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A PROPOSED REVISION OF SECTION 402A OF THE *RESTATEMENT (SECOND) OF TORTS*

James A. Henderson, Jr. † & Aaron D. Twerski ‡

I INTRODUCTION

Only rarely do provisions of the American Law Institute's Restatements of the Law rise to the dignity of holy writ. Even more rarely do individual comments to Restatement sections come to symbolize important, decisive developments that dominate judicial thinking. Nevertheless, section 402A of the *Restatement (Second) of Torts* is such a provision. Literally thousands upon thousands of products liability decisions in the past twenty-five years have explicitly referred to, and come to grips with, that section.¹ Among products liability followers one need only identify an issue as presenting "a comment *k* problem,"² or identify a legislative proposal as "a comment *i* provision,"³ to capture instantly the essence of the relevant debate and incorporate nearly thirty years of legal controversy, development and refinement.

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¹ In a letter to the authors dated October 11, 1991, Marianne M. Walker, A.L.I. Restatement Case Citations Editor, asserts: "In my nine years with the American Law Institute I have found § 402A to be the most frequently cited section of any Restatement." After reviewing more than 700 pages of citations in Appendices and pocket parts, confirmed by a computer-assisted search, we conservatively estimate that no fewer than 3,000 published court opinions have cited § 402A to the time of this writing.

² Comment *k* of the *RESTATEMENT (SECOND) OF TORTS* § 402A (1965) limits the application of strict liability in cases involving "unavoidably unsafe products." For the most part, comment *k* has been used by courts to deny claims against drug manufacturers based on defective design. *See, e.g.*, *Brown v. Superior Ct.*, 751 P.2d 470 (Cal. 1988); *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991).

³ Comment *i* of the *RESTATEMENT (SECOND) OF TORTS* § 402A (1965) imposes strict liability only if the product is "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." *Id.* cmt. *i*. Courts have used this section to preclude liability in cases involving products whose risks are well known whether the claims are based on defective design, *see, e.g.*, *Hartman v. Miller Hydro Co.*, 499 F.2d 191, 194 (10th Cir. 1974); *Vincer v. Esther Williams All-Aluminum Swimming Pool Co.*, 230 N.W.2d 794, 799 (Wis. 1975); or failure to warn, *see, e.g.*, *Seagram & Sons v. McGuire*, 814 S.W.2d 385, 388 (Tex. 1991); *Menard v. Newhall*, 373 A.2d 505, 507 (Vt. 1977).

Given that section 402A has achieved the status of sacred scripture, our proposal to replace it with new text and new comments may strike some readers as blasphemous. What prompts such audacity? Quite simply, doctrinal developments in products liability have placed such a heavy gloss on the original text of and comments to section 402A as to render them anachronistic and at odds with their currently discerned objectives. By changing the relevant language to conform to current understandings—by restating the *Restatement*—we hope to clarify much of the confusion that has arisen over the years.

Only recently, while working on this Article, we learned that the American Law Institute itself has decided that the products liability sections of the *Restatement (Second) of Torts*, including section 402A, needs revision. Even more recently, as this article was going to print, the authors were appointed Reporters for the Products Liability provisions of the *Restatement (Third) of Torts*. Given these developments, we wish to emphasize two points at the outset. First, the proposals we advance in this Article are solely our own and do not reflect the views of the American Law Institute. Over the years the American Law Institute has developed a process of careful deliberation and consultation with a broad group of lawyers, judges, and academics, before Restatement provisions are presented to the membership. This Article has not been subjected to such scrutiny. Second, we have sought to approach the revision of section 402A cautiously, treating existing language and concepts with considerable respect. Language that has been interpreted by so many courts over such a substantial period of time cannot be cavalierly discarded. At the same time, issues that once posed burning questions have now been well settled and new areas of controversy dominate the landscape. We have thus chosen a moderate approach in drafting our suggested revision. We intend to stay as close as possible to shared perceptions of the evolved meanings of the original section and its comments. We do not fancy ourselves as radical reformers, although we express preferences, based on widely recognized normative criteria, when choices are appropriate. Finally, we propose to identify those areas in which true controversy reigns and in which neither predictions nor recommendations are in order.

Rather than indulge in a lengthy introduction detailing the background of section 402A's promulgation in 1963 and its subsequent history to date,⁴ we will (as they say) cut to the chase. With more than a little chutzpah (but not a trace of false modesty), we

⁴ For useful treatments of the background and subsequent history of § 402A, see generally William L. Prosser, *The Fall of the Citadel (Strict Liability to the Consumer)*, 50 MINN. L. REV. 791 (1966); Jay M. Smyser, *Products Liability and the American Law Institute*:

offer our proposed revision of section 402A of the *Restatement (Second) of Torts*, together with our "official" comments. Explanations regarding why it reads the way it does can wait until we get to the "Authors' Notes" following our suggested revisions. The original version of section 402A and comments are reproduced in an Appendix to this Article.

II

A REVISED SECTION 402A WITH REVISED COMMENTS

§ 402A. Special Liability of One Who Sells a Defective Product

1 (1) One who sells any product in a defective
 2 condition is subject to liability for harm
 3 to persons or property proximately caused
 4 by the product defect if the seller is engaged
 5 in the business of selling such a product.
 6

7 (2) The rule stated in Subsection (1) applies in
 8 the case of a claim based on a
 9

10 (a) manufacturing defect even though the seller
 11 exercised all possible care in the preparation
 12 and marketing of the product; or
 13

14 (b) design defect only if the foreseeable
 15 risks of harm presented by the product, when
 16 and as marketed, could have been reduced at
 17 reasonable cost by the seller's adoption of
 18 a safer design; or
 19

20 (c) warning defect only if the seller failed to
 21 provide reasonable instructions or warnings
 22 about nonobvious product-related dangers that
 23 were known, or should have been known, to the
 24 seller.

Comments:⁵

a. This section states a special rule of tort liability applicable to commercial sellers of products. The liability established in this section draws on both warranty law and tort law. The provision holding a seller liable for harm caused by manufacturing defects even though the seller has exercised all possible care in the preparation

A Petition for Rehearing, 42 U. DET. L.J. 343 (1965); John W. Wade, *Strict Tort Liability for Products: Past, Present and Future*, 13 CAP. U. L. REV. 335 (1984).

⁵ In keeping with the original § 402A and comments, we do not footnote our revised comments. For those who must have footnotes, we supply them in our "Authors' Notes," *infra* part III.

and marketing of the product reflects the heritage of warranty. The provisions holding sellers liable for design and warning defects reflect the influence of tort law's traditional risk-utility balancing. The liability set forth in this section should not be confused with liability arising from abnormally dangerous activities, described in sections 519-520 of the *Restatement (Second) of Torts*. Unlike the strict liability set forth in those sections, under which defendants may be held liable even if their activities are socially useful and reasonably conducted, this section requires the plaintiff to establish that the product that caused the harm was defective in one or more of the manners prescribed herein.

b. History. As comment *g* explains in greater detail, manufacturing defects are dangerous departures from a product's intended design, and typically occur in only a small percentage of units in a product line. The imposition of liability for defectively manufactured products has a long history in the common law. As early as 1266, special criminal statutes were enacted in England imposing liability upon victualers, vintners, brewers, butchers, cooks, and other persons who supplied contaminated food or drink. In the early 1960s, American courts came to recognize that a seller of any product containing a manufacturing defect should be liable in tort for harm caused by the defect regardless of the plaintiff's ability to maintain a traditional negligence or warranty action. Liability would attach even if the manufacturer's quality control in producing the defective product was not negligent. Furthermore, the plaintiff need not be in direct privity with the defendant seller to bring an action. This cause of action for defectively manufactured products, recognized by American courts since the early 1960s, is a hybrid. It merges the no-negligence aspects of implied warranty with the no-privity aspects of tort.

Design and warning defects occur when the intended designs and/or modes of marketing are unreasonably dangerous; if the design or marketing of a product is defective, every unit in the product line is defective. *See* comment *h*. Liability for design and warning defects was a relatively rare phenomenon until the late 1960s and early 1970s. A host of limited-duty rules made recovery for such defects, especially design defects, difficult to obtain. Following the erosion of these rules, courts sought to apply the rule of tort liability without fault to design and warning defect cases. Although numerous courts, accepting the invitation of section 402A, held that the doctrine of strict liability applied with equal force to all types of product defects, it soon became evident that the rule created to deal with liability for manufacturing defects could not, without considerable difficulty, be applied to design and warning defect cases. With

respect to manufacturing defects, no conceptual problems arise in identifying product defects. A product unit that fails to meet the manufacturer's own quality standard and thereby fails to perform its intended function is, almost by definition, defective. With regard to design and warning defects, however, the product unit meets the manufacturer's own standard of product quality; therefore, it is necessary to go outside the product unit itself to define "defect."

Subsections (2)(b) and (2)(c) reflect the view adopted by most courts that the rule developed for manufacturing defects is inappropriate for the resolution of design and warning defect cases. The governing standard of liability for design and warning defects requires a determination that a product's reasonably foreseeable risks outweigh its social utility. Although the phraseology of the tests for liability differs, at their core, subsections (2)(b) and (2)(c) both rely on traditional risk-utility balancing.

c. Policy justifications. The rule set forth in this section establishes different standards of liability for manufacturing defects and design and warning defects. Policy justifications that support a strict liability rule with respect to manufacturing defects do not support application of the same rule to design and warning defects. In the case of manufacturing defects, courts have supported the rule imposing strict liability because it enhances social utility by satisfying four major objectives. Strict liability encourages manufacturer investment in product safety; discourages the consumption of defective products by causing the purchase prices of products to reflect the cost of defects; reduces the transaction costs involved in litigating manufacturer fault; and promotes risk spreading by ensuring that the full brunt of a product-related injury does not fall on the victim alone.

Several important fairness concerns also support strict liability for manufacturing defects. Consumers injured by flawed products argue that their fundamental expectations as to product performance have been disappointed. Their dissatisfaction is heightened because manufacturers invest in quality control at consciously chosen levels. The manufacturer's very knowledge that a predictable number of flawed products will enter the marketplace and cause injury lends to the harm an element of deliberate infliction. Finally, it seems only just that consumers who benefit from products should share, through increases in the prices charged for those products, the burden of unavoidable injury costs that result from undetectable manufacturing defects.

In contrast to manufacturing defects, design and warning defects require more flexible definitions. In the first place, one cannot determine mechanically whether the design or marketing of a prod-

uct is defective; some sort of risk-utility balancing is necessary. Products are not defective merely because their designs are dangerous. Users of such products must bear a substantial portion of the responsibility for managing generic product risks. Imposing the unyielding liability rule established for manufacturing defects on design risks would cause more careful product users to subsidize less careful users, a result that would be both inefficient and unfair. For many inherent product risks, therefore, users are the best risk minimizers. Risk-utility balancing is required to determine which risks are more fairly and efficiently borne by product sellers, and thus by users generally, and which should be borne by individual by product users who suffer injury.

Moreover, for the liability system to be fair and efficient, risk-utility balancing must be accomplished in light of the knowledge of risks and risk-avoidance techniques reasonably available at the time of distribution. Application of a rule holding manufacturers liable for risks that were not foreseeable when the product was marketed might arguably foster increased manufacturer investment in safety. However, insurers cannot provide coverage for unforeseeable or indeterminable risks. Furthermore, to impose liability for unforeseeable and hence incalculable risks would violate a manufacturer's right to be held to a liability standard that it is capable of meeting. For these reasons, subsection (2)(b) applies risk-utility balancing to the product "when and as marketed," and subsection (2)(c) holds sellers liable for failing to warn of nonobvious risks "that were known, or should have been known, to the seller."

d. One who sells any product. The rule stated in this section applies only to those who distribute products in commercial markets. It does not impose strict liability on those who primarily distribute services even if, while performing their services, they cause damage through the use of defective products. For example, hospitals and physicians are not held strictly liable when defective instruments they have used to perform medical procedures cause injury. Often a commercial provider of services uses a product ancillary to the performance of a service, in a manner analogous to a sale. Thus, a product repairer may use a replacement part ancillary to the repair service, or a beauty parlor may provide a hair treatment product while performing the services of a beautician. Many courts have applied the rule of this section to cover such product-related transactions. Others have drawn a sharp distinction between sale and service, applying strict products liability only to the former and leaving the latter to be governed by the rules of negligence.

The rule stated in this section is not limited to traditional commercial sales of products. Other forms of mass-marketing are suffi-

ciently sale-like that courts have treated them as the functional equivalent of product sales. Commercial lessors of products for consumer use are thus liable for injuries caused by defective products that they lease to consumers. Courts have also extended the rule of this section to include mass-produced housing marketed by developers, although sales of real property were not historically within the ambit of product sales. When courts find that the policy justifications set forth in Comment *c* are fully applicable to the enterprise in question, they tend to impose the rule stated in this section with little regard to the formal structure of the underlying transaction. By and large, the rule stated in this section leaves such decisions to the developing case law.

e. Alternative liability. For the most part, traditional principles of causation govern products liability litigation under the rule stated in this section. See comment *l*. Thus, it is the plaintiff's burden in most cases to establish that a given product unit sold by a manufacturer or other seller caused or enhanced his injury. Notwithstanding this general rule, this section is not intended to limit the developing case law imposing alternative liability on manufacturers in special circumstances. A significant number of courts have applied various forms of alternative liability to drug manufacturers, almost exclusively in cases involving DES, even though no specific product unit can be shown to be directly responsible for the plaintiff's injury. The long latency period between exposure and manifest injury in such cases, coupled with the generic nature of the medication and the lack of recordkeeping necessary for defendant identification, has led some courts to set aside the traditional rules regarding causation. Other courts have failed to follow this lead. The rule stated in this section sets forth the traditional causation rule as the governing standard. This comment recognizes that digressions from the rule may be called for in unusual circumstances. However, when defendant identification is possible, courts should be reluctant to abandon traditional causation principles. For this reason, even courts that have embraced alternative liability in latent drug injury cases have not done so in asbestos injury cases.

f. Business of selling such a product. The rule stated in this section applies to anyone in the business of selling the type of product that injured the plaintiff. The seller's business need not be limited to the sale of such products. However, the rule does not cover occasional sales outside the regular course of business (frequently referred to as "casual sales"). Thus, a manufacturer who occasionally sells surplus or used equipment does not fall within the ambit of this rule.

