

tion to allocate the costs of product-related injuries, does not really help to answer the question of what makes a product defective or unreasonably dangerous. Nor does it answer the question of which costs should be shifted.¹⁰⁵ Compared with plaintiffs who are injured by products, manufacturers are almost always better able to bear risks by spreading losses through price adjustments and insurance. This rationale would therefore justify imposing liability for harm from risks known as well as unknown, reasonable as well as unreasonable, and ultimately would lead to "ultra-strict" liability. Because it proves too much, this rationale provides only weak justification for a narrower rule of strict liability.

Professor James Henderson has also criticized the risk-spreading rationale on the ground that a hindsight approach would misallocate the costs of liability from products creating risks that were unknown and unknowable at the time of sale. Manufacturers would add this cost to the prices of different, reasonably safe products or to the same products put to different, safe uses. Since the offending products would already have been priced and sold, their liability costs could not be assigned to them. Moreover, once manufacturers discover the danger, the product is removed from the market or redesigned, or appropriate warnings are given, and thus there is no longer any need to assign costs of liability.¹⁰⁶

Such a result—product prices reflecting costs other than those caused by the product itself—would lead to market distortions and destroy the optimality properties that flow from cost-based pricing in a perfectly competitive market.¹⁰⁷ In a perfectly competitive market, cost minimization and profit maximization for a particular product, and not costs from earlier versions of a particular product, or different products altogether, will determine the price of the product. A manufacturer who tries to pass on these costs will be driven from the market by manufacturers who do not. Professor Henderson's argument thus squarely poses a paradox: the market distorting effects of misallocation can occur only in a noncompetitive market, where the effects of misallocation are ambiguous.¹⁰⁸ Because of competitive market pres-

¹⁰⁵ See Owen, *supra* note 91, at 703-07.

¹⁰⁶ See Henderson, *supra* note 11, at 942-44.

¹⁰⁷ A perfectly competitive economy is "efficient" (i.e., scarce resources are allocated optimally) and "Pareto optimal" (i.e., no one can be made "better off" without making someone "worse off"). For a serious yet nonmathematical discussion of these concepts, see J. Quirk, *Intermediate Microeconomics* 229-45 (1976).

¹⁰⁸ The distortions that make a market noncompetitive also destroy the optimality properties of perfectly competitive equilibrium. Adding additional distortions to the market may improve the situation, or it may make the situation worse. Economists have labelled this ambiguity the theory of the "second best." For a general discussion of this theory, see *id.* at 243-44.

tures,¹⁰⁹ unanticipated liability costs are more likely to be paid out of profits, loans, or sources other than price increases.¹¹⁰

It is important to distinguish between the allocation that would result from the retroactive application of a hindsight rule and that from the prospective application.¹¹¹ The court in *Beshada* pointed out that application of the rule of strict liability for unknowable risks “will force the price of any particular product to reflect the cost of insuring against the possibility that the product will turn out to be defective.”¹¹² Thus, the threat of prospective liability would force a proper allocation of product prices.¹¹³ When a court initially adopts a hindsight rule and imposes it retroactively, however, the prices of products marketed years, or, in the case of asbestos, decades, earlier will not bear their own liability costs.¹¹⁴ In the case of asbestos, this “first shot” problem is enormous. The New Jersey Supreme Court did not ask whether considerations of fairness deriving from justifiable reliance by asbestos manufacturers,¹¹⁵ or the enormous potential liability to which the industry might be exposed, supported the recognition of a hindsight rule that would operate prospectively only.¹¹⁶

For all of these reasons—because it proves too much, because it may or may not apply depending on market conditions, and because its effectiveness depends on whether the application is prospective or retroactive—the risk-spreading rationale raises more questions than it answers and provides only weak support for a rule of strict liability.

¹⁰⁹ Whether a particular market is competitive, of course, is an empirical question, and the answer can vary from market to market.

¹¹⁰ If the market is competitive, manufacturers are earning what economists call “normal profits,” the profits necessary to continue functioning as an ongoing business. If profits drop, the manufacturer will encounter problems raising new capital (a result of insufficient returns on the capital already invested in the firm) and may have to withdraw from the market. Recovering liability costs from profits, therefore, may drive firms from the market. In noncompetitive markets, however, where firms earn “super profits,” the result may be entirely different.

¹¹¹ The problem is discussed in Schwartz, *New Products, Old Products, Evolving Law, Retroactive Law*, 58 N.Y.U. L. Rev. 796, 825 (1983).

¹¹² 90 N.J. at 206, 447 A.2d at 547.

¹¹³ This conclusion assumes that a manufacturer will be able to obtain adequate protection against the unknown and the unknowable, risks that would have to be translated somehow into monetary terms and factored into the cost of liability insurance premiums, which product prices would then reflect.

