THE DRAFT ALI PRODUCT LIABILITY PROPOSALS: PROGRESS OR ANACHRONISM?

OSCAR S. GRAY

The American Law Institute's current project on the law of products liability addresses the questions that most lawyers would expect to be considered in such an undertaking, but also contains disturbing proposals that would probably come as a surprise to many.

The expectable issues relate to the strict products liability section of the Restatement (Second) of Torts, section 402A, and to suggestions for its revision. The surprises relate to proposals for radical changes in American negligence law as it affects liability for reasonably dangerous conduct involving the distribution of products, and for corresponding changes in the interpretation of "unmerchantability" for purposes of article 2 of the Uniform Commercial Code.

Under these proposals, there would be no liability in negligence, or for breach of warranty, for marketing an unreasonably dangerous product unless there were a manufacturing or warning defect, or unless the plaintiff could establish the technical and economic feasibility of an alternative design that would make the product in question safer.

Such proposals reach far beyond section 402A, and it would be difficult to demonstrate any case authority for them. That they are contained in the project is not yet widely understood and is cause for considerable concern.

In order to demonstrate how this would come about, Part I of this Article sketches the background of strict liability law under section 402A of the Restatement (Second) of Torts and the changes in strict liability that the Reporters propose to the ALI. Part II explains how these proposed changes in strict liability would purport to have a spillover effect, changing

* Jacob A. France Professor of Torts, University of Maryland School of Law; Adviser, American Law Institute Restatement (Third) of the Law: Products Liability. I have benefited from conversations with and instruction by many, including particularly the Reporters, Professor James A. Henderson Jr. and Professor Aaron D. Twerski; the other Advisers and participants in the ALI proceedings on this project; the participants in a Products Liability Symposium sponsored by the Tennessee Law Review, held in Knoxville on August 13, 1994; Dr. Charles M. Auer; Ms. Kathleen Cross; Mr. Robert Frankel; Professor Robert V. Percival; Evelyn Pisegna-Cook, Esq. (when she was a pre-Esq.); Dr. Ellen Silbergeld; Professor William L. Reynolds; Mr. David Woodworth; and Professor Gordon G. Young. All errors, omissions, and lapses of judgment are, of course, exclusively mine.

1. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY (Tentative Draft No. 1, 1994) [hereinafter Tentative Draft].

1105
negligence and warranty law as well. Part III attempts to demonstrate why these changes are inadvisable.

I. BACKGROUND ON SECTION 402A ISSUES

The issues that are expectably treated in the Reporters' proposal include questions about the applicability of strict liability concepts under section 402A of the Restatement (Second) of Torts to disputes about the safety of product designs and the adequacy of warnings and instructions. It is familiar ground that many, although not all, courts that are rigorous in their application of strict liability concepts to liability for harm arising from manufacturing errors allow negligence concepts to be introduced, and sometimes to dominate, design and warning cases. These distinctions have developed although section 402A of the Restatement (Second) speaks generally of the liability of those who sell products "in a defective condition unreasonably dangerous to the user or consumer or to his property" and does not on its face purport to classify defects in terms of manufacturing, design or warning categories. Two related strict versus nonstrict liability concepts are among those principally at issue here. The first is whether the risk posed by the product must have been foreseeable to the actor at the time of sale. The second is whether a way to avoid the hazard must be known at the time of trial or should have been known at the time of sale.

A. Manufacturing Defects

Where a plaintiff has been injured because of a hazard attributable to a difference between the product as it was sold and the manufacturer's design and specifications for the product, the difference has come to be known as a manufacturing defect, which meets the requirement of the Restatement (Second) for section 402A strict liability that the product be "in a defective condition." For the related requirement, that such product be "unreasonably dangerous," the following rule, known as a "hindsight" test, has become widely accepted: If knowledge of the hazard were imputed to the seller as of the time of sale, liability turns on whether it would have been reasonable in all the circumstances for a seller with that knowledge to have sold the product. There is no further requirement for proof of the existence of a way to avoid the hazard either at the time of sale or at the time of trial. Since knowledge of the hazard is attributed to the seller under this test, strict liability applies for such manufacturing defects even if the risks were not actually foreseeable. On the other hand, risks, even if they

2. Restatement (Second) of Torts § 402A (1965).
3. Id.
follow from defects, are not necessarily unreasonable, even if they are actually foreseeable.

B. Design and Warning Defects

Where the product has been manufactured in accordance with the applicable design but is challenged as "defective" on the ground that the design itself was unreasonably unsafe, certain distinctions in analysis are virtually inevitable and others, while not inevitable, have attained considerable support. It is difficult to conceive of a design as being "defective" except by reference to another design that is not defective. One might characterize a product as being "defective" in its very concept if "defective" were equated with "unreasonably dangerous." Since section 402A does not classify defects as "manufacturing," "design" or "warning," section 402A might be treated as providing strict liability for unreasonably unsafe products, no matter why they are unreasonably unsafe. This line of argument, that the product itself may be deemed "defective" because of dangerousness, without reference to manufacturing, design or warning defects as such, could be augmented by the contention that the "unreasonably dangerous" requirement can also be met in some circumstances without proof of the availability of alternative designs, simply on the basis that certain products are too dangerous to be marketed at all. I shall return to this last contention below.