Traditionally, intermediaries such as wholesalers, retailers and distributors have been held strictly liable as sellers. Their status

under current law is less certain. Some courts continue to treat them as sellers within the scope of this section. However, a substantial number of states have enacted legislation absolving non-manufacturer sellers of strict liability if the manufacturer is subject to the jurisdiction of the court and is capable of paying a potential judgment. Other states have reached similar results through judicial interpretation of the strict liability doctrine. The rule in this section leaves such issues to developing case law and statutes.

The rule stated in this section applies primarily to sellers of new products. The liability of commercial sellers of used products has been widely debated in the courts. Every court agrees that such sellers are liable for their negligence, but whether they may be held strictly liable is disputed. A majority of courts take the position that imposing strict liability on commercial sellers of used products does not further the policies expressed in comment *c*. On this view, used product markets are open to such variation that consumers are better served by freeing the market of the strictures of strict liability. A minority of courts have held that imposing strict liability pressures such sellers to improve inspection of used goods before placing them on the market, thus enhancing the safety of such consumer goods. The rule stated in this section takes no position on this issue, leaving its resolution to developing case law.

g. Manufacturing defects. A product is defective under subsection (2)(a) if it fails to meet the manufacturer's internal quality standards. The plaintiff bears the burden of establishing that such a defect existed in the product when it left the hands of the defendant-seller. It is disputed whether the plaintiff must establish the specific defect that caused the harm. Some courts have held that reasonable inferences may support a finding of liability under subsection (2)(a). Whether a given factual record supports such an inference is an issue for the court to decide as a matter of law in the first instance. In cases in which reasonable persons could differ, the issue is for the trier of fact.

Courts have struggled with the application of this standard in cases involving foodstuffs. Some have created a "foreign-natural" distinction, holding that foreign matter constitutes a defect whereas parts of the foodstuff that are natural to it, even if hazardous, do not. Thus, a fish bone in fish chowder has been held to be natural, whereas a chicken bone in a chicken sandwich has been held to be foreign matter. Courts have increasingly rejected this distinction, opting instead for a consumer-expectation test under which a foodstuff is defective if it contains matter not expected by a reasonable consumer. Although the consumer-expectation test has been widely criticized when applied in generic defect cases (see comment *h*), it

seems peculiarly adapted to cases involving manufacturing defects in foodstuffs.

h. Design defects. Courts have created several different tests to establish liability for design defects. A majority of courts use some version of a risk-utility balancing test, either by directly adopting a negligence approach or by adopting some version of the approach set forth in this section. Liability attaches only when the plaintiff proves that the defendant failed to adopt a safer, cost-effective design that would have prevented all or part of the plaintiff's harm. A significant number of courts, however, make recovery dependent on whether the product design fails to meet reasonable consumer expectations. Most of these courts also consider the availability of a reasonable-cost, safer alternative design in deciding whether the defendant's design is acceptable. Admittedly, the formal structure of the liability standard differs somewhat from one court to another. Whether the risk-utility balancing is based on the view of the reasonable consumer or the reasonable product seller is a detail left to the various jurisdictions.

The requirement in subsection (2)(b) that the plaintiff demonstrates that a safer design could have been adopted at reasonable cost introduces an important element of materiality. The alternative design must be sufficiently safer than the actual design to have prevented or substantially reduced the harm for which the plaintiff seeks recovery. *See* comment *l*. Thus, in almost every case, the plaintiff must do more than merely show that the defendant's design could have been made "just a little safer."

At bottom, the "reasonable-cost, safer design" approach discussed in this section is that taken by a majority of American courts. A few courts have adopted idiosyncratic tests for design defect. For example, one state court applies a standard whereby the manufacturer is made the "guarantor" of the product's safety. Another appears to apply a consumer-expectation test that has no risk-utility component. These opinions are not consistent with the rule stated in this section.

i. Categorical design liability not recognized. By referring explicitly to risk reduction through the adoption of a reasonable-cost, safer design, subsection (2)(b) makes clear that the social risk-utility balancing employed in judging the reasonableness of product designs will not be undertaken on a categorical basis. For the purposes of this analysis, product categories are relatively broad subsets of products for which, given their inherent design characteristics, no adequate alternatives are available. Examples include alcoholic beverages, tobacco products, handguns, and above-ground swimming pools. With respect to a product in such a category, plaintiffs are

unable to prove the availability of a safer design that does not eliminate the inherent characteristic that renders the product and other similar products attractive in the marketplace. For example, removing the alcohol from an alcoholic beverage not only removes the product from the category of alcoholic beverages, but also renders it unattractive to most consumers of alcoholic beverages. Alcohol-free “alcoholic beverages” are not, therefore, available to most consumers at “reasonable cost.” A plaintiff could attack such a product for its alcoholic quality only by attacking the larger category of alcoholic beverages as somehow per se unreasonably dangerous, something that subsection (2)(b) disallows.

Although courts in a few jurisdictions have purportedly allowed plaintiffs to condemn broad product categories as unreasonably dangerous, those decisions have been overturned by statute. Virtually every American jurisdiction now rejects product category liability. The inherent risks associated with product categories are typically open and obvious, and can be adequately managed in the marketplace. Moreover, the legal and factual issues raised in categorical product design litigation are beyond the capacities of courts to resolve. Decisions regarding which product categories should generally be available to users and consumers are best left to the marketplace or, in rare instances, to government regulators other than courts.

Of course, when a plaintiff can establish that a manufacturing defect caused injury; that a product unit could have been designed more safely without eliminating the inherent characteristics that both define it categorically and make it desirable for use and consumption; or that a product unit could have been distributed with more adequate and useful instructions and warnings, then the rule stated in this section supports liability. But judicial attacks on product categories, as such, are not recognized.

j. Warning defects. Subsection (2)(c) embraces a rule of liability long recognized by American courts: product sellers have a duty to provide reasonable instructions or warnings about nonobvious risks of injury associated with their products whenever a reasonable person in the seller’s position would have, or reasonably should have, known of such risks of injury and could have supplied instructions or warnings to someone in a position to act effectively on such information. In most cases, the duty is based on the seller’s knowledge at the time of sale, but under special circumstances post-sale duties to warn, based on later-acquired knowledge, may arise.

In any event, risks that should be obvious to reasonable persons need not be instructed about or warned against. In determining whether a risk is sufficiently obvious not to require a warning,

judges have an important initial role to play in screening cases and keeping clear cases from the jury. It is anticipated, however, that obviousness of risk will be assessed by the jury in all cases in which reasonable minds might differ.

Product warnings help to reduce risks when supplied to persons in positions to act effectively on that information. Thus, the persons to whom product warnings should be given typically include users and consumers, but also include anyone who a reasonable distributor should know is in a position to respond to the instruction or warning by reducing or eliminating the risk of injury. The requirement in subsection 402A(1) that the defective condition be shown to have "proximately caused" the harm to persons or property imposes on plaintiffs in warning cases the burden of proving that, if an adequate instruction or warning had been supplied, use and consumption would have been altered so as to reduce or eliminate the plaintiff's injury.

k. Prescription drugs (first alternative). Subject to the limitation recognized in comment *i*, courts may legitimately entertain causes of action based on most claims of defective product design. Notwithstanding this general rule, the overwhelming majority of jurisdictions have taken the position that a court is not to substitute its judgment for that of the prescribing physician regarding the design of a prescription drug. As long as the drug is marketed with warnings that adequately inform the prescribing physician of the drug's foreseeable dangers, the manufacturer is not held to the risk-utility standard set forth in subsection (2)(b). The position stated in this Comment applies to all prescription drugs as a matter of law, requiring no case-by-case examination of the risks and benefits of individual prescription drugs that are the subject of litigation.

k. Prescription drugs (second alternative). Subject to the limitation recognized in comment *i*, courts may legitimately entertain causes of action based on claims of inadequate design utilizing normal risk-utility standards. Notwithstanding this general rule, a majority of American jurisdictions recognize that special problems attend design defect litigation with respect to prescription drugs. Different drugs provide benefits to various subgroups of patients. It is normally the decision of the prescribing physician, who has received adequate warnings of the drug's benefits and detriments, whether or not to prescribe the drug. Thus, the only basis on which courts traditionally have held drug manufacturers liable is unreasonable failure to warn of known or knowable risks.

On occasion, however, drug designs are attacked as unsound on the ground that the harms they cause outweigh their overall benefit to society. A majority of courts have taken the position that

drug design litigation is unwise, and that a drug manufacturer has a duty only to warn prescribing physicians of foreseeable risks. Other courts allow design defect cases against the manufacturer of a prescription drug, but only after the trial court has made an initial determination that the risk-utility design standard may have been needlessly violated. Even courts that allow design defect litigation involving prescription drugs recognize that risk-utility balancing can only be accomplished based on the knowledge that was or should reasonably have been available to the drug manufacturer. Thus, when a court declares that a prescription drug is not subject to a design defect action it has for all practical purposes eliminated actions based on both negligence and strict liability. Of course, a drug manufacturer can always be held liable for failing to warn about risks associated with ingestion of the drug, pursuant to comment *j*.

l. Proximate causation. As subsection 402A(1) makes clear, the product defect must have proximately caused the plaintiff's harm for liability to be imposed under the rule stated in this section. Courts differ widely in their analysis of causation in products liability cases. Previous comments dealing with other provisions have referred to the causation issue. Regardless of the relevant terminology, causation presents four discrete factual issues in this context. Not every case involves all four; many cases are problematic with respect only to one or at most two such issues. And some courts merge these discrete causation issues under broader headings that tend to obscure the differences. But close analysis of decisions from many different jurisdictions suggests that, beneath the differing and often confusing rhetoric, products liability litigation presents these four basic factual issues.

First, the tribunal must determine whether the product unit (or, in the case of alternative liability, a product unit in the product line—see comment *e*) was a but-for cause-in-fact of the plaintiff's harm. Second, the tribunal must determine (subject to the alternative liability exception discussed in comment *e*) whether the defendant commercially distributed the product unit. Third, the tribunal must determine whether the defective condition of the product unit was a but-for cause of the plaintiff's harm. And fourth, the court must determine whether the type of harm suffered by the plaintiff was among the types of harm reasonably foreseeable when the defendant distributed the defective product unit. In most cases courts place on the plaintiff the burden of proof regarding causation.

In connection with the third causation issue—whether the defective condition of the product was a but-for cause of the plaintiff's harm—the plaintiff bears three different burdens of proof, depending on the type of defect involved. In cases involving manufacturing

defects, the plaintiff must prove that the same harm would not have occurred had the product unit not contained the defect. In cases involving design defects, the plaintiff must prove that the same harm would not have occurred had the defendant adopted the safer design suggested by the plaintiff. And in cases involving warning defects, the plaintiff must prove that the same harm would not have occurred had the defendant provided adequate instructions or warnings.

Again, courts employ different terminology to describe these causation issues. Some courts refer to the first and second issues, taken together, as "cause-in-fact" and to the third and fourth, taken together, as "proximate causation." Other courts refer to the first and third issues, taken together, as "cause-in-fact"; the second issue as "defendant identification"; and the fourth issue, taken alone, as "proximate cause." And some lump all four questions together under broad umbrella terms such as "substantial factor," "legal cause," "superceding or intervening cause," or "proximate causation." The rule stated in this section leaves the nuances of causation terminology to the developing case law. Nevertheless, enhanced clarity would result if courts utilized the functional definitions set forth in this comment.

m. Warranty. Most jurisdictions apply the rule stated in this section under the rubric of tort. Admittedly, the same liability rules could emanate from the action for breach of implied warranty of merchantability under the Uniform Commercial Code. Numerous courts have held that the rule stated in this section and implied warranty of merchantability are virtually identical. Factors collateral to the basic liability rule in this section support the preference for the tort characterization over that of implied warranty. For example, if the warranty framework were utilized, defendants would contend that the U.C.C. statute of limitations, which runs from the time of sale, should govern, rather than the tort statute of limitations, which runs from the time of injury. Or it could be argued that privity limitations, which still retain considerable vigor under traditional contract law, should define the eligibility of parties to suit. Furthermore, courts might be more likely to recognize disclaimers or other contract-based limitations on recovery if the action were contract-based rather than rooted in tort law. Placing the rule stated in this section firmly within tort doctrine permits courts to sidestep these issues.