¹¹⁴ Of course, the same is true whenever liability is expanded at common law—parties who have already avoided liability in the past continue to do so under the new rule as well. See R. Keeton, *Venturing to Do Justice: Reforming Private Law* 25-26 (1969).

¹¹⁵ Since the hindsight approach was first suggested in 1961, see note 98 *supra*, manufacturers were arguably on notice that liability for harm from unknowable risks might one day be imposed upon them. In *Beshada*, however, the exposures to asbestos dust dated back to the 1930's.

¹¹⁶ It would be difficult to apply the hindsight rule prospectively only. If it were limited to injury sustained in the future, or after 1961, problems of proof would greatly complicate cases involving prolonged harmful exposures.

The second policy justification offered in *Beshada* was that a rule of strict liability would spur safety research that might reveal hidden dangers.¹¹⁷ Put another way, a contrary rule would benefit producers who were unaware of risks and thus would tend to perpetuate ignorance, especially if plaintiffs could not easily establish that a hazard might have been detected in the exercise of due care. Admittedly, if the existence of a hazard were completely unknown at the time of marketing, a manufacturer would be unable to determine how much to spend in order to make the discovery, and there may be no increase in safety research.¹¹⁸ On the other hand, if a hazard were suspected or were known to exist but its full extent were not known, the incentive for additional investigation could produce some incremental level of safety. In either instance, though, this incentive for safety research would justify a rule of strict liability because the manufacturer can always uncover the known risks better and more cheaply than the potential victim.¹¹⁹

It is worth noting that *Beshada* involved asbestos rather than a drug. Federal regulation prescribes the nature and amount of safety testing that must be done before the marketing of a new medication.¹²⁰ In using stimulation of safety research as a rationale for a rule of strict liability for unknown risks, a court would be explicitly or implicitly recognizing a general need for more extensive premarket investigation than presently required by the FDA. This recognition, however, goes far beyond judicial determinations in individual cases that FDA approval of a particular new drug does not preclude a finding of negligence or strict liability.¹²¹ While the safety-incentive

¹¹⁷ "The 'state-of-the-art' at a given time is partly determined by how much industry invests in safety research. By imposing on manufacturers the costs of failure to discover hazards, we create an incentive for them to invest more actively in safety research." 90 N.J. at 207, 447 A.2d at 548.

¹¹⁸ It has been argued that the hindsight approach will deter manufacturers from testing to discover whether products already on the market are causing harm. See Henderson, *supra* note 11, at 940-41. This course of action will be effective only if the harm or its connection with the manufacturer's product remains undetected indefinitely. There are, however, many other ways in which such information may come to light. See, e.g., 15 U.S.C. § 2064(b) (1976) (manufacturers of consumer products required to notify Consumer Product Safety Commission of substantial product hazards); 15 U.S.C. § 1411 (1976) (notification requirement for defective automobiles). Manufacturers would therefore benefit from rapid discovery of harm caused by their products: they can undertake a recall or reduce the risks to reasonable proportions by issuing appropriate warnings.

¹¹⁹ See notes 132-33 *infra*.

¹²⁰ See 21 C.F.R. §§ 310, 312, 314 (1983) (FDA regulations governing the approval process for new drugs).

¹²¹ For cases finding that FDA approval of a warning is not conclusive on the issue of the adequacy of the warning, see, e.g., *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 658 (1st Cir. 1981); *Stevens v. Parke Davis & Co.*, 9 Cal. 3d 51, 65-66, 507 P.2d 653, 661-62, 107 Cal. Rptr. 45, 53-54 (1973); *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375, 396-400, 528 P.2d 522, 533-35 (1974).

rationale is not indefensible,¹²² some courts might give it less weight than they would otherwise because of its far-reaching implications.

Another problem with the accident-avoidance rationale is that it leaves open the following question: why should courts impose strict liability upon manufacturers for harm from hazards of unknown scope as an incentive to discover the true scope of the risks, but not apply strict liability as a spur to technological development where at the time of production it was technologically infeasible to eliminate or to reduce risks? There is widespread agreement that in the latter cases, involving the so-called "state of the art" issue,¹²³ manufacturers will not be liable, absent negligence, for having failed to use today's safety technology yesterday.¹²⁴ It is difficult to distinguish between technology that can detect the gravity of risk and technology that can eliminate or reduce risk, or to conclude that strict liability would act as a spur to the advancement of the former but not of the latter.¹²⁵

The third justification for strict liability offered by the *Beshada* court is that the litigation process cannot adequately determine scientific knowability.¹²⁶ But although the same might be said of the need to decide whether a manufacturer failed to exercise reasonable care in designing a product,¹²⁷ courts have not stopped resolving these is-