For present purposes I would, nevertheless, defend the plausibility of a requirement for the existence of a better design, before the design in question is deemed "defective" for purposes of strict liability under section 402A, on two grounds. First, for reasons to be discussed further below, the term "in a defective condition" was inserted in section 402A, as a deliberate addition to "unreasonably dangerous," for a specific purpose: to emphasize that something must be wrong with the product, apart from its unreasonable dangerousness, in order to trigger strict liability. This requirement was adopted to avoid involving section 402A in disputes about whether there should be liability for normal tobacco products or alcoholic beverages in the absence of unusual adulteration or spoilage, notwithstanding the obvious possibilities that they might normally be viewed as unreasonably dangerous. It was thought that, whatever one's views may be about the hazards of tobacco or alcohol, this is not the place to deal with those questions. Section 402A is not a statute, and neither its drafting history nor its black letter text is binding on courts or scholars. Nevertheless, this history at least helps validate the contention that strict liability under section 402A has been limited by a requirement for the existence of something wrong beside

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5. Id. at 581.
6. Id.
unreasonableness of danger. Additionally, the Reporters are correct that the overwhelming body of interpretation by the courts has accepted the three-pronged differentiation between manufacturing, design, and warning defects. I could support a departure from this tradition, but I do not deny its existence.

Accordingly, I think it follows that if we are to continue to talk about strict liability for a design defect as such, we must necessarily imply the possibility of a reasonably safer design, either provable or inferable without specific proof. From this implication it does not follow as a conceptual necessity that the riskiness of the actual design must have been foreseeable at the time of sale or that the feasibility of a safer design must have existed then rather than at the time of trial. Once a safer, feasible design is proved at the time of trial, thereby establishing the “defect,” the “hindsight test” that is generally used for manufacturing defects could be coherently applied to determine whether the design condition was “unreasonably dangerous.” If a manufacturer lacks actual knowledge of hazards and alternatives, one could just as easily ask whether it would have been reasonable in the circumstances for a manufacturer who knew of the possibility of the better design and of the risks of the actual design to sell the product with the actual design as one can ask the corresponding question about a manufacturing defect.

The Reporters have chosen what amounts to a truncated negligence test for design defect. They recommend no liability unless the risk was foreseeable and a reasonable alternative design could have been chosen at the time of manufacture. The Reporters also assert through the comments that the black letter proposals mean that a “risk-utility” balancing test is adopted “as the standard for judging the defectiveness of product designs.” By “the standard,” the Reporters apparently mean “the sole

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7. The “something wrong” requirement is redundant as a barrier to strict liability for harm caused by tobacco, alcohol, and other common items of consumption. According to comment i to § 402A in the Restatement (Second), the requirement that the product be “unreasonably dangerous,” is also not met in the case of “good” tobacco, alcohol, sugar, or butter. To be “unreasonably dangerous” the article “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.” Restatement (Second) of Torts § 402A cmt. i (1965).


9. Id. § 2(b), at 9. There may be an unresolved question whether the Reporters’ suggested terminology, involving a marriage of “could have” with “reasonable,” precisely matches the negligence standard of “should have.”

10. Id. cmt. d, at 19-20. A normal negligence test would merely require that the foreseeable risk be unreasonable, not that a reasonable alternative be possible.

11. Id. cmt. c, at 15. The “risk-utility” test that the Reporters adopt is, presumably, distinguished from other tests such as “consumer expectations” or unmerchantability.
standard." A similar discussion would describe the issues and proposed solutions for warnings defects.

The merits of these proposals are debated in other articles in this Symposium issue and are touched upon further, to some extent, in Part III of this Article. For present purposes, it may be conceded that the dilution of strict liability for design and warning hazards, along the lines of the Reporters' proposals, reflects judicial choices in the interpretation of section 402A that have been made in a good number of, although certainly not all, jurisdictions.

II. ARCHITECTURE AND ITS IMPLICATIONS: THE RADICAL CHANGES

In most American jurisdictions today section 402A, however it be interpreted, is treated as the inspiration for that jurisdiction's law of strict liability in tort for harm caused by defective products. At the same time, in all jurisdictions, an independent body of negligence law, based on the unreasonableness of the conduct of producers and others, governs liability on the part of all actors for harm caused by their unreasonable conduct, whether in the production or distribution of goods or otherwise. Furthermore, there has been the independent possibility of liability for losses caused by products sold in breach of an implied warranty of merchantability based on well-established legal traditions that have their own roots. In a formal sense this liability is usually statutory, under article 2 of the Uniform Commercial Code, although its content has been developed largely as a matter of case law. Other branches of law can also apply to liability for losses in transactions involving products. For example, liability may be imposed in transactions involving fraud.

Since 1965 the development of divergent interpretations of section 402A has led to a condition of unclarity and lack of uniformity that suggests to many the desirability of clarification of this area of strict liability law. In the same period, however, while there have been developments in negligence law, those developments have not been conspicuously driven in the courts by a perception that negligence law requires modification in its basic principles or special treatment where products are concerned. Courts have expressed scant dissatisfaction, if any, with well-established negligence concepts or with traditional warranty concepts in commercial law.

In the current ALI project, however, the Reporters propose to change this architecture. They propose not only to modify section 402A, but to subordinate negligence and warranty law to these modifications as well, and

12. By doing so, the Reporters in this Restatement (Third) segment undercut one of the principal barriers envisioned in the Restatement (Second) against strict liability for unadulterated tobacco or alcohol. See supra note 7.

thereby permanently to curtail the capacity of negligence law to grow in its concept of unreasonableness or of warranty law to grow in its concept of unmerchantability. They do this by a complex process that involves three steps.

First, in section 2 of the proposed Restatement (Third), the Reporters substitute “defect” as the central feature of their treatment in place of the section 402A concept of “product in a defective condition unreasonably dangerous.” In curious ways, they either suppress the concept of “unreasonableness” entirely as a basis for liability or advert to it only as subordinated to the concept of defect as the trigger for liability.