Nonetheless, several jurisdictions have insisted that products liability cases based on the rule stated in this section be prosecuted under the Uniform Commercial Code. For the most part, they have utilized creative statutory interpretations to reach results closely

analogous to those reached by courts utilizing the implied warranty doctrine. Occasionally, decisions utilize “implied warranty strict liability” for product-related personal injury, reflecting the influence of contract doctrine. These nuances tend to be of minor importance. Courts generally have cut through to the bone to determine the essence of the cause of action. Even if the Uniform Commercial Code provides the label for the cause of action, tort doctrine defines the relevant issues for decision.

n. Contributory fault. The application of the contributory fault doctrine to products liability claims raises both serious policy issues and difficult questions of implementation. At the policy level, it has been argued that reducing the plaintiff’s recovery by the percentage of his fault compromises the policy decision to impose primary responsibility for such injuries on manufacturers to encourage them to produce safer products. At the level of practical implementation, courts have noted that comparing the fault of the plaintiff to a defect in the product is no easy task. This is especially true with regard to manufacturing defect cases in which no form of risk-utility balancing is utilized in establishing the defect. Notwithstanding these arguments, a majority of courts use comparative fault to reduce the recovery of a products liability plaintiff whose negligence has contributed to his injury. In cases involving design and warning defects, the issue takes on an added dimension because the defect is often the manufacturer’s failure to account for foreseeable (albeit arguably unreasonable) conduct on the part of the plaintiff. Thus, some courts hesitate to find plaintiffs contributorily at fault in design and warning defect cases. On the other hand, relieving consumers of all responsibility for safe product use defeats the objectives of products liability and runs against the grain of common sense. *See comment c.* The rule stated in this section accepts the majority view, allowing comparative fault to operate as a partial or total defense to a products liability claim depending on the general comparative fault rules in a given jurisdiction. This section takes no position on whether some forms of comparative fault should not be allowed as a defense or even partial mitigation; nor does it resolve the issue of whether assumption of the risk should operate as a total bar in some instances. This section leaves these issues for the developing case law.

o. Misuse, alteration, and modification. Occasionally a product is subject to post-sale misuse, alteration, or modification. When third persons engage in such conduct, its effects will be determined under the rules of proximate cause that govern products liability cases. *See comment l.* When plaintiffs engage in such conduct, its effects will ordinarily be determined by the rules of comparative fault set forth

herein. See comment *n*. Occasionally a plaintiff's misconduct is so egregious that it constitutes an intervening cause, eliminating the defendant's liability altogether.

p. Pure economic loss. The rule stated in this section applies only to products that cause harm to persons or property. If the plaintiff suffers only economic loss (e.g., loss of profits, costs of repair or replacement of the defective product), recovery is governed by the rules of the Uniform Commercial Code. The line of demarcation between physical damage to property and pure economic loss is not easy to draw. The courts appear intent on distinguishing between tort and contract, based on the nature of damages suffered. In doing so they generally pay little attention to whether the defective product had the inherent potential to cause serious physical harm to persons or property. This section leaves these issues for the developing case law.

III

AUTHOR'S NOTES

A. General Observations

If the truth be known, section 402A as originally drafted was not really a restatement of existing law.⁶ Products liability was in its infancy in 1963 when the American Law Institute (ALI) promulgated this most important provision. No one, for example, could have foreseen that language written primarily to govern manufacturing defect cases⁷ might be used by courts in design and warning defect cases. The common law rules governing design and warning defect litigation were still heavily mired in the limited-duty setting of the previous half-century.⁸ Nor could anyone have foreseen the dif-

⁶ Smyser, *supra* note 4, at 344. *But see* WILLIAM L. PROSSER, HANDBOOK OF THE LAW OF TORTS § 97 (3d ed. 1964).

⁷ See PROSSER, *supra* note 6, § 96. Almost contemporaneously with the writing of the *Restatement*, Prosser acknowledges that strict liability has had little impact on product liability claims based on defective design or failure to warn. Prosser predicts that these claims, unlike claims based on manufacturing defect, will continue to be grounded in negligence. It is clear from reading the treatise sections dealing with product liability that Prosser envisaged § 402A as having its primary effect on cases of manufacturing defects. George L. Priest, *Strict Products Liability: The Original Intent*, 10 CARDOZO L. REV. 2301 (1989).

⁸ See, e.g., *Evans v. General Motors Corp.*, 359 F.2d 822 (7th Cir.) (no duty to design accident-proof vehicles), *cert. denied*, 385 U.S. 836 (1966), *overruled by* *Huff v. White Motor Corp.*, 565 F.2d 104 (7th Cir. 1977); *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 901 (Cal. 1962) (manufacturer's liability goes only to product's intended use), *modified by* *Barker v. Lull Eng'g Co.*, 573 P.2d 443, 457-58 (Cal. 1978) (liability attaches when plaintiff is injured while foreseeably misusing a product); *Campo v. Scofield*, 95 N.E.2d 802 (N.Y. 1950) (no duty to design against open and obvious dangers), *overruled by* *Micallef v. Miehle Co.*, 348 N.E.2d 571 (N.Y. 1976). When § 402A was written, contributory negligence was still a total bar to recovery in most jurisdictions.

ficult causation problems that would arise with regard to defendant identification.⁹ The list of unresolved issues could go on and on.¹⁰ In any event, as a prestatement, section 402A served as a marvelous catalyst to change. It shook American courts out of their doldrums and invited them to re-examine many premises that stood as impediments to plaintiff recovery. "Strict liability" became more than a legal doctrine. It was the clarion call for a liability system free of artificial and often wooden restraints on liability. Faced with substantial authority to the contrary, plaintiffs could point to section

Though the comments limited the role of contributory negligence in products liability cases, it and its twin, assumption of the risk, played an important role in limiting liability for generic defects. Since then, of course, comparative fault has been enacted in 45 jurisdictions. For the most part, contributory negligence has thus departed from the scene as a total bar to recovery. See VICTOR E. SCHWARTZ, *COMPARATIVE NEGLIGENCE* § 1.1 (2d ed. 1986).

⁹ See *Sindell v. Abbott Lab.*, 607 P.2d 924 (Cal.), *cert. denied*, 449 U.S. 912 (1980); *Hymowitz v. Eli Lilly & Co.*, 539 N.E.2d 1069 (N.Y.), *cert. denied*, 493 U.S. 944 (1989).

¹⁰ The following is a partial list of issues that were either unresolved or totally unforeseen when § 402A was drafted:

(1) Liability to the indeterminate plaintiff or liability based on proportional causation. See *In re Agent Orange Prod. Liab. Litig.*, 597 F. Supp. 740, 837 (E.D.N.Y. 1984), *aff'd*, 818 F.2d 145 (2d Cir. 1987), *cert. denied*, 484 U.S. 1004 (1988); *Herskovits v. Group Health Coop.*, 664 P.2d 474 (Wash. 1983);

(2) Liability for lessors, commercial builders, franchisors, etc. See, e.g., *Harris v. Aluminum Co. of Am.*, 550 F. Supp. 1024 (W.D. Va. 1982); *Cintrone v. Hertz Truck Leasing & Rental Serv.*, 212 A.2d 769 (N.J. 1965); *Schipper v. Levitt & Sons, Inc.*, 207 A.2d 314 (N.J. 1965);

(3) The problems of damage assessment arising from second-collision liability, whether against defendant in crashworthiness cases or against plaintiff in failing to use seat belts. See, e.g., *Huddell v. Levin*, 537 F.2d 726 (3d Cir. 1976); *Waterson v. General Motors Corp.*, 544 A.2d 357 (N.J. 1988);

(4) Liability in cases involving sale of used products. See, e.g., *Crandell v. Larkin and Jones Appliance Co.*, 334 N.W.2d 31 (S.D. 1983);

(5) The difficulty in drawing a line between sales and service. See, e.g., *Murphy v. E.R. Squibb & Sons, Inc.*, 710 P.2d 247 (Cal. 1985); *Magrine v. Krasnica*, 227 A.2d 539 (N.J. Super. Ct. Law Div. 1967), *aff'd sub nom. Magrine v. Spector*, 250 A.2d 129 (N.J. 1969);

(6) The difficulties of working out the relationship between comparative fault and strict tort liability. See, e.g., *Murray v. Fairbanks Morse*, 610 F.2d 149 (3d Cir. 1979);

(7) The problems related to recognizing a cause of action for mental distress arising from products related injuries. See, e.g., *Payton v. Abbott Lab.*, 437 N.E.2d 171 (Mass. 1982); *Kennedy v. McKesson Co.*, 448 N.E.2d 1332 (N.Y. 1983);

(8) The difficulties in deciding which forms of product related economic loss were to be covered by products liability law and which were to be governed by the Uniform Commercial Code. See, e.g., *East River S.S. Corp. v. Transamerica Delaval Inc.*, 476 U.S. 858 (1986);

(9) Whether there is a duty to warn of scientifically unknowable or unforeseeable risks. See, e.g., *Anderson v. Owens-Corning*, 810 P.2d 549

402A and argue with relative impunity that the old rules governed only the universe of negligence. Strict liability was different.¹¹

A quarter century has passed. The pace of American products liability litigation has been fast and furious. We can say with some confidence that if we have not yet seen all the problems raised in such litigation, we have seen most of them. It is also fair to say that although courts continue to differ on many issues, enormous consensus has evolved regarding fundamental questions. This consensus requires further description and elaboration. First, on many issues there is simply broad-based, flat-out agreement as to doctrine.¹² Second, in those instances in which courts differ with respect to doctrine, careful analysis reveals that despite the somewhat different verbalizations, the core approaches to the underlying problems are remarkably similar.¹³ Third, even where underlying differences can be substantiated, the practical implications for litigants often turn out to be smaller than they seem at first.¹⁴ Finally, we believe that some of the disagreement is the product of a fragmented approach to the subject matter. In the absence of a thorough and easily articulated alternate standard, courts often opt to

(Cal. 1991); *Beshada v. Johns-Manville Prods. Corp.*, 447 A.2d 539 (N.J. 1982);

(10) A product manufacturer's duty to provide an informed choice warning even when the warning would not reduce risk. *See, e.g., Finn v. G.D. Searle & Co.*, 677 P.2d 1147 (Cal. 1984);

(11) The complex interaction between design defect and failure to warn. *See, e.g., Uloth v. City Tank Corp.*, 384 N.E.2d 1188 (Mass. 1978);

(12) Whether liability will attach even if manufacturer met state-of-the-art standards extant at the time of manufacture. *See, e.g., Boatland of Houston v. Bailey*, 609 S.W.2d 743 (Tex. 1980);

(13) Whether a manufacturer has a duty to install safety devices rather than provide such devices as options to the purchaser. *See, e.g., Bilotta v. Kelley Co.*, 346 N.W.2d 616 (Minn. 1984);

(14) Liability of successor corporations for product related harms caused by their predecessors. *See, e.g., Martin v. Abbott Lab.*, 689 P.2d 368 (Wash. 1984).

¹¹ *See, e.g., Barker v. Lull Eng'g Co.*, 573 P.2d 443 (Cal. 1978) (altering burden of proof as to risk-utility balancing on grounds of strict liability); *Prutch v. Ford Motor Co.*, 618 P.2d 657 (Colo. 1980) (requiring each member of the distributive chain to prove that the product was not defective when it left its hands in order to effectuate the policies behind strict liability); *Jacobs v. Technical Chem. Co.*, 472 S.W.2d 191 (Tex. Civ. App. 1971) (altering traditional causation rules on grounds of strict liability), *rev'd*, 480 S.W.2d 602 (Tex. 1972).

¹² There is, for example, virtually no disagreement that:

(1) strict liability sans risk-utility is the governing standard for manufacturing defect cases;

(2) strict liability does not apply to pure services or to cases in which the service function predominates;

(3) strict liability applies to commercial lessors, sellers of new homes, franchisors, etc.

¹³ *See infra* notes 21-23 and accompanying text.

¹⁴ *See infra* notes 24-25 and accompanying text.

go their own way, carving out a separate niche for themselves.¹⁵ In short, the time is ripe for a true restatement of products liability law.

We make no bones about it. We have drafted our proposed revision of section 402A to reflect a broad consensus view. When faced with a choice of drafting language in either the black letter text or the comments that introduces nuanced conflict or reflects consensus, we have opted for the latter. If courts in the future wish to debate the niceties and fine points, that is their prerogative. This proposed revision of section 402A, were it eventually to be adopted, would not stand in their way. But we hope the courts will also come to realize that beyond the minor points of disagreement stands a rather imposing doctrinal structure to which almost all pay allegiance.

In drafting our proposed revision, we face a logistical problem of considerable magnitude. Over the past decade thirty-eight state legislatures have passed statutes dealing with product liability law as part of their tort reform proposals.¹⁶ Had we sought to account for all the differences among states, it would have been impossible to draft a restatement. However, by dealing with broad consensus principles, it is possible to embrace a basic structure without running afoul of the state statutes. For the most part, products liability reform statutes do not stake out new principles of law; rather, they constitute adaptations of fundamental principles, each setting forth its own nuances. Thus, most reform statutes fit nicely into our revised black letter restatement of existing law.¹⁷

Products liability mavens will note that we have not dealt with or commented upon every controversial issue in products liability

¹⁵ Cases such as *Azzarello v. Black Bros. Co.*, 391 A.2d 1020 (Pa. 1978), and *Campbell v. General Motors Corp.*, 649 P.2d 224 (Cal. 1982), came about, in our opinion, because the *Restatement* had failed to update its definition of defect to reflect the broad consensus that exists among the states. In the absence of a broadly stated consensus view, courts have tended toward idiosyncratic and extremist positions.

¹⁶ The statutes are collected in the *Prod. Liab. Rep.* (CCH) vol. 2.