¹²² Proposed FDA regulations would streamline the drug-approval process and hence reduce the time required to bring new medications into unrestricted commercial use. See New Drug and Antibiotic Regulation, 47 Fed. Reg. 46,622 (to be codified at 21 C.F.R. pts. 310, 312, 314, 430, 431, 433) (proposed June 23, 1982). The recent removal of the antiarthritic drug Oralflex from the market because of its association with the deaths of a number of users, see Newsweek, Aug. 16, 1982, at 59, col. 1, however, has provoked criticism about the adverse implications for safety of drug deregulation. See N.Y. Times, Aug. 15, 1982, at 7F, col. 2. That the new proposal would permit the FDA to rely more heavily upon foreign clinical studies also has been seriously questioned. See The New Drug Review Process: Hearings on the Regulation of New Drugs by the Food and Drug Administration Before the Subcomm. on Intergovernmental Relations and Human Resources of the House Comm. on Government Operations, 97th Cong., 2d Sess. 312-52 (1982).

¹²³ The term is used here to mean technological feasibility. See note 104 *supra*.

¹²⁴ See, e.g., *Wilson v. Piper Aircraft Corp.*, 282 Or. 61, 67-69, 577 P.2d 1322, 1326-27 (1978); *Boatland of Houston, Inc. v. Bailey*, 609 S.W.2d 743, 746, 748 (Tex. 1980).

¹²⁵ Professor Henderson, who disapproves of the hindsight rule, argues that strict liability would not provide increased incentives for manufacturers to develop technology that eliminates or lessens risks; the incentive already exists in the market. Even Henderson recognizes, however, that although information about product risks does not generate profits, the subsequently developed risk-reduction technology might well provide competitive advantages to its creator, and a strict liability rule might well stimulate this type of technology. See Henderson, *supra* note 11, at 952-53. Moreover, risk information may have considerable value in discrediting a competitor's product. See Page, Not So Sure: The Underarm Menace, *The New Republic*, Apr. 12, 1975, at 8 (competitor discovered hazards associated with a rival's antiperspirant and submitted the data to the FDA).

¹²⁶ 90 N.J. at 206-07, 447 A.2d at 548-49.

¹²⁷ See Henderson, *Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication*, 73 Colum. L. Rev. 1531 (1973) (developing the idea of "polycentricity"—that

sues.¹²⁸ The scientific speculation inherent in deciding whether a particular hazard was knowable may produce more uncertainty than a dispute about whether designing out a known danger was feasible; this greater degree of uncertainty might tip the balance in favor of giving at least some weight to this particular rationale for strict liability. The elimination of the need to establish knowability would certainly reduce trial costs, but so would dispensing with the burden of proving lack of due care in design cases.

Since design and warning cases generally are decided by balancing factors that are virtually identical to those used to determine negligence, it is difficult to justify treating unknown or unknowable generic risks as falling within the duty to design or warn but outside the balancing approach. Ultimately, however, a *de facto* negligence test for all generic risks is unsatisfactory because this standard does not take into account the compelling policy reasons for adopting a strict liability theory. I now turn to those policy reasons, which have been recognized in the context of nongeneric risks.¹²⁹

B. Justifying Strict Liability for Generic Risks: Are the Policies Underlying Strict Liability in Construction Defect Cases Adequate?

The conceptual treatment of liability for harm from unknowable generic risks as deriving from the manufacturer's duty to design or to warn creates a discomfoting impression: that liability is being imposed for a failure to do the impossible. An alternative approach is to view generic risk through the same lens that, when focused upon the risk of harm from construction defects, has produced a rule of strict liability even when it might have been economically infeasible or technologically impossible to eliminate the hazard. Here the theory

design decisions are multifaceted and altering one aspect of a design might cause a "defect" in another part of the design); R. Epstein, *Modern Product Liability Law* 84-90 (1980) (agreeing with Professor Henderson). For judicial concurrence with this view, see *Dawson v. Chrysler Corp.*, 630 F.2d 950, 962-63 (3d Cir. 1980) (recognizing in dictum that design decisions are polycentric), cert. denied, 450 U.S. 959 (1981).

¹²⁸ For explicit rejections of this criticism in the product-design context, see *Bowman v. General Motors Corp.*, 427 F. Supp. 234, 242, 245-46 (E.D. Pa. 1977); *Owens v. Allis-Chalmers Corp.*, 326 N.W.2d 372, 377-78 (Mich. 1982); *McMullen v. Volkswagen of Am.*, 274 Or. 83, 86-90, 545 P.2d 117, 119-21 (1976); Schwartz, *supra* note 91, at 449-51.

¹²⁹ The criticism that these same policy reasons might support extensions of the strict liability doctrine beyond product liability does not necessarily preclude modest steps in that direction. Courts traditionally have permitted the common law to develop gradually and incrementally; indeed, case-by-case lawmaking permits no other method. The central role of consumerism in contemporary Western society makes especially appropriate the use of product liability as a testing ground for deviations from traditional fault principles and toward risk spreading.

does not rest so much on any real or presumed inadequacy in the manufacturing process as on a policy decision to impose liability without fault. Thus, it may be appropriate to inquire whether the bases of strict liability for construction defects support a similar rule for generic risks.