Second, the Reporters break their discussion into three sharply defined categories: the “manufacturing defect,”14 the defect “in design,”15 and defectiveness that exists “because of inadequate instructions or warnings.”16 They define the characteristics of each type of defect in each subparagraph of section 2. The design and warning defects are also required to “render [] the product not reasonably safe,” while the manufacturing defect is not.17 They then present “risk-utility balancing” as the sole meaning of the “reasonableness” test.18 The Reporters would also require proof that a “reasonable alternative design” could have reduced the “foreseeable risks of harm posed by the product” as a condition for liability for a “design” defect.19

Lastly, the architectural implications of section 2 are developed in comment j to that section.20 These implications may not be apparent to all from the black letter text of the section without the aid of comment j, and the meaning of comment j in turn may well escape the rapid reader in the absence of reference to the Reporters’ Note on comment j.21 A quick glance at comment j might leave the reader with the impression that the rules in that section are intended to define only “the bases of tort liability

15. Id. § 2(b), at 9.
16. Id. § 2(c), at 9-10.
17. Id. § 2, at 9-10.
18. Id. § 2 cmt. c, at 15.
19. Id. § 2(b), at 9. Since the completion of this article the Reporters have indicated willingness to accept an inference of “product defect” when “the incident resulting in the harm was of a kind that ordinarily occurs only as a result of product defect” and “evidence . . . supports the conclusion that more probably than not . . . the cause of the harm was a product defect.” Memorandum from the Reporters to the A.L.I. Council, Nov. 17, 1994, Appendix # 5. If, however, the meaning of the term “product defect” for purposes of this provision remains limited by the definitions in § 2, it may still be necessary, in order to establish a basis for the inference, to establish the probable existence of either a manufacturing defect or a reasonable alternative design, absent the likelihood that a negligently omitted warning would have made the product reasonably safe.
20. Id. § 2 cmt. j, at 30-33.
21. Id. § 2, Reporters’ Note to cmt. j, at 75-77.
for harms caused by product defects existing at time of sale,"22 and that the restrictions described in comment j are limited to multi-count complaints based on design or warning claims.23 The argument seems to be that the basis for defective design and warning liability under sections 2(b) and 2(c) has now been reduced to negligence,24 and it would be confusing to permit two claims based on negligence regarding the same defective design or warning to go to a jury in the same action under different sets of instructions. The Reporters’ Note, however, discloses that the purpose of comment j is far more ambitious.25 The comment is designed to make section 2 govern not only negligence claims that assert defect in design or warning, but also unreasonableness of conduct claims, in the sale of unreasonably dangerous products, that do not assert such a defect. It would do so by invalidating such other claims precisely for failure to rest on a “defect” as newly defined in section 2. Comment j, furthermore, is intended to make section 2 of the Restatement (Third) govern not only tort claims, to the extent that they turn on the unreasonableness of a product’s hazards, but also unmerchantability claims arising under article 2 of the Uniform Commercial Code, for breach of the implied warranty of fitness for the general purposes for which a product is sold. These spillover effects of section 2, as established by comment j, are evidently not limited to multicount claims in which a danger of confusion from inconsistent or overlapping instructions might be a matter of concern. They are intended to govern single-count claims as well, such as claims for negligence or breach of warranty alone, brought without any conscious reliance on either section 402A of the Restatement (Second) of Torts or on its proposed replacement, section 2 of the proposed Restatement (Third). As the Reporters explain:

Comment j takes the position that as long as the plaintiff establishes defect under Subsection (a), (b), or (c) [of Section 2], courts are free to utilize the doctrines of negligence, strict liability, or implied warranty of merchantability as theories of liability. Conversely, failure to meet the requisites of Subsection (a), (b), or (c) will defeat a cause of action under either negligence, strict liability, or the implied warranty of merchantability.26

This I consider to be a proposition of breathtaking audacity. Seldom can the articulation of such radical innovations have been entrusted to a Reporters’ Note to a comment, much less a comment sequenced, alphabetically, so deeply into the alphabet.

22. Id. § 2 cmt. j, at 30.
23. Id. at 30-31.
24. But see supra notes 9-10 and accompanying text (suggesting that the § 2(b) test is not the same as a normal negligence test).
25. See Tentative Draft, supra note 1, § 2, Reporters’ Note to cmt. j, at 75-77.
26. Id. at 75-76 (emphasis added).
If courts have defined negligence in the sale of unreasonably dangerous products as necessarily requiring, in the absence of a section 2(a) manufacturing "defect" or a section 2(e) warning "defect," proof of a "reasonable alternative design," I have not seen the cases that say so. I have thought that "unreasonableness in the circumstances" of the actors' conduct was the test for negligence, however that may be developed. Furthermore, whether courts have required, for unmerchantability claims under article 2 of the Uniform Commercial Code, the proof of a section 2 "defect," or that unmerchantability be proved in terms of "risk-utility balancing," I do not know. The Reporters cite no such authority for this aspect of their proposal.

The Reporters, of course, would not concede that their proposals amount to radical changes in negligence law. In part, they claim to derive, from certain cases that have failed to condemn particular products as unreasonably unsafe in all circumstances and from a few similar statutes, a general principle of negligence law that no product can be so considered "categorically" unsafe.27 I see no evidence of such a general rule. In addition, the section 2(b) definition of "defect" ignores the possibility that a product is unreasonably dangerous because of hazards that are not present in an entirely different substitute product that serves the same function or through an alternative course of conduct that avoids the need for the product. In neither case has a safer alternative design for the dangerous product itself been demonstrated, but, in each case, assuming technical feasibility of the substitute product or alternative course of conduct and comparable cost, the dangers can be shown to be unreasonable for purposes of negligence law because they are unnecessary.