¹⁷ For example, statutes requiring a technologically feasible alternative as a predicate to design-based liability are fully consistent with our proposed *Restatement*. See, e.g., IOWA CODE ANN. § 668.12 (West 1987); N.J. STAT. ANN. § 2A: 58C-3.a.(1) (West 1987); OHIO REV. CODE ANN. § 2307.75(F) (Anderson 1991). Other statutes present slightly different nuances, but fall well within the tenor of the revision. See, e.g., ARIZ. REV. STAT. ANN. § 12-683(1) (1992) (authorizing affirmative defense upon proof that product plans, manufacturing methods, inspection, testing, and labelling conformed with state of the art); KY. REV. STAT. ANN. § 411.310(2) (Baldwin 1991) (authorizing presumption of no defect upon proof of manufacturer's adherence to state of the art in design, manufacturing methods, and testing); WASH. REV. CODE ANN. § 7.72.050(1) (West Supp. 1992) (allows trier of fact to consider evidence-of-industry custom, technological feasibility, or compliance with nongovernmental or legislative regulatory standards).

Similarly, statutes dealing with such issues as product misuse, modification and alteration fall within the general framework of comment o of our proposed *Restatement*. See, e.g., ARIZ. REV. STAT. ANN. § 12-683 (1992); IDAHO CODE § 6-1405(4) (1990); IND.

law. We acknowledge that we have omitted many issues from our discussion.¹⁸ To do otherwise would require that we abandon our effort to write a restatement and instead author a treatise on the law of products liability. On the other hand, we have taken firm positions on a number of central issues, especially when the comments are taken into account.¹⁹ By definition, a restatement challenges the writer to outline the widely accepted principles that govern an area of the law. Others working from our proposal may challenge the wisdom of any given omission. Such debate is welcome, with the proviso that the sum of suggested additions not undo the effort to restate the law in a manner that is both useful to and useable by the bench and bar. It would be helpful to bear in mind that if efforts to revise section 402A fail, the alternative is the retention of an outdated and misleading section 402A—one that might have been a work of art in the era of violent change that followed its adoption, but which is today incapable of reflecting the reality of literally thousands upon thousands of decided cases.

B. Specific Problems

1. *Negligence vs. Strict Liability*

The reader will search the proposed black letter and comments in vain to find explicit language outlining whether design and warning defects are governed by strict liability. We have taken no explicit position on this issue because it seems to us that the debate is

CODE § 33-1-1.5-4 (1982). *But see* MONT. CODE ANN. § 27-1-719 (1991); N.D. CENT. CODE § 28-01.1-04 (1991).

Many of the subjects of statutory tort reform are not touched upon in our proposed *Restatement* and its comments. Thus, subjects such as statutes of repose, punitive damages, joint and several liability, caps on damages for pain and suffering, and worker's compensation, which have been the subject of considerable legislative attention, are not discussed in the proposed revision of the *Restatement*.

¹⁸ For example, we have not dealt with such questions as: (1) who has the burden of proving enhanced damages in second-collision litigation; (2) whether the manufacturer has a duty to install safety features or can shift the duty to purchasers by providing optional equipment; (3) whether disclaimers can play any role in precluding liability in cases in which plaintiffs have suffered personal injury; or (4) whether compliance with statutory standards or industry custom is a defense to a claim based on design defect or failure to warn.

¹⁹ The most significant position we have taken, of course, relates to the legal standards for determining product defectiveness. Subsections (2)(a), (b) and (c) set forth the relevant substantive provisions for the three basic types of defect. In addition, we opt for a time-of-distribution perspective regarding knowledge of risks and risk avoidance, and reject consumer-expectation as an independently sufficient test for generic defect. We also explicitly reject product category liability and spell out the substance, if not the superficial rhetoric, of causation. Our first alternative version of comment *k*, which we prefer, explicitly precludes design review of prescription drugs. Further, we exclude casual sales. Thus, those critics who conclude we have not been aggressive enough may not have read our proposal carefully enough.

of little substance. As we note in comment *b*, liability attaches for a manufacturing defect even though the seller has exercised reasonable care. Manufacturing defect injuries are random and relatively rare events. Imposing strict liability achieves all the policy benefits described in comment *c* and presents virtually no downside costs. On the other hand, liability for design and warning defects cannot be established by merely mouthing the word "defect." An overwhelming consensus favors some sort of risk-utility balancing test to judge the adequacy of product design and marketing.²⁰

Are the risk-utility tests set forth in subsections (2)(b) and (2)(c) synonymous with a negligence standard? They may be so viewed, but need not be. Clearly, if risk-utility balancing were accomplished by utilizing time-of-trial information, the risk-utility test would be far different from a negligence standard.²¹ But we have carefully examined the case law and have concluded that the overwhelming majority of jurisdictions impose a time-of-sale foreseeability limita-

²⁰ See, e.g., *Camacho v. Honda Motor Co.*, 741 P.2d 1240 (Colo. 1987), *cert. dismissed*, 485 U.S. 901 (1988); *Lease v. Int'l Harvester Co.*, 529 N.E.2d 57, 62 (Ill. App. Ct. 1988); *Aller v. Rodgers Mach. Mfg. Co.*, 268 N.W.2d 830 (Iowa 1978); *Nichols v. Union Underwear Co.*, 602 S.W.2d 429 (Ky. 1980); *Lavespere v. Niagara Mach. & Tool Works, Inc.*, 910 F.2d 167 (5th Cir. 1990) (applying Louisiana law and adopting risk-utility test as standard for design defect liability); *St. Germain v. Husqvarna Corp.*, 544 A.2d 1283 (Me. 1988); *Troja v. Black & Decker Mfg. Co.*, 488 A.2d 516, 518-19 (Md. Ct. Spec. App.), *cert. denied*, 494 A.2d 939 (Md. 1985); *Kotler v. Am. Tobacco Co.*, 926 F.2d 1217 (1st Cir. 1990) (applying Massachusetts law); *Back v. Wickes Corp.*, 378 N.E.2d 964, 970 (Mass. 1978); *Prentis v. Yale Mfg. Co.*, 365 N.W.2d 176 (Mich. 1984); *Billota v. Kelley Co.*, 346 N.W.2d 616, 622 (Minn. 1984); *Whitley v. City of Meridian*, 530 So.2d 1341 (Miss. 1988); *Lewis v. Bucyrus-Erie, Inc.*, 622 S.W.2d 920, 927 (Mo. 1981); *Rix v. General Motors Corp.*, 723 P.2d 195 (Mont. 1986); *Thibault v. Sears, Roebuck & Co.*, 395 A.2d 843 (N.H. 1978); *Michalko v. Cooke Color & Chem. Corp.*, 451 A.2d 179, 183 (N.J. 1982); *Voss v. Black & Decker Mfg. Co.*, 450 N.E.2d 204 (N.Y. 1983); *Roach v. Kononen*, 525 P.2d 125, 129 (Or. 1974); *Azzarello v. Black Bros. Co.*, 391 A.2d 1020 (Pa. 1978); *Motter v. Everest & Jennings, Inc.*, 883 F.2d 1223, 1227 (3d Cir. 1989) (applying Pennsylvania law) (court held trial judge must "evaluate the risks of a product versus its social utility" in order to determine whether the issue of defect should be submitted to a jury); *Turner v. General Motors Corp.*, 584 S.W.2d 844 (Tex. 1979); *Falk v. Keene Corp.*, 782 P.2d 974, 979-80 (Wash. 1989); *Baughn v. Honda Motor Co.*, 727 P.2d 655 (Wash. 1986); *Morningstar v. Black & Decker Mfg. Co.*, 253 S.E.2d 666, 682-83 (W. Va. 1979). The language in *Falk* is confusing. It would appear that Washington may now apply an alternative liability test allowing recovery based on either failed consumer expectations or risk-utility. See *infra*.

Several states allow a plaintiff to establish a case of generic defect by establishing that the product either failed to meet consumer expectations or failed to meet risk-utility norms. See, e.g., *Caterpillar Tractor Co. v. Beck*, 593 P.2d 871 (Alaska 1979); *Dart v. Wiebe Mfg.*, 709 P.2d 876 (Ariz. 1985); *Barker v. Lull Eng'g Co.*, 573 P.2d 443 (Cal. 1978); *Ontai v. Straub Clinic & Hosp. Inc.*, 659 P.2d 734 (Haw. 1983); *Knitz v. Minster Mach. Co.*, 432 N.E.2d 814 (Ohio), *cert. denied*, 459 U.S. 857 (1982); *Falk*, 782 P.2d at 980.

²¹ See, e.g., *Beshada v. Johns-Manville Prods. Corp.*, 447 A.2d 539, 545-46 (N.J. 1982); *Carreter v. Colson Equip. Co.*, 499 A.2d 326, 332 (Pa. Super. Ct. 1985).

tion on the definitions of design and warning defect,²² subject to exceptions for post-sale obligations.²³ A manufacturer is not held liable for unforeseeable risks or for failing to utilize unforeseeable technology to avoid known risks. Comment *c* reflects this position as that of our revision. From this perspective, design and warning defect liability begins to look very much like negligence. However, it is still possible to articulate a test slightly more stringent than that used to establish negligence, even with the imposition of a foreseeability requirement. Under this rule, liability would be strict if, utilizing only foreseeable data, the product as designed and marketed should not have been distributed in light of risk-utility norms.²⁴ In our opinion, it is unlikely that the distinction between this test and the negligence test is sufficiently significant to warrant the creation of a separate track for liability. In any event, we do not believe that the issue is of sufficient moment to saddle our revision with it.

2. Risk Utility vs. Consumer Expectations

The black letter rule in our revised section 402A establishes reasonableness as the governing standard for liability in design de-

²² The overwhelming majority of jurisdictions that adopt some form of state-of-the-art policy limit liability to foreseeable risks. See authorities cited *supra* note 17. The leading case imposing liability for unforeseeable risks, *Beshada*, 447 A.2d 539, has been drastically limited by a later case, *Feldman v. Lederle Labs.*, 479 A.2d 374 (N.J. 1984). Foreseeability is a mandatory element of failure-to-warn criteria in all but a few jurisdictions. See James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. REV. 265, 274-75 (1990).

²³ See, e.g., *Kozlowski v. John E. Smith's Sons Co.*, 275 N.W.2d 915 (Wis. 1979) (manufacturer who had maintained contact with purchaser owed duty to notify him of post-sale availability of safety device); see generally Robert A. Royal, *Post Sale Warnings: A Review and Analysis Seeking Fair Compensation Under Uniform Law*, 33 DRAKE L. REV. 817 (1984) (discussing post-sale duty to warn).

²⁴ See, e.g., *Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549, 559 (Cal. 1991)

([A] reasonably prudent manufacturer might reasonably decide that the risk of harm was such as not to require a warning as, for example, if the manufacturer's own testing showed a result contrary to that of others in the scientific community. Such a manufacturer might escape liability under negligence principles. In contrast, under strict liability principles the manufacturer has no such leeway; the manufacturer is liable if it failed to give warning of dangers that were known to the scientific community at the time it manufactured or distributed the product.);

Falk v. Keene Corp., 767 P.2d 576, 580-81 (Wash. Ct. App.) ("[Strict liability] focuses on a manufacturer's defective product, the burden of an alternative design, and consumer expectations. As such, it is a fundamentally and irreconcilably different analysis from negligence, which focuses on a manufacturer's conduct."), *aff'd*, 782 P.2d 974 (Wash. 1989) (en banc); see also *Woodill v. Parke Davis & Co.*, 402 N.E.2d 194, 198 (Ill. 1980) (failure to warn requires scienter, but "strict liability has been upheld as a distinguishable doctrine from its counterpart in negligence, based on the fact that it is the inadequacy of the warning that is looked to, rather than the conduct of the particular manufacturer"); *Owens-Illinois, Inc. v. Zenobia*, 601 A.2d 633 (Md. 1992).

fect and failure to warn cases. The only serious alternative to such a standard is the consumer-expectation test.²⁵ Based on our review of the cases, however, we conclude that even courts that apply a consumer-expectation test rarely do so without tempering it with significant risk-utility balancing.²⁶ Consumer expectations are at the very least one factor to work into a risk-utility analysis.²⁷ What consumers expect from product performance suggests how risks are perceived and whether consumers can take self-protective action to avoid injury. That some courts would put greater emphasis on consumer expectations within the context of risk-utility, and some less, is not surprising. As long as risk-utility standards are part of the

²⁵ See *supra* note 20. The six states that have adopted liability based on either consumer expectations or risk-utility must be included in the category of those which allow liability to be predicated on consumer expectations. See, e.g., *Campbell v. General Motors Corp.*, 649 P.2d 224 (Cal. 1982). Other states appear to have adopted a consumer-expectation test as the sole standard for imposing liability. See, e.g., *Lester v. Magic Chef, Inc.*, 641 P.2d 353 (Kan. 1982); *Rahmig v. Mosely Mach. Co.*, 412 N.W.2d 56 (Neb. 1987). The UTAH CODE ANN. § 78-15-6(2) (1992) explicitly adopts the consumer-expectation test as the standard for establishing defect.

The authors confess to having had difficulty in getting a clear reading on the number of states that use a consumer-expectation test to impose liability. Many states have expressed some allegiance to a consumer-expectation test. However, the courts adopting the consumer-expectation test often deny liability on the grounds that the product met the expectations of the ordinary consumer. See, e.g., *Gray v. Manitowoc Co.*, 771 F.2d 866 (5th Cir. 1985); *Vincer v. Esther Williams All-Aluminum Swimming Pool Co.*, 230 N.W.2d 794 (Wis. 1975). The acid test determining whether liability will attach based on consumer expectations alone asks whether, if the product met risk-utility norms, liability could be separately established based on failed consumer expectations. That issue has rarely been addressed directly by the courts.