Manufacturers are strictly liable for harm from construction defects even if they could not have eliminated, or discovered, such defects by exercising reasonable care.¹³⁰ Held to the standard of their own plans and specifications, manufacturers must answer for imperfections that arise from their production processes.¹³¹ Of the various reasons that have been advanced to justify this rule of strict liability in construction defect cases,¹³² three seem worthy of discussion in the context of generic risks: accident avoidance, loss spreading, and the satisfaction of justifiable consumer expectations.¹³³

¹³⁰ See Restatement (Second) of Torts § 402A(2)(a) (1965).

¹³¹ See R. Epstein, *supra* note 127, at 68. As Epstein notes, this obligation is well settled.

¹³² Professors John E. Montgomery and David G. Owen have identified seven policy justifications for imposing strict tort liability on manufacturers of defective products:

- (1) Manufacturers convey to the public a general sense of product quality through the use of mass advertising and merchandising practices, causing consumers to rely for their protection upon the skill and expertise of the manufacturing community.
- (2) Consumers no longer have the ability to protect themselves adequately from defective products due to the vast number and complexity of products which must be "consumed" in order to function in modern society.
- (3) Sellers are often in a better position than consumers to identify the potential product risks, to determine the acceptable levels of such risks, and to confine the risks within those levels.
- (4) A majority of product accidents not caused by product abuse are probably attributable to the negligent acts or omissions of manufacturers at some stage of the manufacturing or marketing process, yet the difficulties of discovering and proving this negligence are often practicably insurmountable.
- (5) Negligence liability is generally insufficient to induce manufacturers to market adequately safe products.
- (6) Sellers almost invariably are in a better position than consumers to absorb or spread the costs of product accidents.
- (7) The costs of injuries flowing from typical risks inherent in products can fairly be put upon the enterprises marketing the products as a cost of their doing business, thus assuring that these enterprises will fully "pay their way" in the society from which they derive their profits.

Montgomery & Owen, *Reflections on the Theory and Administration of Strict Tort Liability for Defective Products*, 27 S.C.L. Rev. 803, 809-10 (1976). Although these policy justifications apply generally to product liability law, they are particularly relevant to construction-defect cases, where there is general agreement that strict liability should apply.

¹³³ Judge Traynor advanced these arguments in his seminal concurring opinion in *Escola v. Coca Cola Bottling Co.*, 24 Cal. 2d 453, 461-63, 150 P.2d 436, 440-41 (1944), to support a rule of "absolute liability" for product defects.

The need to protect consumers from the complexities of modern product technology, the manufacturer's superior capacity to control risks, and the desirability of forcing manufacturers to internalize costs associated with product risks all justify the public policy objective of accident

Whether strict liability will actually foster accident avoidance has been seriously questioned. It has been argued that producers will avoid only those accidents worth avoiding—if it is cheaper to let an accident happen and to pay the resulting liability costs, the profit-maximizing manufacturer will follow that course. Thus, if testing and quality-control procedures would cost more than projected liability costs, a rule of strict liability would not encourage manufacturers to adopt procedures to prevent accidents.¹³⁴

This argument, however, is not entirely persuasive. A manufacturer bound by negligence principles might foresee escaping some liability costs that should attach when it does not exercise due care. The difficulties of proving fault might be too great for injured plaintiffs in certain kinds of cases,¹³⁵ or economic constraints might force plaintiffs to accept unfavorable settlements.¹³⁶ Anticipating these lower liability costs, manufacturers might spend less on accident prevention. By reducing plaintiffs' burdens, a strict liability rule might well encourage manufacturers to increase safety expenditures to the level they might reach under a negligence system that functioned optimally.¹³⁷

The adoption of a rule of strict liability in cases where a manufacturer knew a risk existed but did not know its full extent also might increase safety by providing an incentive to perform additional investigations.¹³⁸ Indeed, assuming that manufacturers foresee that, under negligence principles, not every injured plaintiff will recover full damages for harm from a particular design feature or warning, the application of strict liability to all generic hazards, known and unknown, will increase the prospect of full recovery, encouraging safety

avoidance. Liberalized discovery procedures and doctrines such as *res ipsa loquitur* appear sufficient to overcome barriers that might once have been insurmountable to many plaintiffs suffering product-related harm.

¹³⁴ See Posner, *Strict Liability: A Comment*, 2 *J. Legal Stud.* 205, 209 (1973); Sachs, *Negligence or Strict Product Liability: Is There Really a Difference in Law or Economics?*, 8 *Ga. J. Int'l & Comp. L.* 259, 274-76 (1978).