The attempt to confine the generality of negligence law is particularly pernicious. It is understandable that potential defendants perceive, with unease, in the liability for unreasonableness, a potentially wide-open gateway to the expansion of liability, bounded on its face (in the absence of judicial control) only by the sense and restraint of juries. But this aspect of negligence law, its capacity to adapt to new conditions and hazards and knowledge, has been the means by which accident law has stayed alive, responsive to the requirements of a developing society, and, on the whole,

27. The Reporters seem driven (unnecessarily, I think) by the fear that juries might be permitted to consider it unreasonable to sell normal tobacco products or alcoholic beverages on the ground that they are unreasonably unsafe. There are overriding reasons to consider the conduct of the sellers of those products to be not unreasonable in the absence of adulteration or fraud, notwithstanding the hazards of those products, because of the virtually explicit approval of their marketing by policy-making institutions such as legislatures. This consideration does not apply to products that have not had the same degree of authoritative social scrutiny and acceptance. In addition, the retention of comment i to § 402A of the Restatement (Second) and, perhaps, its elevation to a black letter provision, would meet this problem without mutilating negligence law in its application to other products. See supra note 7.
conformable to society’s norms of fairness.\textsuperscript{28} Stifling the growth principle in negligence law, by attempting to specify for the future the detailed terms on which common law courts may permit unreasonableness to be found, runs counter to the essence of the negligence concept as the courts have explained it over most of the twentieth century. It is questionable whether an attempt to do so in the Restatement (Third) would be at all wise, in the absence of explicitly demonstrable support in the cases, even if such an attempt were otherwise advisable. In the circumstances, the advisability is dubious. Furthermore, whether courts are likely to accept such guidance, found in a Reporters’ Note to a comment to a novel provision in a restatement of torts, as a persuasive reason to depart from the instructions they are accustomed to give on unmerchantability in breach of warranty cases arising under article 2 of the Uniform Commercial Code, is not for me to say. It seems unlikely, however, that the credibility and influence of the ALI are likely to be enhanced by the attempt to require such a change.

III. REFLECTIONS ON POLICY

The Reporters have attempted to explain their reasons for recommending that the rule of section 402A for strict liability for design and warning defects not be “strict” but instead be diluted to a set of requirements more nearly like negligence.\textsuperscript{29} The Reporters’ explanations deserve careful reading. They are detailed and serious and very difficult to reflect fairly in brief summary. Some, however, are more understandable than others. For instance, it is fair to note, as the Reporters have done, that the proposed rules reflect the positions taken in a good number of jurisdictions by courts and legislatures. On the other hand, it may be thought—as the Reporters apparently do, although I, as a former chemical manufacturer, do not and never have shared the sentiment—that it is somehow unfair for manufacturers to be subject to liability in the absence of culpability for harm to users or others that their products cause when the harm is caused because the products are unreasonably unsafe.\textsuperscript{30} If the Reporters’ view prevails on this question of moral judgment, distinctions can indeed be drawn between the

\textsuperscript{28} This is not to suggest that a proper application of traditional negligence concepts in light of society’s norms of fairness will always yield expanded liability. Contractions of liability may also be necessary for a fair application of traditional concepts. For instance, as I have suggested elsewhere, a firmer judicial control of juries may be desirable to protect sellers from incoherent liability where competing safety considerations lead to honest, reasonable conflicts in design choices. See HARPER ET AL., supra note 4, § 28.32A, at 585 n.43. Improvements may also be necessary in present methods of the adjudication of causation. Confusion, for instance, in areas of statistical proof, appears to be a particularly troublesome current problem.

\textsuperscript{29} See Tentative Draft, supra note 1, § 2 cmt. a, at 11-12.

\textsuperscript{30} Id. at 13.
fairness of strict liability for manufacturing defects, on the one hand, and design or warning defects, on the other. It is probably the case that, if all were known, the overwhelming majority of manufacturing defects could be attributed to negligence for which the manufacturer is subject to liability or for which the manufacturer would be entitled to indemnity from a supplier. For manufacturing defects, therefore, the strict liability rule may merely represent a device for administrative convenience rather than a substantive departure from the fault principle as a limit on liability. It is not self-evident that this is likely to be the case to the same degree for design defects.\footnote{31}

The Reporters attempt to make a supplemental distinction based on the deliberateness of the manufacturer’s decisions on how much to invest in quality control as a check on manufacturing defects.\footnote{32} This is a point I also have made in the past to help justify strict liability for manufacturing defects. I am not satisfied, however, that this explains why a difference should be recognized in the case of design defects. Presumably, the decisions made by the manufacturer about how much to invest in safety analysis and testing of the product in its intended condition are equally deliberate. It may be easier to demonstrate how much additional quality control inspection would have been necessary to detect a given manufacturing defect than to demonstrate how much additional safety testing would have disclosed a design hazard or its remedy. The general notion, however, that the manufacturer who decides how much to invest in one kind of testing or another should bear the risk of the inadequacy of that decision, may be substantially applicable to both situations.

Other reasons referred to provide less clear justification for the dilution of supplier liability for defects of the non-manufacturing varieties while strict liability is retained for manufacturing defects. The Reporters assert, for instance, certain purported insurance considerations as a reason to limit the liability for design defects.\footnote{33} “To insure against future claims,” they say, “an insurer must be able to estimate fairly accurately the likelihood of such claims being made, together with their size and number. Thus, with respect to unforeseeable or incalculable risks, manufacturers would find it difficult, if not impossible, adequately to protect themselves with insurance.”\footnote{34} Here, again, is a consideration about which I have speculated in the past. But the accuracy of the Reporters’ assumptions and the validity of their conclusions are not free from doubt. Product liability insurance is, in fact, readily available for manufacturers today, even for those who do business in states, like Massachusetts, where the courts still talk about strict

\footnote{31} It is also not, I think, self-evident that the opposite—the actual freedom from fault on the part of the manufacturer—is likely to be the case either.