²⁶ See, e.g., *Aller v. Rodgers Mach. Mfg. Co.*, 268 N.W.2d 830, 835 (Iowa 1978) (After concluding that risk-utility balancing was necessary to establish defect, the court said,

In strict liability the plaintiff takes the design as it was finalized in the finished product and shows it was both dangerous and that it was unreasonable to subject the user to this danger because the user would not contemplate the danger in the normal and innocent use of the product or consumption of the product.);

Baughn v. Honda Motor Co., 727 P.2d 655, 660 (Wash. 1986) (describing the *Tabert* test as "a consumer expectations test with a risk-utility base"); *Seattle-First Nat'l Bank v. Tabert*, 542 P.2d 774, 779 (Wash. 1975) ("In determining the reasonable expectations of the ordinary consumer, a number of factors must be considered [including t]he relative cost of the product, the gravity of the potential harm from the claimed defect and the cost and feasibility of eliminating or minimizing the risk . . .").

²⁷ The original § 402A held strictly liable "[o]ne who sells any product in a defective condition unreasonably dangerous to the user or consumer." RESTATEMENT (SECOND) OF TORTS § 402A (1965). Comment *i* contained the following definition of "unreasonably dangerous": "The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it . . ." *Id.* cmt. *i*. In one of the most influential law review articles ever written on the subject, Professor Wade suggested seven factors that should be balanced in determining whether a product is "reasonably safe." See John Wade, *On the Nature of Strict Tort Liability for Products*, 44 *Miss. L.J.* 825, 837-38 (1973). Wade's sixth factor closely resembles "consumer expectations."

mix, whether courts characterize the test for defect as "risk-utility" or "consumer-expectation" is of relatively minor importance. Terminology does count for something, and we urge courts to use terminology that clarifies rather than obfuscates. At most, however, the various formulations express slightly different points of emphasis.

A few courts do seem to follow a straightforward consumer-expectation test, untempered by considerations of reasonable product safety.²⁸ As numerous courts and commentators have noted, this approach to liability is so open-ended and unstructured that it provides almost no guidance to the jury in determining whether a defect existed.²⁹ It also leaves manufacturers uncertain of the law's demands regarding product design. Our proposed restatement rejects this extreme view and reflects the broad consensus that dominates design and warning defect litigation.

3. *Causation*

Our proposed revision takes the position that the plaintiff normally has the burden of proving causation. Comment *l* details the various uses of the term "causation" that courts have applied in products liability decisions. We have not touched on all the causation problems that arise in products liability litigation—to do so would require a long exegesis. For example, the phrase "burden of proof" consists of two components: the burden of production and the burden of persuasion. Most courts place the latter burden on the plaintiff with respect to all issues of causation, and initially place the burden of production regarding defendant identification and cause-in-fact on the plaintiff as well.³⁰ Many courts minimize the plaintiff's burden of production regarding but-for proximate causation and foreseeable consequences.³¹ This approach comports with common sense; once the plaintiff has demonstrated a product defect

²⁸ See authorities cited *supra* note 25.

²⁹ See, e.g., *Bilotta v. Kelley Co.*, 346 N.W.2d 616 (Minn. 1984); *Turner v. General Motors Corp.*, 584 S.W.2d 844, 851 (Tex. 1979); W. Page Keeton, *Products Liability—Design Hazards and the Meaning of Defect*, 10 CUMB. L. REV. 293, 310 (1979); Gary Schwartz, *Foreword: Understanding Products Liability*, 67 CAL. L. REV. 435, 476 n.241 (1979); Model Uniform Product Liability Act, 44 Fed. Reg. 62, 714; analysis accompanying § 104.

³⁰ See, e.g., *Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823, 825 (D.C. Cir. 1988) ("[J]udgment n.o.v. was proper because the opinions of the [plaintiff's] experts were inadequate to demonstrate causation [in fact] by a preponderance of the evidence."), *cert. denied*, 493 U.S. 882 (1989).

³¹ See, e.g., *Bastow v. General Motors Corp.*, 844 F.2d 506, 508 (8th Cir. 1988) ("Questions of proximate cause generally are for the jury . . ."); *Landis v. Sumner Mfg. Co.*, 750 S.W.2d 466 (Mo. Ct. App. 1988) (after proof of defective design and cause-in-fact, issue of whether defect proximately caused injury was for the jury to determine based on all the factual circumstances).

and cause-in-fact, it is the defendant who normally raises "but it would have happened anyway" arguments.

Moreover, our revision does not address issues such as whether the plaintiff bears the burden of establishing second-collision injuries,³² or whether the plaintiff in a warning case is entitled to a presumption that had a warning been given it would have been heeded.³³ From time to time issues will arise in which courts will be required to alter traditional burdens of proof. When they do so, it should be with the realization that they are departing from the general governing rule that the plaintiff bears the burden of proving causation. Case law reflecting these departures from traditional causation rules does not lend itself to a consensus rule.³⁴ We prefer to establish the generalization and leave the subtleties to the courts as the problems arise.

With respect to terminology, we are aware of the *Restatement (Second) of Torts*'s use of the phrase "legal cause"³⁵ and the confusion generated in some settings by use of the phrase "proximate cause."³⁶ Nevertheless, we believe that the latter phrase is used

³² For an excellent discussion of the conflicting views as to who should bear the burden of proof as to the extent of second collision injuries once it is established that defendant contributed to the enhanced injuries, see *Sumnicht v. Toyota Motor Sales, U.S.A.*, 360 N.W.2d 2 (Wis. 1984).

³³ Several courts have adopted such a presumption. See, e.g., *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1281 (5th Cir.) (applying Texas law), cert. denied, 419 U.S. 1096 (1974); *Nissen Trampoline Co. v. Terre Haute First Nat'l Bank*, 332 N.E.2d 820, 826-27 (Ind. Ct. App. 1975), rev'd on procedural grounds, 358 N.E.2d 974 (Ind. 1976); *Wooderson v. Ortho Pharmaceutical Corp.*, 681 P.2d 1038, 1057 (Kan.), cert. denied, 469 U.S. 965 (1984); *Wolfe v. Ford Motor Co.*, 376 N.E.2d 143, 147 (Mass. App. Ct. 1978); *Butz v. Werner*, 438 N.W.2d 509, 517 (N.D. 1989); *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 838 (Ohio 1981); *Technical Chem. Co. v. Jacobs*, 480 S.W.2d 602, 606 (Tex. 1972). But see *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 812 (5th Cir. 1992) (holding that plaintiff must establish that an adequate warning would have been heeded); *Potthoff v. Alms*, 583 P.2d 309, 311 (Colo. Ct. App. 1978) (affirming trial court's refusal to instruct jury that if a warning is given, it will be heeded).

³⁴ The time is not yet ripe for drawing any conclusions with regard to the warning presumption, as too few courts have spoken definitively on the subject. Furthermore, it is not yet clear what kind of evidence will be sufficient to rebut such a presumption. *Compare Magro v. Ragsdale Bros., Inc.*, 721 S.W.2d 832 (Tex. 1986) with *Overpeck v. Chicago Pneumatic Tool Co.*, 823 F.2d 751, 756 (3d Cir. 1987).

³⁵ See RESTATEMENT OF TORTS (SECOND) § 431 (1965).

³⁶ See, e.g., NEBRASKA JURY INSTRUCTIONS § 3.41 (1969):

By "proximate cause" is meant a moving or effective cause or fault which, in a natural and continuous sequence (unbroken by an efficient intervening cause), produces the (harm, accident, injury, collision, occurrence) and without which the (harm, accident, injury, collision, occurrence) would not have occurred.

A "proximate result" is that result brought about or produced by a proximate cause. It must have been a natural and probable consequence which was, or ought to have been, reasonably foreseen or anticipated in the light of attendant circumstances. (It is not required, however, that the particular [harm, accident, injury, collision, occurrence], or the pre-

much more frequently than the former,³⁷ and should not create confusion given the content of comment *l*.

4. *Prescription Drugs*³⁸

We have presented two alternative versions of comment *k*, each addressing prescription drugs. The shorter version, which limits plaintiffs in this area to actions for failure to warn, reflects the traditional approach. The longer version, which allows for limited judicial review of drug design, reflects recent developments in a growing minority of jurisdictions. We prefer the shorter version embracing traditional law; in our view, courts should not review the adequacy of prescription drug designs. But if one views the recent departures from that tradition as the beginning of a significant trend, one should at least consider an approach more in keeping with that trend. In any event, one's choice should be constrained to one or the other proffered alternatives, both of which were drafted in light of the issues raised by courts inclined to question the traditional "no design liability" gloss placed on comment *k*. These issues include whether comment *k* should apply only to prescription drugs; whether the defendant drug companies should bear the burden of proving the unavoidably unsafe nature of their drugs, and if so, how heavy that burden should be; whether judges or juries should perform the relevant design review; and whether, if comment *k* applies and bars strict liability for drug design under section 402A, the plaintiff should be allowed to seek judicial review of the defendant's design choices on the basis of negligence.

cise nature and extent thereof, or the exact manner of its happening, was or should have been foreseen.)

See generally JAMES A. HENDERSON, JR. & AARON D. TWERSKI, *PRODUCTS LIABILITY: PROBLEMS AND PROCESS* 240-42 (2d ed. 1992).

³⁷ The following LEXIS searches were conducted in the products liability library using the combined state and federal files: prox! caus! and legal! caus!. The search revealed that in the last ten years courts have used "proximate cause" 4,261 times, and "legal cause" only 606. Thus, courts favored "proximate cause" over "legal cause" by more than seven to one.

³⁸ Almost all jurisdictions pay some allegiance to comment *k*. The text of comment *k* is reproduced in an appendix to this Article. We have found only one state court decision that claims to reject comment *k*. *Collins v. Eli Lilly Co.*, 342 N.W.2d 37, 52 (Wis.), cert. denied, 469 U.S. 826 (1984). A handful of states have not spoken to the issue. The various interpretations of comment *k* are discussed in the ensuing material. The subject of liability for prescription drugs has drawn considerable academic attention. See, e.g., Frank M. McClellan, *Strict Liability For Drug Induced Injuries: An Excursion Through the Maze of Products Liability, Negligence and Absolute Liability*, 25 WAYNE L. REV. 1 (1978); Richard A. Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1 (1973); Joseph A. Page, *Generic Product Risks: The Case Against Comment k and for Strict Tort Liability*, 58 N.Y.U. L. REV. 853 (1983); John P. Reilly, *The Erosion of Comment k*, 14 U. DAYTON L. REV. 255 (1989); Victor E. Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment k*, 42 WASH. & LEE L. REV. 1139 (1985); Sidney H. Willig, *The Comment k Character: A Conceptual Barrier to Strict Liability*, 29 MERCER L. REV. 545 (1978).

Our first alternative version of comment *k* reflects a disposition to exclude judicial inquiry into any of the foregoing issues. The second alternative version intends to exclude inquiry into the last two issues identified above, but arguably leaves the first three to developing case law. The second alternative on its terms limits itself to prescription drugs. But having to some extent opened drug design to judicial review, the second alternative invites, to a greater extent than the first, further developments with respect to the first three issues identified above.

In attacking the “no drug design liability” gloss traditionally placed on comment *k*, courts in recent years have re-examined the text of that comment and have purported to find therein support for the various positions they have adopted. In doing so courts have committed serious error. Indeed, in a growing number of states the case law addressing the standard for establishing liability in prescription drug cases is in disarray. The problem can in large part be attributed to the existing comment *k*, which is poorly drafted and internally inconsistent. But the major difficulty with using the existing comment *k* to resolve questions of whether and how courts should review design of prescription drugs is that these issues were not at all within the contemplation of its drafters. To draw on comment *k* as authority to resolve problems that no one even contemplated at the time of its adoption is sheer foolishness.

Before undertaking a search for the appropriate standard to govern drug design and warning litigation, it is imperative that we fully understand the factual predicate that triggers the need for a discrete design standard. The overwhelming majority of prescription drug liability cases are based on the failure to adequately warn or inform³⁹ either the doctor or patient of risks attending ingestion of the drug. Cases alleging that a drug was defectively designed are uncommon.⁴⁰

³⁹ Drug warnings can serve either to reduce the risk of injury or to provide a patient or doctor with the information to choose a form of drug therapy that involves a non-reducible risk of injury. For an extensive discussion of these two types of warnings, see Henderson & Twerski, *supra* note 22, at 285-89; see also Wooderson, 681 P.2d at 1057 (risk-reduction warning) and Reyes, 498 F.2d at 1280-82 (informed choice warning).

⁴⁰ See *infra* note 65 (listing cases in which courts have dealt directly with allegations that a drug was defectively designed). Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652 (1st Cir. 1981), is widely believed to be the first case directly raising a defective drug design claim. However, in an early article on the subject of liability for prescription drugs, Professor Merrill suggests that two 1969 drug cases relating to the drug Quadriagen may qualify as the progenitors of this cause of action. See Merrill, *supra* note 38, at 35 (citing Tinnerholm v. Parke Davis & Co., 285 F. Supp. 432 (S.D.N.Y. 1968), *aff'd as modified*, 411 F.2d 48 (2d Cir. 1969), and Stromsodt v. Parke Davis & Co., 257 F. Supp. 991 (D. N.D. 1966), *aff'd*, 411 F.2d 1390 (8th Cir. 1969)).