¹³⁵ Indeed, Judge Traynor relied in part on this rationale in his concurrence in *Escola*. See 24 *Cal. 2d* at 463, 150 P.2d at 441.

¹³⁶ Product liability suits usually are financed through contingent fees. To the extent attorneys perceive "tougher odds" under a negligence regime, they will be less willing to take on cases than they would be under a rule of strict liability. Plaintiffs will thus be unable to "finance" their litigation. Moreover, some plaintiffs may need the money now, even if it is less than they might receive later.

¹³⁷ This criticism uses economic theory to respond to an economic argument. In the presence of market imperfections like problems of proof (imperfect information) and costs of litigation (capital market imperfections), there may well be a role for intervention (a rule of strict liability) in the market.

¹³⁸ See text accompanying note 118 *supra*.

expenditures and accident avoidance. This increase in safety enhancement standing alone, however, is probably insufficient to justify liability without fault in these cases.

The "loss-spreading" rationale rests on the manufacturers' ability to use insurance to spread the costs¹³⁹ of harm caused by construction defects more efficiently and more easily than product victims can.¹⁴⁰ Construction defects are easily insurable for two reasons: the number of claims likely to arise from such defects is fairly predictable, and this number is likely to be relatively small in comparison with the total number of products placed into the market.¹⁴¹ Insurance against these risks, therefore, is readily available because the costs are predictable and the harm to be insured against normally will remain within modest bounds.¹⁴² The number of known generic risks likely to occur—ranging from adverse drug reactions for which warnings have been given¹⁴³ to automobile accidents¹⁴⁴—can also be predicted with some certainty. Rough estimates can even be made about risks whose presence is known but whose extent cannot be calculated. The only type of hazard that would not permit even a guess would be the unknown and undiscoverable danger.

In the case of generic risks, however, the other aspect of insurability—a comparatively small number of risks—is absent. Unlike construction defects that affect only a small percentage of users, every generic risk will endanger every user of the product. Thus, the amount of damage attributable to generic product risks could be enormous, even if recoveries are reduced to take into account the

¹³⁹ As noted earlier, this rationale leaves open the question of which costs ought to be shifted. See text accompanying note 105 *supra*.

¹⁴⁰ When dealing with both the manufacturers' and consumers' abilities to insure, I assume the existence of well-functioning insurance markets to which the respective parties have access. Depending on the type of loss one seeks insurance against, this may or may not be an empirically justifiable assumption.

¹⁴¹ See Owen, *supra* note 91, at 691-92; Schwartz, *supra* note 97, at 585. Professor Owen, while acknowledging the predictability of construction defects ("product flaws"), does not view this predictability as a valid basis for distinguishing construction defects from design defects.

¹⁴² Some construction defects, however, have significant costs. For example, construction defects in automobiles may affect large numbers of vehicles. See, e.g., Brown, *Rear-Wheel Loss Feared in Millions of GM's Sedans*, Wash. Post, Apr. 2, 1983, at C7, col. 5 (improperly manufactured component associated with partial or total separation of rear axle shaft and wheel assembly). A defect affecting every automobile could have even more disastrous consequences. See Werber, *Automobile Recall Campaigns: Proposals for Legislative and Judicial Responses*, 56 U. Det. J. Urb. L. 1083, 1085 (1979).

¹⁴³ The FDA approves new drugs on the basis of cost-benefit judgments that take into account the risks of adverse reactions. See 1 J. O'Reilly, *supra* note 59, § 14.05.

¹⁴⁴ See Owen, *supra* note 91, at 692 (discussing cost-benefit assessments of fuel tanks in the rear of Pintos).

comparative responsibilities of plaintiffs, third persons, and other enterprises that might appropriately share the losses. One might argue, then, that loss spreading makes sense only in the context of construction defects, where the relatively modest costs can be more easily absorbed by the manufacturer.

An intermediate position might hold manufacturers strictly liable for unavoidable hazards, such as adverse reactions to toxic products, but not for designed-in, functional dangers, such as the speed of an automobile. This compromise position, however, has several problems. As a practical matter, it is difficult to base a rule of strict liability on degrees of potential damage: the notion that the more harm a defendant may cause the less likely it is that liability will attach strikes a somewhat perverse chord. Moreover, the focus on the quantity of loss may well be misguided. If the purpose of loss spreading is to deflect the economic impact of product-related harm away from those who may not be able to absorb it, perhaps the focus should be on the victims' capacity to pay for their own injuries, and not on the aggregate cost of all such injuries.

Consumers' ability to foresee product risks is relevant to a determination of their ability to insure themselves against those risks, and thus to a determination of their capacity to absorb the cost of their own injuries. The policy of satisfying justifiable consumer expectations¹⁴⁵ may shed light on this issue of cost absorption in particular and on the appropriateness of strict liability for generic product risks in general.