\footnote{32} Tentative Draft, supra note 1, § 2 cmt. a, at 11.

\footnote{33} Id. at 13.

\footnote{34} Id.
products liability without apparent limitation to manufacturing defects.\textsuperscript{35} The insurance policies now being sold do not exclude claims arising from what the Reporters call “unforeseeable or incalculable risks.” Therefore, manufacturers do not find it “impossible” to insure against such risks, nor do they even find it “difficult,” in general, to insure against such risks. The cost of product liability insurance is still relatively low for most manufacturers, typically about one to three percent of the cost of sales.\textsuperscript{36} It can, of course, be higher for some. Consequently, a few industries may require special rules. For instance, the risk of unknowable toxic side effects with pharmaceutical products might well impose serious obstacles to insurability, particularly for products for which there is relatively small demand. For this and other reasons, the Reporters suggest an entirely separate regime of liability for pharmaceutical products.\textsuperscript{37} I do not object to such special treatment for pharmaceuticals. The insurability of most products, however, remains not seriously impaired by the existence of strict liability for design defects. There may, of course, be quibbles about the adequacy of available insurance; no one can buy infinite coverage. But the cases where industry liability has outstripped coverage—principally the “mass tort” product liability cases, like asbestos and Dalkon Shield—have not usually represented the strict liability of innocents, regardless of any uncertainty there may be about the legitimacy of some of the claims on other grounds, such as proof of causation of injury.\textsuperscript{38} They have been, for the most part, cases of

\textsuperscript{35} Cf. Simmons v. Monarch Mach. Tool Co., 596 N.E.2d 318, 320 n.3 (Mass. 1992) (discussing the status of Massachusetts products liability law). For the availability of product liability insurance, I rely on conversations held in July 1994 with executives and senior supervisors of leading brokerage and insurance organizations, including Ms. Kathleen Cross, Mr. Robert Frankel, and Mr. David Woodworth.

\textsuperscript{36} A one percent “benchmark cost” was reported a decade ago. Harper et al., supra note 4, § 28.32A, at 590 n.54. I am told by product liability insurance managers that the estimate appears plausible; in light of their experience, the current premiums typically range between fifty cents and fifty dollars per thousand dollars of sales. Cf. conversations cited at supra note 35. Cf. also Marc Galanter, News from Nowhere: The Debased Debate on Civil Justice, 71 Denv. U. L. Rev. 77, 96 (1993) (citing one report that “at most” the net liability “on average could be as high as 2 percent of the cost of all products and services sold in the United States” although “effects on individual products could be much greater” and another that “all product liability insurance premiums in 1991 . . . added up to about .21 (twenty-one one-hundredths of one percent) of the total retail sales of products in the United States in 1991”). Cf. Dennis R. Connoly, Insurance: The Liability Messenger, in PRODUCT LIABILITY AND INNOVATION: MANAGING RISK IN AN UNCERTAIN ENVIRONMENT 131 (Janet R. Hunziker & Trevor O. Jones eds., 1994) (“Today . . . the insurance market is soft overall. . . . Even so, insurers are choosing not to divert . . . surplus capacity to cover certain classes of product liability risk, especially in industries such as pharmaceuticals, chemicals, automobiles, and aviation.”).

\textsuperscript{37} Cf. Tentative Draft, supra note 1, § 4, at 88.

\textsuperscript{38} See, e.g., Moran v. Johns-Manville Sales Corp., 691 F.2d 811 (6th Cir. 1982);
liability for egregious misconduct involving heavy punitive damages and affirmed with relish on appellate review. For the most part, manufacturers have enjoyed primary liability coverage, often supplemented by relatively inexpensive umbrella coverage, which is adequate for their liabilities.

One distinction may be worth noting. There are different kinds of surprises for insurers. Insurers do indeed have difficulty with new kinds of liability of which they were ignorant at the time of insuring, such as subsequently imposed liability for toxic waste cleanup. The fact that such changes in the law can play havoc with actuarial assumptions may well be true, but these legal changes involve a different order of surprise from that experienced by the insurer who knowingly sold product liability insurance, when faced with claims for a defect that the insurer did not understand when the policy was sold. This is precisely one of the risks that the insurer knew it was covering. All such design defects, when they emerge, are equally surprising, or not surprising, from the point of view of the insurer, whether or not they should have been anticipated by the insured's employees. It makes no difference in the actuarial process whether a risk results from a defect that was not understood but should have been understood by the insured, or from one of which the insured could not know, so long as the hazard could not have been anticipated by the insurer. The unavailability to the insurer of information about that risk, for use in calculating the premium, is precisely the same in both cases, and due allowance for that possibility of ignorance is always necessary as a normal ingredient in the art of underwriting product liability risks.

Knowledge of design risks on the part of the manufacturer is, of course, desirable. That the law should encourage the acquisition of such knowledge and its use to make products safer is virtually axiomatic. Yet the ALI drafts to date are less clear than might be hoped on the extent to which it would be considered desirable for the proposed rules to affect manufacturers' conduct in this regard.