Most design litigation has involved industrial or non-description consumer products.⁴¹ Plaintiffs base their claims on the ground that a better alternative design would have avoided the injury. The mere fact that a danger was obvious or adequately warned against will not protect the manufacturer from liability.⁴² Momentary forgetfulness and inattention cause many injuries. Products are often foreseeably misused, causing injury to the users or third persons. Product warnings cannot bear the full burden of ensuring that products will be used safely. If a sensible design alternative can significantly reduce risk, the law will demand that the manufacturer design out the risk rather than merely warn against it.⁴³

In cases involving drugs, the claim of defective design is much more difficult to sustain. Different drugs provide different benefits to patients. What may be beneficial to one group of patients may be less so for another, who may in turn benefit from a drug with a slightly different composition. It appears elementary that so long as a group exists for whom the drug in question is the drug of choice, then the issue of design has no place in the applicable liability law. The only issue is whether the drug manufacturer provided the prescribing physician with adequate warnings of the drug's benefits and detriments, so that the physician could make an intelligent judgment regarding prescription of the drug. Unlike cases involving industrial and consumer products, in which design liability is necessary to protect against consumer inadvertence and product misuse, here such liability is neither necessary nor desirable. As long as the dangers related to drug ingestion are fully warned against, the physician stands as an expert intermediary whose func-

⁴¹ An extensive literature has developed describing how courts have dealt with classic design defect litigation. For a list of the major articles and cases, see Henderson & Twerski, *supra* note 22, at 271 n.23.

⁴² See, e.g., Stanton G. Darling II, *The Patent Danger Rule: An Analysis and a Survey of Its Vitality*, 29 MERCER L. REV. 583, 588 (1978); Patricia Marschall, *An Obvious Wrong Does Not Make A Right: Manufacturers' Liability for Patently Dangerous Products*, 48 N.Y.U. L. REV. 1065, 1083 (1973); see also Holm v. Sponco Mfg., Inc., 324 N.W.2d 207 (Minn. 1982); Micallef v. Miehle Co., 348 N.E.2d 571 (N.Y. 1976).

⁴³ See, e.g., Ulth v. City Tank Corp., 384 N.E.2d 1188 (Mass. 1978), in which the court held:

An adequate warning may reduce the likelihood of injury to the user of a product in some cases. We decline, however, to adopt any rule which permits a manufacturer or designer to discharge its total responsibility to workers by simply warning of the dangers of a product. Whether or not adequate warnings are given is a factor to be considered on the issue of negligence, but warnings cannot absolve the manufacturer or designer of all responsibility for the safety of the product. . . .

[A] warning is not effective in eliminating injuries due to instinctual reactions, momentary inadvertence, or forgetfulness on the part of a worker. One of the primary purposes of safety devices is to guard against such foreseeable situations.

Id. at 1192 (footnote omitted).

tion it is to make informed and knowledgeable decisions about the appropriateness of the drug for the particular patient.⁴⁴ In an area in which such careful attention is given to the individual patient and to the duration of product use, inadvertence and misuse are not significant problems. And even if they were, there is no justification for denying one set of patients the benefits of an important drug merely because some doctors or patients will not take the trouble to read warnings or follow instructions as to proper use.

If the aforementioned observations are accurate, then the only drug design cases warranting judicial inquiry are those in which the drugs in question have no special utility for *any* group of patients. The claim must be either that the drug was useless, or that a fully acceptable alternative drug existed that was just as effective but had fewer of the detriments of the drug in question. Cases predicated on such claims have, in fact, been litigated.⁴⁵ However, in assessing whether such design claims are necessary to prosecute a drug case, it is important to recall that the failure-to-warn claim stands in the wings. In our hypothetical drug design case, the manufacturer would almost certainly have run afoul of its obligation to warn.⁴⁶ To warn adequately, the manufacturer would have to inform the medical profession either that its product is useless or that a fully acceptable alternative to the drug exists that has all the benefits but fewer of the detriments of the drug in question. If the manufacturer failed to give such warnings, it would be liable for that failure. And in fact the manufacturer would presumably prefer to withdraw the drug than to warn, because to give such warnings would destroy the drug's marketability.

The availability of a failure-to-warn cause of action in drug cases does not *ipso facto* support the denial of design claims. One could argue that a plaintiff should be allowed to proceed on both

⁴⁴ The overwhelming majority of courts limit a manufacturer's duty to warn of risks relating to the use of ethical drugs to the physician alone. In *Reyes v. Wyeth Lab.*, 498 F.2d 1264, 1276 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974), Judge Wisdom set forth the rationale that supports this almost universal rule. Some courts have made an exception and required direct warning to consumers in the case of birth control pills or vaccines that are provided to the public without any medical intermediary. *See id.* at 1276 (quoting *Davis v. Wyeth Labs.*, 399 F.2d 121, 131 (9th Cir. 1968)); *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65, 69-70 (Mass.), *cert. denied*, 474 U.S. 920 (1985).

⁴⁵ *See* cases cited *infra* note 65.

⁴⁶ In most of the cases cited *infra* note 65, the plaintiff has proceeded on both design and failure-to-warn claims. In rare cases, the design claim may be the only viable one. *Toner v. Lederle Lab.*, 732 P.2d 297 (Idaho 1987), may be such a case. In *Toner*, the plaintiff, who suffered injury after being immunized against pertussis by the Lederle drug Tri-Immunol, contended that the defendant drug company was negligent in failing to develop a vaccine (fractionated cell product) that had less of the paralysis-causing side effects of Tri-Immunol. *Id.* at 301. Because there was no alternative product available on the market, it would be difficult to sustain a failure-to-warn cause of action.

grounds. However, almost all observers agree that significant limitations must be imposed on drug design litigation. In seeking to ascertain appropriate limitations, it is good to know that the drug design claim is rarely, if ever, the only road to plaintiff recovery.

Having stated the problem, we must now ask whether the existing comment *k* speaks to the question of whether courts should exercise design review for drugs the dangers of which are fully warned against. As noted earlier, we believe that one cannot fairly read comment *k* to address this question. Our reasons for so concluding are several. First, when the ALI in 1961 first raised the issue of liability for prescription drugs,⁴⁷ design review of industrial and consumer products was in its infancy. The classic no-duty defenses of patent danger,⁴⁸ intended use,⁴⁹ and no-bystander recovery⁵⁰ stood as significant obstacles to the imposition of design liability of any kind. The only reported cases were those in which the manufacturer had committed an "inadvertent design error."⁵¹ The entire body of cases predicated on "conscious design choices"⁵² was simply not part of the American product liability scene at the time. To conclude that at this primitive stage of product design liability comment *k* sought to establish sophisticated rules governing judicial review of conscious *drug* design choices is simply untenable. It is the functional equivalent of utilizing a modern day catalytic converter to neutralize the pollutants on a Model T Ford.

⁴⁷ 38 A.L.I. PROC. 90-92 (1962).

⁴⁸ The leading case expressing the patent danger rule was *Campo v. Scofield*, 95 N.E.2d 802 (N.Y. 1950). *Campo* was overruled by *Micallef v. Miehle Co.*, 348 N.E.2d 571 (N.Y. 1976).

⁴⁹ It should be recalled that the case heralding the adoption of strict liability in tort limited liability to defects that make a product unsafe for its intended use. See *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 901 (Cal. 1963). This position was later modified in *Cronin v. J.B.E. Olson Corp.*, 501 P.2d 1153, 1157 (Cal. 1972), to include liability for reasonably foreseeable uses.

⁵⁰ RESTATEMENT (SECOND) OF TORTS § 402A (1965) contained a caveat indicating that the American Law Institute expressed no opinion as to whether § 402A applied to persons other than users or consumers. See also *id.* cmt. o. The unanimous opinion of the courts since 1964 has been that § 402A applies to bystanders. See, e.g., *Elmore v. American Motors Corp.*, 451 P.2d 84 (Cal. 1969); *Howes v. Hansen*, 201 N.W.2d 825 (Wis. 1972).

⁵¹ Inadvertent design errors are design defects that cause products to fail to perform their intended functions. They are functionally similar to manufacturing defects. See generally James A. Henderson, Jr., *Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication*, 73 COLUM. L. REV. 1531, 1547-1552 (1973). RESTATEMENT (SECOND) OF TORTS § 398 (1965), establishing a broad rule of manufacturer liability for negligent design, relies entirely for its authority upon decisions involving inadvertent design errors. Henderson, *supra*, at 1550 n.70.

⁵² Conscious design choices are choices deliberately made by product designers with full knowledge of the risks created thereby. Presumably, the benefits generated by such choices outweigh the risks. See generally Henderson, *supra* note 51.

Second, there is strong evidence that Dean Prosser, who was the Reporter for the Second Restatement and who dominated the development of section 402A, was addressing a very different problem in his draft of comment *k*. Section 402A adopted for the first time a rule of strict liability for manufacturing defect cases.⁵³ A plaintiff injured as a result of a manufacturing defect could no longer be confronted with testimony of reasonable quality control on the part of the manufacturer.⁵⁴ By definition, manufacturing defects arise only sporadically and are idiosyncratic in nature. Prosser and others were concerned that manufacturers of even well-designed drugs of unquestioned social utility would be subject to liability for idiosyncratic drug reactions whose dangers were known and warned against. In the ALI proceedings concerning this issue, Prosser gave the example of a cancer-curing drug known to have fatal consequences to a small percentage of users.⁵⁵ At another session, he said that comment *k* was designed to protect “the person who is selling a drug which is necessarily unsafe although its utility outweighs the risk.”⁵⁶ In his treatise on the law of torts, Prosser cites an article by Professor Fleming James⁵⁷ advocating that liability be imposed *without regard to defect* for idiosyncratic drug reactions, and says:

The argument that industries producing potentially dangerous products should make good the harm, distribute it by liability insurance, and add the cost to the price of the product, encounters reason for pause, when we consider that two of the greatest medical boons to the human race, penicillin and cortisone, both have their dangerous side effects, and that drug companies might well have been deterred from producing and selling them.⁵⁸

Since comment *k* speaks only to cases in which no defect of any kind exists, there is almost no warrant for citing comment *k* as au-

⁵³ The thrust of § 402A was clearly directed toward manufacturing defects. See *supra* note 7.

⁵⁴ RESTATEMENT (SECOND) OF TORTS § 402A(2) and cmts. a, b (1965).

⁵⁵ 38 A.L.I. PROC. 54, 93 (1962).

⁵⁶ 41 A.L.I. PROC. 360 (1965). This argument is not frivolous. It has recently been raised anew in James A. Henderson, Jr., *Process Norms in Products Litigation: Liability For Allergic Reactions*, 51 U. PITT. L. REV. 761 (1990). Courts have used comment *k* to deny liability in deciding such claims. See, e.g., *Stone v. Smith Kline & French Labs.*, 447 So.2d 1301, 1304 (Ala. 1984) (no liability attaches to Thorazine merely because it causes cholestatic jaundice in a small percentage of cases. Thorazine does not present unreasonable risks and the risks are fully warned against); *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 425 & nn.11-12 (2d Cir. 1969) (comment *k* precludes liability for idiosyncratic reaction arising from useful drug whose dangers are adequately warned against).

⁵⁷ Fleming James, *The Untoward Effects of Cigarettes and Drugs: Some Reflections on Enterprise Liability*, 54 CAL. L. REV. 1550, 1557 (1966).

⁵⁸ WILLIAM L. PROSSER, *HANDBOOK OF THE LAW OF TORTS* § 99 at 661 (4th ed. 1971).

thority regarding whether and under what test drug manufacturers should be liable for defective design.

The text of comment *k* itself provides little insight. As Professor Joseph Page has so ably demonstrated, comment *k* is truly an enigma.⁵⁹ Page notes that neither Prosser nor any other ALI member indicated how section 402A would apply to prescription drugs without the comment *k* exemption.⁶⁰ To understand the scope of an exemption, one must articulate the substratum to which the exemption relates. Furthermore, the language of comment *k* appears to be directed to warnings rather than design. The discussion exempting new and experimental drugs from strict liability suggests that there is no liability for failure to warn against *unknown or unforeseeable* risks. However, the language of comment *k* and its examples refers throughout to application of the comment *k* exemption only when *known risks* are warned against, implying that liability might attach when unknown or unforeseeable risks were realized.

It seems clear that instead of speculating about the meaning of comment *k* as applied to a problem never contemplated by its drafters, we should direct our attention to how the courts have grappled with the question of judicial review of drug design. We acknowledge that courts have sought to justify their decisions by using the comment *k* language to bolster one position or another.⁶¹ Since we view this use of comment *k* as illegitimate, we shall direct our attention to the holdings and policy discussions in the cases, disregarding the interpretive gloss given to the existing comment *k*.

It is not at all difficult to summarize the standards courts have used in deciding prescription drug cases. The overwhelming majority of drug cases have been based on failure to warn. Almost without exception, the courts impose a standard of reasonable foreseeability on the drug manufacturer, who is held to the standard

⁵⁹ Page, *supra* note 38, at 864-72.

⁶⁰ Thus, the notion that comment *k* exempts drugs from actions for strict tort liability based on defective design or failure to warn seems strangely inconsistent with Prosser's position that all design and warning claims are based in negligence. *See supra* note 7. If all design and warning claims are based in negligence, no exemption seems necessary.

⁶¹ *See, e.g.*, *Toner v. Lederle Labs.*, 732 P.2d 297, 305 n.6 (Idaho 1987); *White v. Wyeth Labs.*, 533 N.E.2d 748, 752 n.4 (Ohio 1988).

of an expert.⁶² Most courts have openly admitted that this test is functionally identical to a negligence standard.⁶³

Regarding design review, the case law in a growing minority of states is very confused. Some courts take the position that while comment *k* exempts all prescription drugs from design review under strict liability,⁶⁴ a cause of action based on negligence may nevertheless be prosecuted. Other courts hold that prescription drugs are not automatically exempt from strict liability. Rather, they advocate a case-by-case examination to determine whether the drug is "unavoidably unsafe."⁶⁵ To resolve that issue, a court must determine that "there must be at the time of the subject product's distribution,

⁶² See, e.g., *DeLuryea v. Winthrop Labs.*, 697 F.2d 222, 228-29 (8th Cir. 1983); *Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87, 91 (2d Cir. 1980); *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 426 (2d Cir. 1969); *Gaston v. Hunter*, 588 P.2d 326, 340 (Ariz. Ct. App. 1978); *Brown v. Superior Ct.*, 751 P.2d 470, 480 (Cal. 1988); *Woodill v. Parke Davis & Co.*, 374 N.E.2d 683, 686-87 (Ill. App. Ct. 1978), *aff'd*, 402 N.E.2d 194 (Ill. 1980); *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541, 548 (Ind. Ct. App. 1979); *Moore v. Vanderloo*, 386 N.W.2d 108, 116 (Iowa 1986).