The notion that manufacturers should be strictly liable for harm from product frustration is rooted in the doctrine of implied warranty of merchantability, which holds goods to the standard of reasonable fitness for their intended use.¹⁴⁶ Products placed into the stream of commerce carry with them a representation of safety, the scope of which is determined by what the ordinary consumer would expect of those products.¹⁴⁷ This representation of safety underlies the consumer contemplation test set out in comment i of the Restatement.

¹⁴⁵ For articulations of the consumer-contemplation approach to strict product liability, see generally Hubbard, *Reasonable Human Expectations: A Normative Model for Imposing Strict Liability for Defective Products*, 29 *Mercer L. Rev.* 465 (1978); Shapo, *A Representational Theory of Consumer Protection: Doctrine, Function and Legal Liability for Product Disappointment*, 60 *Va. L. Rev.* 1109 (1974).

¹⁴⁶ U.C.C. § 2-314 (1978).

¹⁴⁷ See Fischer, *Products Liability—The Meaning of Defect*, 39 *Mo. L. Rev.* 339, 348-52 (1974).

It is important to distinguish between two uses of consumer expectations: the goal of meeting justifiable consumer expectations as a policy behind strict tort liability, and the use of consumer expectations as a criterion for deciding whether strict liability should apply in a particular instance. The former derives from the conviction that, as a matter of fairness, consumers should be entitled to rely on the representation of safety made by the seller of a product and by any information accompanying the product. Consumers depend on the manufacturer to provide goods that will meet these implied representations so that they can make rational judgments affecting their own well-being. The imposition of strict liability will encourage producers to satisfy these consumer expectations, will permit consumers to act on the assumption that expectations will be met, and will enable consumers to survive the economic hardship of unexpected losses.¹⁴⁸

When using consumer expectations as a criterion for applying strict liability, the critical task is to determine which consumer expectations are justifiable. The rule in construction defect cases suggests that courts have found such defects to lie outside the ambit of consumer contemplation; consumers, therefore, may justifiably expect products to be free of construction flaws, and manufacturers will be held strictly liable for all such flaws: known, unknown, and unknowable.¹⁴⁹ In design defect cases, however, courts apply what amounts to a negligence test¹⁵⁰ and say in effect that consumers justifiably may expect only that due care, measured as of the time of manufacture, will be exercised with regard to design and warning decisions.

Is this distinction tenable? Given what the average person undoubtedly knows about product quality (especially in light of the publicity given to recalls of automobiles and other household products), all types of risk-creating flaws, both in construction and design, are arguably within the contemplation of ordinary consumers.¹⁵¹ In some cases, awareness of a vague possibility that some defect might

¹⁴⁸ See Shapo, *supra* note 145, at 1124-31. When consumers expect a loss, they can insure against the loss themselves. It is only when the loss is unexpected that compensation, under a rule of strict liability, is needed.

¹⁴⁹ See text accompanying notes 130-33 *supra*.

¹⁵⁰ See note 97 and accompanying text *supra*.

¹⁵¹ As Professor Owen has argued,

[F]rom a more abstract perspective of social psychology, it may well be that the typical consumer knows full well that of the thousands of cars spewed out by Detroit on a daily basis many hundred at least will house production errors of various types and levels of danger It thus may be that consumer expectations are no more violated in cases of production flaws than in those involving design adequacies.

Owen, *supra* note 91, at 693.

lurk somewhere within a product ought not to establish the risk as within the consumers' contemplation. The wide range of potential flaws, especially in complex items such as automobiles and workplace machinery, and the varying degrees of potential risk associated with such flaws, renders a general awareness practically useless to the consumer.¹⁵² Moreover, the marketing image of a product may dim an already faint awareness of the risk. A rule of strict liability for construction defects, then, reflects a justifiable judicial determination that consumers merit protection under a standard requiring goods to be completely free of such defects.

A practical reason for limiting justifiable consumer expectations to the exercise of reasonable care in the design of products is that there is no other workable standard by which courts may determine whether a product is unreasonably dangerous. Consumers usually are unable to form an expectation about the extent to which design defects will be eliminated: it is not a matter of expecting one unit of a particular product to be as good as the next.¹⁵³ Therefore, the best that consumers can justifiably expect in the design defect context is that manufacturers will use technologically and economically feasible methods to reduce or eliminate foreseeable risks.

The policy of satisfying justifiable consumer expectations also dictates the refusal to impose strict liability for harm from known generic risks. The ordinary consumer appreciates the dangers posed by a speeding automobile or a sharp knife, and would therefore have no cause to believe that a manufacturer would do more than use due care to reduce these hazards. Contemporary smokers know of the risk of cancer from cigarettes. The presence of warnings on the label of prescription drugs makes physicians, acting on their patients' behalfs, aware of the relevant risks. In each of these cases, consumers can make a rational judgment about the scope of the hazard and act accordingly.¹⁵⁴

¹⁵² See Dickerson, *Products Liability: How Good Does a Product Have to Be?*, 42 *Ind. L.J.* 301, 315-16 (1967).