In discussing, for instance, the advisability of strict liability for manufacturing defects on the one hand, and for design defects on the other, the Reporters advance two lines of reasoning, which can hardly be correct simultaneously. In explaining the rationale for strict liability for manufacturing defects, they report:

From the perspective that tort law serves the instrumental function of creating safety initiatives, imposing strict liability on manufacturers for harm caused by manufacturing defects is thought to encourage greater investment in product safety than does a regime of fault-based liability

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39. Id.
under which, as a practical matter, sellers may escape their appropriate share of responsibility.}

This "escape" from the "appropriate share of responsibility" flows, presumably, from the inability of all accident victims of negligence to prove negligence and the consequent windfall to the defendants who should, but do not, lose. If the Reporters see here any danger that strict liability for manufacturing defects might lead to an excessive investment in safety, or if they disagree with the contention that fault-based liability may "as a practical matter" permit sellers to "escape their appropriate share of responsibility," they do not say so.

One might have inferred that for design defects it would also be desirable "to encourage greater investment in product safety than does a regime of fault-based liability under which, as a practical matter, sellers may escape their appropriate share of responsibility." The need here for an incentive to safety might well appear to be greater than for manufacturing defects, since design defects could affect the safety of all products made to that design while manufacturing errors usually occur in less than all the products manufactured. However, when it comes to design defects, the Reporters no longer discuss the likelihood, which appears to be the same in either case, that sellers subject only to fault-based liability will "escape their appropriate share of responsibility." Nor do they suggest that it is desirable "to encourage greater investment in product safety than does a regime of fault-based liability." Instead, we are now told that "society does not benefit from products that are excessively safe . . . any more than it benefits from products that are too risky." Society does not benefit at all from products that are too risky. The benefit from them is negative. If, as the Reporters say, the benefits from "excessive safety" are no greater, the Reporters are now telling us that in connection with design defects "excessive safety" is detrimental. "Society benefits most when just the right, or optimal, amount of built-in product safety is achieved."

Maybe so. But if this argument is correct, should we not have the same concern with manufacturing defects, that the encouragement of a greater investment for product safety than a regime of fault-based liability would encourage will lead to excessive safety, a condition described by the Reporters in the design context as no more beneficial than excessive riskiness? Conversely, should we not object to a rule that encourages sellers to "escape their appropriate share of responsibility" when the defect is one in design as much as when it is a manufacturing defect?

40. Tenative Draft, supra note 1, § 2 cmt. a, at 10.
41. See id.
42. Id. at 12.
43. Id.
The failure of the Reporters to explore the obvious here might be viewed as a mere editorial glitch, a loose end remaining for attention in a later draft. There is reason, however, for concern that it signifies a more serious problem with the proposal. The anomaly under discussion was identified at some length at a 1993 meeting of the Reporters with the project Advisers. The fact that it remains unresolved is unlikely to be an oversight. Perhaps there is an explanation for the suggestion that the optimum investment in safety, relative to the investment that would be encouraged by fault-based liability, is treated as different for manufacturing defects than for design defects. Perhaps the Reporters will be able to express such a reason more clearly with the benefit of further reflection. An alternative possibility, however, requires consideration: that the project is fundamentally flawed on the ground that the fault-based proposals for design defect liability tend systematically to under-deter. It is specifically in connection with safety testing to discover design hazards that this deficiency is most serious, because it is in this connection that the need for the tort system to provide adequate incentives is most critical and may be least understood.

The need for such tort incentives is particularly marked in the case of toxic chemicals, because a federal regulatory scheme has been adopted that gives American manufacturers a perverse disincentive to learn about the hazards of their products. For most industrial chemicals the rules are quite different from those that have become familiar in the area of traditionally regulated products like drugs, cosmetics, and food additives. For the latter classes of products, and a few others, a manufacturer must obtain federal agency approval before manufacture and distribution. In order to support an application for such approval, a manufacturer must submit extensive, stipulated test data.44 For most chemicals, however, a different regulatory regime applies under the Toxic Substances Control Act (TSCA).45 Under the TSCA, the manufacturer must merely notify the Environmental Protection Agency before a new chemical may be manufactured or imported. In such “premanufacturing notices” (PMNs), the manufacturer must disclose “any test data in the possession or control of the person giving such notice” as to the effect of the substance on health or the environment.46 There is no duty to have tested the chemicals at all. The less testing that the manufacturer does, the less risk the manufacturer has that unfavorable test results will become reportable. “While EPA requires that manufacturers submit whatever toxicity data have been gathered, the majority of PMNs lack any toxicity data, and those that have data frequently have only minimal information.”47 For instance, it has been reported that the most

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47. PERCIVAL ET AL., supra note 44, at 431 (emphasis added); see also Charles M.
commonly provided health test data, in the minority of notices that do contain some such data, are limited to studies of "acute toxicity and local irritation," whereas other studies, "such as sensitization, mutagenicity, carcinogenicity, reproductive/developmental toxicity, repeated dose toxicity, etc., are generally viewed as more critical to the overall assessment of health hazards than acute studies." 48 The EPA may order further studies but only on the basis of elaborate statutory findings that must be made in order to justify a test requirement. 49 It is reported to have done so only infrequently. "EPA received more than 10,000 PMNs between 1976 and 1987, but it required the manufacturers of only 149 new chemicals to conduct additional testing." 50 The EPA may prohibit or limit the manufacture or distribution of the product on a finding that "there is a reasonable basis to conclude" that the product "presents or will present an unreasonable risk of injury to health or environment . . . ." 51 Otherwise sales may proceed.