⁶³ *Werner v. Upjohn Co.*, 628 F.2d 848, 858 (4th Cir. 1980), *cert. denied*, 449 U.S. 1080 (1981); *Basko*, 416 F.2d at 426; *Snawder v. Cohen*, 749 F. Supp. 1473, 1476 n.3 (W.D. Ky. 1990); *Wells v. Ortho Pharmaceutical Corp.*, 615 F. Supp. 262, 296 (N.D. Ga. 1985), *aff'd*, 788 F.2d 741 (11th Cir.), *cert. denied*, 479 U.S. 950 (1986); *Stone v. Smith, Kline & French Lab.*, 447 So.2d 1301, 1303 n.2 (Ala. 1984); *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541, 553 (Ind. Ct. App. 1979); *Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 928 (Kan. 1990); *Kinney v. Hutchinson*, 468 So.2d 714, 718 (La. Ct. App. 1985); *Miller v. Upjohn Co.*, 465 So.2d 42, 45 (La. Ct. App. 1985).

⁶⁴ See, e.g., *Brown*, 751 P.2d at 481; *Grundberg v. Upjohn Co.*, 813 P.2d 89, 91-92 (Utah 1991) (in both *Brown* and *Grundberg* the courts mentioned exemption for strict liability only). For cases representing the traditional rule immunizing drug companies against design litigation, see *Basko*, 416 F.2d at 425 n.12; *Snawder*, 749 F. Supp. at 1476 (apparently providing drug manufacturers with full immunity from design defect litigation, with no reference to case-by-case determination); *Walker v. Merck & Co.*, 648 F. Supp. 931, 933 (M.D. Ga. 1986); *Chapman*, 388 N.E.2d 541 (apparently providing manufacturers of ethical drugs with across-the-board immunity from design litigation); *Moore v. Vanderloo*, 386 N.W.2d 108 (Iowa 1986); *Smith v. E.R. Squibb & Sons, Inc.*, 273 N.W.2d 476, 479 (Mich. 1979). But see *Koehler v. Wyeth Labs.*, 1987 WL 47831, at *2-4 (S.D. Ind. Sept. 8, 1987) (court makes factual investigation as to whether drug was unavoidably unsafe). This is only a partial listing of cases that adopt the traditional view. It is fair to say that almost all courts other than those listed *infra* note 65 adopt the traditional view that drug litigation is based solely on failure-to-warn grounds.

⁶⁵ See, e.g., *Rohrbough v. Wyeth Labs.*, 719 F. Supp. 470, 477 (N.D. W. Va. 1989), *aff'd*, 916 F.2d 970 (4th Cir. 1990); *Williams v. Ciba-Geigy Corp.*, 686 F. Supp. 573, 577-78 (W.D. La.) (apparently adopting a case-by-case approach, but applying a high threshold test to be administered by the court as to whether there is a jury question; stating that it is presumptively inappropriate for a jury to apply a pure "risk utility test"), *aff'd*, 864 F.2d 789 (5th Cir. 1988); *Kociemba v. G.D. Searle & Co.*, 695 F. Supp. 432, 433 (D. Minn. 1988); *West v. Searle & Co.*, 806 S.W.2d 608, 612-13 (Ark. 1991); *Belle Bonfils Memorial Blood Bank v. Hansen*, 665 P.2d 118 (Colo. 1983); *Adams v. G.D. Searle & Co.*, 576 So.2d 728, 733 (Fla. Dist. Ct. App. 1991); *Toner*, 732 P.2d at 308-09; *Savina*, 795 P.2d at 924-26; *Feldman v. Lederle Lab.*, 479 A.2d 374, 382-83 (N.J. 1984); *Davila v. Bodelson*, 704 P.2d 1119 (N.M. Ct. App. 1985); *White*, 533 N.E.2d at 752; *Senn v. Merrell-Dow Pharmaceuticals, Inc.*, 751 P.2d 215, 218 n.4 (Or. 1988); *Castrignano v. E.R. Squibb & Sons*, 546 A.2d 775, 781 (R.I. 1988).

no feasible alternative design which on balance accomplishes the subject product's purpose with a lesser risk." Furthermore, the courts relying on the language of comment *k* hold that the balance need only "apparently" tip toward the product's benefit at the time of distribution.⁶⁶ Once again, some courts take the position that a drug that meets this standard is exempt from strict liability but remains open to an attack based on negligence.⁶⁷

None of these positions, each based on a close re-reading of the text of comment *k*, make much sense. Consider first those courts that undertake a case-by-case approach to comment *k* application. To discover whether a comment *k* exemption from strict liability is appropriate, they undertake risk-utility balancing, insisting that this balancing process be performed as of the time when the drug was distributed.⁶⁸ This is nothing other than a negligence test. If a court finds that the product meets the threshold test for a strict liability exemption, it has perforce made a finding that the defendant was not negligent. How then can the courts declare that the exemption is only for strict liability?

What is in fact happening is that courts are engaging in initial screening to decide whether a risk-utility case is at all viable. In doing so, they inquire whether a drug manufacturer could conclude that the drug design was "apparently useful" at the time of distribution. If the defendant meets this threshold, there is no sense in allowing the straightforward negligence case to go to a jury. By definition, the courts have already decided that the manufacturer, given the knowledge that it had or should have had at the time of distribution, was justified in distributing the drug. One perceptive court has noted this anomaly,⁶⁹ but believes that the language of the existing comment *k* dictates this kind of nonsensical result. As we have already shown, however, comment *k* does not stand in the way of formulating rational rules for design review of drug cases. Comment *k* never addressed the question.

The same problem exists in cases that provide an across-the-board exemption from strict liability. The primary reason that these courts reject design review for drugs is because they believe risk-utility balancing for drugs to be unworkable.⁷⁰ It becomes no less unworkable in the context of a negligence case.

⁶⁶ *Williams*, 686 F. Supp. at 577-78 (high threshold to make a risk-utility case); *West*, 806 S.W.2d at 613; *Adams*, 576 So.2d at 733; *Toner*, 732 P.2d at 306-07.

⁶⁷ See authorities cited *supra* note 24.

⁶⁸ See, e.g., *West*, 806 S.W.2d at 613; *Adams*, 576 So.2d at 733; *Toner*, 732 P.2d at 306-07; *Savina*, 795 P.2d at 926.

⁶⁹ *Toner*, 732 P.2d at 309-11.

⁷⁰ See, e.g., *Brown v. Superior Ct.*, 751 P.2d 470, 478-79 (Cal. 1988).

We noted earlier that it would be unlikely indeed for a drug design declared unreasonably dangerous under a risk-utility standard not also to support a cause of action for failure to warn.⁷¹ It is hard to see how a drug manufacturer could honestly market a drug if it had to inform physicians that its drug had dangers that could be avoided by prescribing an alternative with all the benefits and fewer of the detriments of the drug in question. We thus believe that drug design review should be barred on both strict liability and negligence grounds. Deserving plaintiffs would lose very few, if any, legitimate cases. Courts would, however, be spared the need to review design in an area in which risk-utility balancing is extraordinarily difficult to accomplish.

If, however, courts prefer a case-by-case approach to the issue of drug design review, they should opt for a threshold risk-utility test that asks whether at the time of distribution the manufacturer of a drug had “apparent” reasons for believing that the product met risk-utility norms. Because this is fundamentally a negligence test, it makes no sense to put a manufacturer through an ordinary negligence test once it has passed the threshold test for design immunity. Furthermore, since such a screening process implicates important public policy questions, the issue should be for the court as a matter of law rather than for the jury.

We have provided two alternate drafts for comment *k* reflecting the views we have set forth above. As noted earlier, this is not an area in which we can satisfy ourselves with a restatement of the case law. Case law that is unintelligible cannot be intelligibly restated. There is a need in this area to clarify the issues and to provide direction to the courts as to how this very special genre of cases can be sensibly approached.

5. *Misuse, Modification, and Alteration*

Problems related to product misuse, modification, and alteration are the subject of considerable litigation. When these forms of user and third-party conduct are extreme, the defendant may legitimately claim that the product was simply non-defective. It may be impossible or impractical to design or warn against some forms of misuse. As one court has noted, one cannot hold the manufacturer of a knife liable when the plaintiff uses it as a toothpick and then complains that the sharp edge cuts.⁷² A knife cannot be designed to cut meat and not injure human tissue. More commonly, the plaintiff is able to establish that the product was defective, and the question

⁷¹ See *supra* note 46.

⁷² *General Motors Corp. v. Hopkins*, 548 S.W.2d 344, 349 (Tex. 1977).

then becomes whether the harm was within the risk created by the defective product. Stated in this way, the issue is that of proximate cause. Normally proximate cause is part of the plaintiff's burden of proof; however, a fair number of courts and products reform statutes have taken the position that product misuse, alteration, or modification are affirmative defenses.⁷³ Although we believe there is no good reason why the plaintiff should not bear the usual burden of proof, subject to the caveats described in the previous discussion of causation, we have left this issue to developing law. Once courts perceive that these various forms of product misuse do not raise discrete issues but are part of classic proximate cause analysis, they will most likely revert to placing the burden of proof onto the plaintiff.

CONCLUSION

It has not been a well-kept secret. Anyone familiar with the law of products liability knows that section 402A is out of date and requires revision. We are heartened that the ALI has taken up the task of formally revising its products liability provisions. We began our own revision efforts with the guiding principle that we would seek to write a Revised Restatement section that reflects those areas in which the courts by and large agree. We were pleased to discover that substantial agreement exists over much of the terrain of products liability law. Our Revised Restatement, together with our "official" comments, reflect this consensus. Our draft takes no formal position on much of the debate over terminology. Frankly, the buzz words have stood in the way of rational analysis of the underlying problems. In capturing consensus we have not papered over real differences. Rather, we have simply allowed sufficient breathing room for those who wish to continue debating the verbal niceties. But the remaining substantive differences constitute a relatively small slice of a very large pie. We have taken clear positions on a significant number of the core issues whenever we could detect broad agreement approaching consensus.⁷⁴ We offer this Revised Restatement to the legal community with the hope that, in the debate it may generate, its consensus-based tone remains intact.

⁷³ For an extensive discussion of this issue, see *Ellsworth v. Sherne Lingerie, Inc.*, 495 A.2d 348 (Md. 1985).

⁷⁴ See *supra* note 19.

Appendix: Original § 402A and Comments**§ 402A. Special Liability of Seller of Product for Physical Harm to User or Consumer**

1 (1) One who sells any product in a defective condition
2 unreasonably dangerous to the user or consumer or to his
3 property is subject to liability for physical harm thereby
4 caused to the ultimate user or consumer, or to his property,
5 if

6 (a) the seller is engaged in the business of
7 selling such a product, and

8 (b) it is expected to and does reach the user or
9 consumer without substantial change in the condition in
10 which it is sold.

11 (2) The rule stated in Subsection (1) applies although

12 (a) the seller has exercised all possible care in
13 the preparation and sale of his product, and

14 (b) the user or consumer has not bought the
15 product from or entered into any contractual relation with
16 the seller.

Caveat:

The Institute expresses no opinion as to whether the rules stated in this Section may not apply

(1) to harm to persons other than users or consumers;

(2) to the seller of a product expected to be processed or otherwise substantially changed before it reaches the user or consumer; or

(3) to the seller of a component part of a product to be assembled.

Comment:

a. This Section states a special rule applicable to sellers of products. The rule is one of strict liability, making the seller subject to liability to the user or consumer even though he has exercised all possible care in the preparation and sale of the product. The Section is inserted in the Chapter dealing with the negligence liability of suppliers of chattels, for convenience of reference and comparison with other Sections dealing with negligence. The rule stated here is not exclusive, and does not preclude liability based upon the alternative ground of negligence of the seller, where such negligence can be proved.

b. History. Since the early days of the common law those engaged in the business of selling food intended for human consumption have been held to a high degree of responsibility for their products. As long ago as 1266 there were enacted special criminal statutes imposing penalties upon victualers, vintners, brewers, butchers, cooks, and other persons who supplied "corrupt" food and drink. In the earlier part of this century this ancient attitude was reflected in a series of decisions in which the courts of a number of states sought to find some method of holding the seller of food liable to the ultimate consumer even though there was no showing of negligence on the part of the seller. These decisions represented a departure from, and an exception to, the general rule that a supplier of chattels was not liable to third persons in the absence of negligence or privity of contract. In the beginning, these decisions displayed considerable ingenuity in evolving more or less fictitious theories of liability to fit the case. The various devices included an agency of the intermediate dealer or another to purchase for the consumer, or to sell for the seller; a theoretical assignment of the seller's warranty to the intermediate dealer; a third party beneficiary contract; and an implied representation that the food was fit for consumption because it was placed on the market, as well as numerous others. In later years the courts have become more or less agreed upon the theory of a "warranty" from the seller to the consumer, either "running with the goods" by analogy to a covenant running with the land, or made directly to the consumer. Other decisions have indicated that the basis is merely one of strict liability in tort, which is not dependent upon either contract or negligence.