¹⁵³ For criticisms of the consumer-contemplation test in the design defect context, see Keeton, *Products Liability—Design Hazards and the Meaning of Defect*, 10 *Cum. L. Rev.* 293, 300-05 (1979); Montgomery & Owen, *supra* note 132, at 823; Schwartz, *supra* note 91, at 471-81.

¹⁵⁴ Dean Keeton has argued that the consumer-contemplation approach to strict liability would deny recovery to plaintiffs injured by an open and obvious design defect. See Keeton, *supra* note 153, at 302. The so-called "patent danger" rule, developed under negligence law, has been severely criticized. See generally Marschall, *An Obvious Wrong Does Not Make a Right: Manufacturers' Liability for Patently Dangerous Products*, 48 *N.Y.U. L. Rev.* 1065 (1973). The recent trend has been to reject the rule and to permit obviousness of risk to be weighed as merely one factor in determining whether a product is unreasonably dangerous. See *Pike v. Frank G.*

But if the danger or its full dimensions do not become evident until after the plaintiff has been exposed to the product, the consumer-contemplation policy supports the imposition of strict liability. The product has inflicted an unpleasant surprise. Although the manufacturer could not have discovered the danger or its extent, the marketing of the product misled the consumer with an implied representation of safety that was not met and thus deprived the consumer of the opportunity to evaluate the risk and to decide whether to accept it.¹⁵⁵ Under this new view of consumer expectations, a product posing an unknown or unknowable generic hazard would stand on the same footing as a product with a construction flaw: each product would be considered unreasonably dangerous for purposes of strict liability because it frustrated justifiable consumer expectations recognized by the law.

The need to integrate liability for product-related harm to non-consumers into a scheme structured around consumer expectations raises a conceptual problem. Professor Gary Schwartz has noted that a third-party beneficiary theory can preserve the viability of the consumer-expectations test in instances where the consumer could reasonably be deemed to have contemplated the conferral of accident-avoidance benefits upon others.¹⁵⁶ The extension of the implied warranty of merchantability, which under the Uniform Commercial Code protects anyone "who may reasonably be expected to use, consume or be affected by the goods,"¹⁵⁷ lends support to this argument by analogy. But it would be stretching things beyond the breaking point to assume that a consumer intends to protect bystanders, especially those who are total strangers. As a practical matter, this problem will be limited to construction defect cases: the *de facto* negligence test used to determine liability in design defect cases applies equally well to consumers and bystanders;¹⁵⁸ and unknown generic risks will rarely endanger

Hough Co., 2 Cal. 3d 465, 473-74, 467 P.2d 229, 234-35, 85 Cal. Rptr. 629, 634-35 (1970); *Micallef v. Miehle Co.*, 39 N.Y.2d 376, 384-85, 348 N.E.2d 571, 576-77, 384 N.Y.S.2d 115, 120-21 (1976). See generally Phillips, *Products Liability: Obviousness of Danger Revisited*, 15 Ind. L. Rev. 797 (1982). Hence, where product risks are open and obvious, plaintiffs may still be able to establish negligent design.

¹⁵⁵ Note that this consumer-expectations rationale, unlike the safety enhancement and loss-spreading rationales discussed above, applies to risks unknown or even unknowable; the focus is on the consumer's state of knowledge, and not on the manufacturer's state of technology.

¹⁵⁶ See Schwartz, *supra* note 91, at 474-75.

¹⁵⁷ U.C.C. § 2-318 (1978) (alternatives B and C).

¹⁵⁸ Under a negligence test, the manufacturer's duty would be to avoid creating unreasonable risks of harm to foreseeable victims, a class that would include bystanders as well as users. See 1 L. Frumer & M. Friedman, *supra* note 87, § 5.03(1)(e).

anyone other than a product user.¹⁵⁹ These limitations, however, do not eliminate the theoretical hurdle.