In the absence of test data from which it can analyze a product, the EPA employs a mode of analysis based on "structure-activity relationships" (SAR). 52 If a new chemical appears structurally similar to others about which information is available, the EPA derives estimates as to whether further test data are needed for the new chemical based on what is known about the dangers of the other chemicals. This leads to what has been called "the paradox of the unknown: that is, in . . . regulatory policy based on toxicology, we are often guilty of 'looking under the lamp post'—focussing our investments upon refining our knowledge about those chemicals about which we already have sufficient information to consider them 'suspect.'" 53


EPA . . . receives test data on fewer than 50% of all new chemical PMNs submitted. Further, when data are provided they most commonly consist of human-health-related acute lethality and local irritation studies. Other types of studies, such as acute aquatic toxicity . . . , environmental fate, mutagenicity, repeated dose toxicity, and so on, are received in fewer than 15% of the notices. Auer et al., supra, at 32.


49. 15 U.S.C. § 2603(a) (1988). The less testing the manufacturer undertakes initially, and the fewer test results reported to the EPA, the less information the EPA has on the basis of which to make the findings requisite to a requirement for further testing.

50. PERCIVAL ET AL., supra note 44, at 431.


52. See generally Auer & Gould, supra note 48.

The TSCA regulatory philosophy has accordingly been described by an experienced observer as a “culture of denial [which] has asserted that we do not need information in order to assess risks, a nonsensical and anti-scientific posture that can only condemn us to ill-informed and unproductive debates conducted in a vacuum of real information.”

As noted above, “TSCA stands in sharp contrast to the federal Food, Drug, and Cosmetic Act, which requires extensive testing and express approval before food additives and therapeutic drugs can be marketed or used.” It stands in contrast with the rules in the European Union, under which “a comprehensive battery of toxicity tests [must] be performed prior to the introduction of new chemicals.” It also stands in contrast with programs undertaken in Germany, the Netherlands and Japan—our most significant competitors—for more comprehensive evaluation of chemical hazards. It can also be contrasted with a compromise approach that has been developed in the Organization for Economic Cooperation and Development (OECD) for defining a relatively inexpensive “screening information data set” (SIDS) to identify chemicals that require further testing.

For the vast number of chemicals on the American market, the effectiveness of regulation is, accordingly, limited by the adequacy of safety data, which is affected in the case of new chemicals by the statutory disincentive to test at all. The prospect of tort liability, especially strict liability, for harm caused by unreasonably dangerous products provides the most effective external counter-incentive to manufacturers, apart from their own perception of their commercial interests, to encourage them to learn of any bad news before the product is sold. That counter-incentive is weakened under the proposed requirements of section 2(b) to the extent that manufacturers can count on a safe haven from liability unless the victims of their products’ hazards can establish the foreseeability of those risks and the availability of a reasonable alternative design for the chemical in question which could have reduced the risks.

with author).

54. Dr. Ellen Silbergeld, Senior Toxicologist with the Environmental Defense Fund, is Professor of Epidemiology and Preventive Medicine at the University of Maryland School of Medicine, and Adjunct Professor of Environmental Health Sciences and Health Policy and Management at the Johns Hopkins School of Hygiene and Public Health. She has served as a staff scientist at the National Institutes of Health, as a member of several United States delegations to the OECD (Organization for Economic Cooperation and Development) Chemicals and Environment Programme and as a consultant to the OECD Environmental Programme. She is also a MacArthur Fellow.

55. See Silbergeld, supra note 53, at 3.

56. PERCIVAL ET AL., supra note 44, at 431.

57. Id. at 516; see also Auer & Gold, supra note 48, app. I at 66.


59. Id. at 7. The SIDS is based, pragmatically, on the projected volume of production of the chemicals in question.
This suggests that the proposed Restatement (Third) moves in precisely the wrong direction from the Restatement (Second) on product liability. The proposals harden the requirement for "defect" by purporting to make it dominate negligence cases, and give up strict liability except for manufacturing errors. It would make more sense, from the standpoint of encouraging safety, to give up the "defect" requirement, except for manufacturing errors, and to keep strict liability for all unreasonably dangerous products. Clean tobacco and liquor could still be treated as not unreasonably dangerous to sell, in light of the authoritative and pervasive social acceptance of these products, if it were understood that "risk-utility balancing" does not exhaust the meaning of "reasonableness" in the English language.  

Moreover, the difficulty at issue here, while it illustrates a difference in potential impact between no-fault liability and fault-based liability, transcends the difference. Even if liability were limited to fault, a reasonable chemical manufacturer might well be expected to understand that the risks of unknown health hazards require testing of incompletely characterized products. This is not to suggest that the EPA's decisions on the need for further testing, based on its SAR analyses, are usually wrong. The EPA's decisions are very likely to reflect the hazards that are foreseeable in the absence of test data. It is also likely, however, that other serious risks would become foreseeable with the aid of test data. A study undertaken by the EPA, in cooperation with the European Union, has indeed confirmed that the foreseeability of risks as estimated according to the SAR analysis is usually, but by no means always, consistent with the conclusions suggested by the European test data. A reasonable person undertaking the manufac-

60. See also supra notes 7 and 27.
61. EPA, U.S. EPA/EC Joint Project on the Evaluation of (Quantitative) Structure Activity Relationships, EPA 743-R-94-001 (Mar. 1994) (on file with author). On repeated dose toxicity, that is, "the adverse effects which may arise in humans exposed to a chemical at frequent, regular intervals over a prolonged period of time, for example at their daily work," the study concluded:

[Although for 74% of the chemicals in this study, correct or near-correct predictions of concern level were made, it is not considered possible to consider the predictive methods as an adequate substitute for conducting repeated dose toxicity testing of a random/heterogeneous group of chemicals because of under-prediction of toxicity.]

Id. at 39-41.

On mutagenicity, the study concluded:

Although the number of test-positive chemicals was small, it is also of concern that six of them were called low [by the EPA]. The observation that 123 of 142 data pairs (87%) were apparently correctly predicted thus has to be seen in the light of the above comment. For this reason it would not be prudent at this time to replace mutagenicity testing of new chemicals in the EC with the predictive methods used in the US for PMN chemicals.