Recent decisions, since 1950, have extended this special rule of strict liability beyond the seller of food for human consumption. The first extension was into the closely analogous cases of other products intended for intimate bodily use, where, for example, as in the case of cosmetics, the application to the body of the consumer is external rather than internal. Beginning in 1958 with a Michigan case involving cinder building blocks, a number of recent decisions have discarded any limitation to intimate association with the body, and have extended the rule of strict liability to cover the sale of any product which, if it should prove to be defective, may be expected to cause physical harm to the consumer or his property.

c. On whatever theory, the justification for the strict liability has been said to be that the seller, by marketing his product for use and consumption, has undertaken and assumed a special

responsibility toward any member of the consuming public who may be injured by it; that the public has the right to and does expect, in the case of products which it needs and for which it is forced to rely upon the seller, that reputable sellers will stand behind their goods; that public policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained; and that the consumer of such products is entitled to the maximum of protection at the hands of someone, and the proper persons to afford it are those who market the products.

d. The rule stated in this Section is not limited to the sale of food for human consumption, or other products for intimate bodily use, although it will obviously include them. It extends to any product sold in the condition, or substantially the same condition, in which it is expected to reach the ultimate user or consumer. Thus the rule stated applies to an automobile, a tire, an airplane, a grinding wheel, a water heater, a gas stove, a power tool, a riveting machine, a chair, and an insecticide. It applies also to products which, if they are defective, may be expected to and do cause only "physical harm" in the form of damage to the user's land or chattels, as in the case of animal food or a herbicide.

e. Normally the rule stated in this Section will be applied to articles which already have undergone some processing before sale, since there is today little in the way of consumer products which will reach the consumer without such processing. The rule is not, however, so limited, and the supplier of poisonous mushrooms which are neither cooked, canned, packaged, nor otherwise treated is subject to the liability here stated.

f. Business of selling. The rule stated in this Section applies to any person engaged in the business of selling products for use or consumption. It therefore applies to any manufacturer of such a product, to any wholesale or retail dealer or distributor, and to the operator of a restaurant. It is not necessary that the seller be engaged solely in the business of selling such products. Thus the rule applies to the owner of a motion picture theatre who sells popcorn or ice cream, either for consumption on the premises or in packages to be taken home.

The rule does not, however, apply to the occasional seller of food or other such products who is not engaged in that activity as a part of his business. Thus it does not apply to the housewife who, on one occasion, sells to her neighbor a jar of jam or a pound of sugar. Nor does it apply to the owner of an

automobile who, on one occasion, sells it to his neighbor, or even sells it to a dealer in used cars, and this even though he is fully aware that the dealer plans to resell it. The basis for the rule is the ancient one of the special responsibility for the safety of the public undertaken by one who enters into the business of supplying human beings with products which may endanger the safety of their persons and property, and the forced reliance upon that undertaking on the part of those who purchase such goods. This basis is lacking in the case of the ordinary individual who makes the isolated sale, and he is not liable to a third person, or even to his buyer, in the absence of his negligence. An analogy may be found in the provision of the Uniform Sales Act, § 15, which limits the implied warranty of merchantable quality to sellers who deal in such goods; and in the similar limitation of the Uniform Commercial Code, § 2-314, to a seller who is a merchant. This Section is also not intended to apply to sales of the stock of merchants out of the usual course of business, such as execution sales, bankruptcy sales, bulk sales, and the like.

g. Defective condition. The rule stated in this Section applies only 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. The seller is not liable when he delivers the product in a safe condition, and subsequent mishandling or other causes make it harmful by the time it is consumed. The burden of proof that the product was in a defective condition at the time that it left the hands of the particular seller is upon the injured plaintiff; and unless evidence can be produced which will support the conclusion that it was then defective, the burden is not sustained.

Safe condition at the time of delivery by the seller will, however, include proper packaging, necessary sterilization, and other precautions required to permit the product to remain safe for a normal length of time when handled in a normal manner.

h. A product is not in a defective condition when it is safe for normal handling and consumption. If the injury results from abnormal handling, as where a bottled beverage is knocked against a radiator to remove the cap, or from abnormal preparation for use, as where too much salt is added to food, or from abnormal consumption, as where a child eats too much candy and is made ill, the seller is not liable. Where, however, he has reason to anticipate that danger may result from a particular use, as where a drug is sold which is safe only in limited doses, he

may be required to give adequate warning of the danger (see Comment *j*), and a product sold without such warning is in a defective condition.

The defective condition may arise not only from harmful ingredients, not characteristic of the product itself either as to presence or quantity, but also from foreign objects contained in the product, from decay or deterioration before sale, or from the way in which the product is prepared or packed. No reason is apparent for distinguishing between the product itself and the container in which it is supplied; and the two are purchased by the user or consumer as an integrated whole. Where the container is itself dangerous, the product is sold in a defective condition. Thus a carbonated beverage in a bottle which is so weak, or cracked, or jagged at the edges, or bottled under such excessive pressure that it may explode or otherwise cause harm to the person who handles it, is in a defective and dangerous condition. The container cannot logically be separated from the contents when the two are sold as a unit, and the liability stated in this Section arises not only when the consumer drinks the beverage and is poisoned by it, but also when he is injured by the bottle while he is handling it preparatory to consumption.

i. Unreasonably dangerous. The rule stated in this Section applies only where the defective condition of the product makes it unreasonably dangerous to the user or consumer. Many products cannot possibly be made entirely safe for all consumption, and any food or drug necessarily involves some risk of harm, if only from over-consumption. Ordinary sugar is a deadly poison to diabetics, and castor oil found use under Mussolini as an instrument of torture. That is not what is meant by "unreasonably dangerous" in this Section. The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics. Good whiskey is not unreasonably dangerous merely because it will make some people drunk, and is especially dangerous to alcoholics; but bad whiskey, containing a dangerous amount of fusel oil, is unreasonably dangerous. 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. Good butter is not unreasonably dangerous merely because, if such be the case, it deposits cholesterol in the arteries

and leads to heart attacks; but bad butter, contaminated with poisonous fish oil, is unreasonably dangerous.

j. Directions or warning. In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use. 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. Where, however, 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 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 unduly dangerous for other reasons, warning as to use may be required.

But a seller is not required to warn with respect to products, or ingredients in them, which are only dangerous, or potentially so, when consumed in excessive quantity, or over a long period of time, when the danger, or potentiality of danger, is generally known and recognized. Again the dangers of alcoholic beverages are an example, as are also those of foods containing such substances as saturated fats, which may over a period of time have a deleterious effect upon the human heart.

Where warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous.

k. 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.

1. *User or consumer.* In order for the rule stated in this Section to apply, it is not necessary that the ultimate user or consumer have acquired the product directly from the seller, although the rule applies equally if he does so. He may have acquired it through one or more intermediate dealers. It is not even necessary that the consumer have purchased the product at all. He may be a member of the family of the final purchaser, or his employee, or a guest at his table, or a mere donee from the purchaser. The liability stated is one in tort, and does not require any contractual relation, or privity of contract, between the plaintiff and the defendant.

“Consumers” include not only those who in fact consume the product, but also those who prepare it for consumption; and the housewife who contracts tularemia while cooking rabbits for her husband is included within the rule stated in this Section, as is also the husband who is opening a bottle of beer for his wife to drink. Consumption includes all ultimate uses for which the product is intended, and the customer in a beauty shop to whose hair a permanent wave solution is applied by the shop is a consumer. “User” includes those who are passively enjoying the benefit of the product, as in the case of passengers in automobiles or airplanes, as well as those who are utilizing it for the purpose of doing work upon it, as in the case of an employee of the ultimate buyer who is making repairs upon the automobile which he has purchased.

Illustration:

1. A manufactures and packs a can of beans, which he sells to B, a wholesaler. B sells the beans to C, a jobber, who resells it to D, a retail grocer. E buys the can of beans from D, and gives it to F. F serves the beans at lunch to G, his guest. While eating the beans, G breaks a tooth, on a pebble of the size, shape, and color of a bean, which no reasonable inspection could possibly have discovered. There is satisfactory evidence that the pebble was in the can of beans when it was opened. Although there is no negligence on the part of A, B, C, or D, each of them is subject to liability to G. On the other hand E and F, who have not sold the beans, are not liable to G in the absence of some negligence on their part.

m. "Warranty." The liability stated in this Section does not rest upon negligence. It is strict liability, similar in its nature to that covered by Chapters 20 and 21. The basis of liability is purely one of tort.

A number of courts, seeking a theoretical basis for the liability, have resorted to a "warranty," either running with the goods sold, by analogy to covenants running with the land, or made directly to the consumer without contract. In some instances this theory has proved to be an unfortunate one. Although warranty was in its origin a matter of tort liability, and it is generally agreed that a tort action will still lie for its breach, it has become so identified in practice with a contract of sale between the plaintiff and the defendant that the warranty theory has become something of an obstacle to the recognition of the strict liability where there is no such contract. There is nothing in this Section which would prevent any court from treating the rule stated as a matter of "warranty" to the user or consumer. But if this is done, it should be recognized and understood that the "warranty" is a very different kind of warranty from those usually found in the sale of goods, and that it is not subject to the various contract rules which have grown up to surround such sales.

The rule stated in this Section does not require any reliance on the part of the consumer upon the reputation, skill, or judgment of the seller who is to be held liable, nor any representation or undertaking on the part of that seller. The seller is strictly liable although, as is frequently the case, the consumer does not even know who he is at the time of consumption.

The rule stated in this Section is not governed by the provisions of the Uniform Sales Act, or those of the Uniform Commercial Code, as to warranties; and it is not affected by limitations on the scope and content of warranties, or by limitation to "buyer" and "seller" in those statutes. Nor is the consumer required to give notice to the seller of his injury within a reasonable time after it occurs, as is provided by the Uniform Act. The consumer's cause of action does not depend upon the validity of his contract with the person from whom he acquires the product, and it is not affected by any disclaimer or other agreement, whether it be between the seller and his immediate buyer, or attached to and accompanying the product into the consumer's hands. In short, "warranty" must be given a new and different meaning if it is used in connection with this Section. It is much simpler to regard the liability here stated as merely one of strict liability in tort.

n. Contributory negligence. Since the liability with which this Section deals is not based upon negligence of the seller, but is strict liability, the rule applied to strict liability cases (see § 524) applies. Contributory negligence of the plaintiff is not a defense when such negligence consists merely in a failure to discover the defect in the product, or to guard against the possibility of its existence. On the other hand the form of contributory negligence which consists in voluntarily and unreasonably proceeding to encounter a known danger, and commonly passes under the name of assumption of risk, is a defense under this Section as in other cases of strict liability. If the user or consumer discovers the defect and is aware of the danger, and nevertheless proceeds unreasonably to make use of the product and is injured by it, he is barred from recovery.

Comment on Caveat:

o. Injuries to non-users and non-consumers. Thus far the courts, in applying the rule stated in this Section, have not gone beyond allowing recovery to users and consumers, as those terms are defined in Comment *l*. Casual bystanders, and others who may come in contact with the product, as in the case of employees of the retailer, or a passer-by injured by an exploding bottle, or a pedestrian hit by an automobile, have been denied recovery. There may be no essential reason why such plaintiffs should not be brought within the scope of the protection afforded, other than that they do not have the same reasons for expecting such pro-

tection as the consumer who buys a marketed product; but the social pressure which has been largely responsible for the development of the rule stated has been a consumers' pressure, and there is not the same demand for the protection of casual strangers. The Institute expresses neither approval nor disapproval of expansion of the rule to permit recovery by such persons.

p. Further processing or substantial change. Thus far the decisions applying the rule stated have not gone beyond products which are sold in the condition, or in substantially the same condition, in which they are expected to reach the hands of the ultimate user or consumer. In the absence of decisions providing a clue to the rules which are likely to develop, the Institute has refrained from taking any position as to the possible liability of the seller where the product is expected to, and does, undergo further processing or other substantial change after it leaves his hands and before it reaches those of the ultimate user or consumer.

It seems reasonably clear that the mere fact that the product is to undergo processing, or other substantial change, will not in all cases relieve the seller of liability under the rule stated in this Section. If, for example, raw coffee beans are sold to a buyer who roasts and packs them for sale to the ultimate consumer, it cannot be supposed that the seller will be relieved of all liability when the raw beans are contaminated with arsenic, or some other poison. Likewise the seller of an automobile with a defective steering gear which breaks and injures the driver, can scarcely expect to be relieved of the responsibility by reason of the fact that the car is sold to a dealer who is expected to "service" it, adjust the brakes, mount and inflate the tires, and the like, before it is ready for use. On the other hand, the manufacturer of pigiron, which is capable of a wide variety of uses, is not so likely to be held to strict liability when it turns out to be unsuitable for the child's tricycle into which it is finally made by a remote buyer. The question is essentially one of whether the responsibility for discovery and prevention of the dangerous defect is shifted to the intermediate party who is to make the changes. No doubt there will be some situations, and some defects, as to which the responsibility will be shifted, and others in which it will not. The existing decisions as yet throw no light upon the questions, and the Institute therefore expresses neither approval nor disapproval of the seller's strict liability in such a case.

g. Component parts. The same problem arises in cases of the sale of a component part of a product to be assembled by another, as for example a tire to be placed on a new automobile, a brake cylinder for the same purpose, or an instrument for the panel of an airplane. Again the question arises, whether the responsibility is not shifted to the assembler. It is no doubt to be expected that where there is no change in the component part itself, but it is merely incorporated into something larger, the strict liability will be found to carry through to the ultimate user or consumer. But in the absence of a sufficient number of decisions on the matter to justify a conclusion, the Institute expresses no opinion on the matter.