One answer is simply to recognize that the policy of satisfying justifiable expectations supports the imposition of strict liability only on behalf of consumers and their intended beneficiaries. To hold manufacturers liable without fault for harm to bystanders would then require a separate, independent rationale. A second, and perhaps preferable, solution lies in a reassessment of the consumer-contemplation policy. Its roots, as has been noted,¹⁶⁰ go back to the doctrine of implied warranty of merchantability, the primary concern of which was the adjustment of the rights of parties to commercial transactions. Although courts fashioning tort doctrine may legitimately borrow from sales law, they need not feel fettered by sales law constraints. Where the same policy goals would be applicable to nonconsumers, it might be logical to extend strict liability protection beyond the purchaser. Thus, the user of a product personally relies upon the implied representations of safety inherent in the product. Certain bystanders may also entertain similar expectations that a product will not injure them. This approach would require courts to differentiate between two classes of bystanders: the first is exemplified by a pedestrian injured when an automobile goes out of control because of a construction defect; the second by the person harmed while asleep at home by an airplane that crashed because of a flaw in its assembly. In the latter case, the victim had no expectation generated or frustrated by the product.¹⁶¹ The falling airplane was like a falling meteorite—completely unexpected—an event for which there is no tort remedy. Hence the consumer-contemplation rationale, expanded to take into account the actual expectations of users and bystanders, would not support recovery by such victims under strict liability.

CONCLUSION

This Article has proposed a conceptual framework for determining when to apply strict liability to generic product risks. On the twentieth anniversary of the first decision to hold product manufacturers strictly liable in tort,¹⁶² the parameters of the doctrine remain in

¹⁵⁹ For one example of how generic risks may endanger bystanders, see P. Brodeur, *Asbestos and Enzymes* 25 (1972) (report that wives of seven asbestos workers who had regularly brushed their husbands' work clothes died from mesothelioma, a cancer associated with exposure to asbestos dust).

¹⁶⁰ See text accompanying note 146 *supra*.

¹⁶¹ This conclusion is based on the assumption that airplanes do not regularly fly over the house.

¹⁶² *Greenman v. Yuba Power Prods., Inc.*, 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1962).

flux. Federal legislation threatens to restrict the doctrine to harm from nongeneric risks.¹⁶³ Conflicts and uncertainties in the common law of product liability as it has evolved in the states have been cited as a major justification for federal action.¹⁶⁴

The case for salvaging some remnant of strict liability within the area of generic product risks is not an easy one. The use of a policy-based analysis, however, makes it possible to link the accepted view that the rule should apply to construction defects to the admittedly controversial proposition that harm from unknown or unknowable generic risks should be compensated in the same fashion. The advantage of this approach is that it provides a coherent, principled basis for excluding other kinds of generic product risks from a rule of strict tort liability. Both the satisfaction of justifiable expectations on the part of product victims and the achievement of modest advances in safety justify the application of strict liability to harm from unknowable generic hazards.

Neither section 402A and comment k, interpreted as denying strict liability for unknowable generic risks, nor *Beshada*, forthrightly permitting recovery in such cases, presents a satisfactory resolution to the problem. The proposed federal Product Liability Act uncritically accepts comment k,¹⁶⁵ while *Beshada* has provoked an outpouring of criticism.¹⁶⁶ The tide at the moment apparently is running against strict liability in generic-risk cases. But the last words have not yet been spoken.

¹⁶³ See note 14 *supra*.

¹⁶⁴ See S. Rep. No. 670, 97th Cong., 2d Sess. 3-10 (1982).

¹⁶⁵ See S. 44, 98th Cong., 1st Sess. § 5(c), 129 Cong. Rec. S285 (daily ed. Jan. 26, 1983):

A product is not unreasonably dangerous in design or formulation if the harm was caused by an unavoidably dangerous aspect of a product. As used in this paragraph, an "unavoidably dangerous aspect" means that aspect of a product which could not, in light of knowledge which was reasonably accepted in the scientific, technical, or medical community at the time of manufacture, have been eliminated without seriously impairing the effectiveness with which the product performs its intended function or the desirability, economic and otherwise, of the product to the person who uses or consumes it.

See also S. Rep. No. 670, 97th Cong., 2d Sess. 30 (1982) (accompanying S. 2631, 97th Cong., 2d Sess., 128 Cong. Rec. S6846 (daily ed. June 16, 1982), a bill with a section virtually identical to this section of S. 44).

¹⁶⁶ See Schwartz, *supra* note 111, at 824-25; Schwartz, *The Post-Sale Duty to Warn: Two Unfortunate Forks in the Road to a Reasonable Doctrine*, 58 N.Y.U. L. Rev. 892, 901-05 (1983); Wade, *supra* note 99, at 738-39, 744; Comment, *Requiring Omniscience: The Duty to Warn of Scientifically Undiscoverable Product Defects*, 71 Geo. L.J. 1635 (1983); Birnbaum & Wrubel, *N.J. High Court Blazes New Path in Holding a Manufacturer Liable*, Nat'l L.J., Jan. 24, 1983, at 24, col. 1; Platt & Platt, *Moving from Strict to "Absolute" Liability*, Nat'l L.J., Jan. 17, 1983, at 18, col. 3.

For a defense of *Beshada* by the attorneys for the plaintiffs in the case, see Placitella & Darnell, *Beshada v. Johns-Manville Products Corp.: Evolution or Revolution in Strict Products Liability?*, 51 Fordham L. Rev. 801 (1983).