Id. at 43.
ture of a new chemical may therefore be expected to understand the need for
testing beyond that required by the EPA under its limited statutory authority.
To sell chemical products that have not been so tested, much less to sell
such products that have not been tested at all, might well be deemed
unreasonable. Under comment j and the Reporters’ Note to comment j,
however, the availability of even a negligence action for the failure to do
such safety testing becomes questionable in the absence of a “defect” as
defined under section 2(b), that is, absent proof of an alternative design for
that chemical compound which would have made the product reasonably
safe in terms of “risk-utility balancing.”

One question that remains is how to determine whether the prospect of
such risks to health—unforeseeable in the absence of testing but potentially
discoverable by testing—justifies the expense of testing. Here it will be
seen how the decision whether to invest in safety testing and the judgment
about how much should be invested takes on aspects of deliberativeness
comparable to that manifested by the decision of how much to invest in
inspections for quality control. As noted above, the deliberativeness of the
latter decision has been recognized by the Reporters as a reason for strict
liability for manufacturing defects. The corresponding argument for strict
liability for design defects seems evident, at least in the case of chemicals,
because of the corresponding deliberativeness of the judgment of how much,
if anything, to invest in safety testing. This seems especially clear in the
case of potentially toxic chemicals, where testing is not required by the EPA
but the results of any tests made must be submitted to the EPA. Further-
more, it is probable, both for chemicals and other products, that the actor in
the best position to conduct a cost-benefit analysis on the advisability of
testing is the manufacturer—another consideration relevant to the imposition

“Overall the [EPA’s] water solubility estimates were judged to have marginal acceptability
since the values were both over- and under-estimated by the US.” Id. at 47. On
biodegradability, the study concluded:

[T]he present US modelling scheme appears to be reasonably effective in predicting
biodegradability that is consistent with experimentally derived results. However, given
the uncertainty in the analysis, in the instances for which fate is a major contributor to
the overall risk projection . . . it is advisable to confirm the prediction with appropriate
testing.

Id. at 47-48.

“For acute effects [on health] the US predictions corresponded to the EC results between
78-88% of the time. . . .” [F]or mutagenicity the US predictions corresponded to the EC
results 94% of the time.” Id. at 48. For systemic toxicity, “for 57% of the 138 chemicals
assessed the scores were identical and for 43% the scores disagreed. Further analysis
revealed that the US tends to under-predict systemic toxicity . . . .” Id. at 49.

In a similar study, comparing SAR predictions with test data that were available from
industry on aquatic hazards of new chemicals, 85% of the predictions were determined to be
within a range of “acceptable” accuracy. Auer et al., supra note 47, at 36.
of strict liability on that actor. It is at least uncertain, and probably unlikely, that this analysis by the manufacturer will adequately consider the overall interests of society unless the social consequences of an unreasonably dangerous product are internalized to the manufacturer by strict liability for such consequences. Accordingly, these considerations, derived from the foreseeability that untested new chemicals may have unsuspected hazards, run counter to the recommendations of both comment j, which would unrealistically limit the negligence liability of the manufacturer who undertakes no safety testing, and of section 2(b), which rejects strict liability for design defects in favor of fault-based liability that requires proof of an alternative design for the product.

In any event, the most disturbing feature of the product liability proposals currently before the ALI may be that they dilute the incentives for manufacturers to discover the hazards in their products before they market them, and thereby to design for safer output before any manufacture is undertaken. In this respect, it is ironic that the direction of legal thinking exemplified by these proposals appears opposed to the direction of developments in management theory in recent decades as they relate to issues of quality control. Quality control specialists can choose between three basic strategies: better design, better production control, and better inspection. The legal system expresses its preferences through the incentives and deterrents it provides. Its tendency to affect conduct is strongest where liability is strictest. To provide for strict liability for undetected production errors, and only fault-based liability for undue danger in design, is to provide greater pressure to modify behavior in the former area than in the latter. By contrast, modern business management theory, as expressed in the teachings of W. Edwards Deming, lately deceased, has emphasized a concept called "Total Quality Management." Deming's key contribution has been described as the proposition that "the never-ending pursuit of improved quality would inevitably lower cost, improve profits and bring greater levels of customer satisfaction to business than methods that viewed quality as an expense." The current Reporters' proposals almost seem, in their obsession with "risk-utility balancing" as a pervasive limitation to

62. Cf. Guido Calabresi & Jon T. Hirshoff, Toward a Test for Strict Liability in Torts, 81 YALE L.J. 1055, 1060 (1972) (suggesting that the judge or jury make a decision as to which of the parties is in the best position to make a cost-benefit analysis).

63. In materials disseminated since the completion of this article the Reporters recognize that evidence of defendant's failure to conduct adequate research may be used to establish the foreseeability of risks, or as evidence of "reckless, willfully indifferent, or intentionally wrongful conduct," for purposes of the measure of plaintiff's recovery, or of the choice of applicable statute of limitations. Memorandum from the Reporters, supra note 19, Appendix # 4.


65. Id.
the law's aspirations for safe design, to view quality as an expense. They
de-emphasize the importance of requiring quality in the product's design in
the first place, by providing for only a truncated fault-based liability for the
failure to do so, in favor of the less expensive technique of culling from the
production line rejects that do not even meet the chosen design (for which
failures strict liability is imposed). In this respect, the philosophy underly-
ing the current proposals may well be viewed as retrogressive, if not
anachronistic, by thoughtful critics in the business community, as well as by
lawyers who have found the thrust of section 2 and comment j disquieting.