Recent Federal and American Law Institute Products Liability Reform Initiatives

M. Stuart Madden
Pace Law School

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RECENT FEDERAL AND AMERICAN LAW INSTITUTE
PRODUCTS LIABILITY REFORM INITIATIVES

M. Stuart Madden

I. INTRODUCTION

In 1993 both the United States Senate and the American Law Institute waded once more into the swampy reaches of products liability reform and reconciliation. On the legislative side, in March 1993 the Senate Commerce, Science and Transportation Committee received for review S. 687, the Product Liability Fairness Act of 1993.1 On April 30, 1993, H.R. 1910, the Fairness in Product Liability Act,2 was forwarded jointly to the House Judiciary Committee and the House Energy and Commerce Committee. On May 5, a second product liability bill, H.R. 1954, was submitted simultaneously to the same two House committees.3

In May 1992 the Council of the American Law Institute decided to begin a Restatement (Third) of Torts and to make its first initiative a Restatement of Products Liability. On April 20, 1993, the Reporters for this project, Professors Aaron D. Twerski of Brooklyn Law School and James A. Henderson, Jr. of Cornell Law School, published their “Preliminary Draft Number No. 1” of the products liability component.4 After a late spring and summer of energetic exchange with lawyers, jurists, and teachers, both within the Institute and beyond, the Reporters published “Council Draft No. 1”5 for presentation to the sixty-one member ALI Council. The Council requested certain revisions that will be incorporated into a


M. Stuart Madden is Charles A. Frueauff Research Professor at the Pace University School of Law and the Chair of the Academic Advisory Subcommittee of the Products, General Liability and Consumer Law Committee of the Tort and Insurance Practice Section. Mr. Madden wishes to acknowledge the research assistance of James Wittstein in the preparation of this article.
"Council Draft No. 2," which is scheduled for further Council review at its February 1994 meeting.\(^6\)

This article, with some selectivity, will describe and analyze the substance of the Senate version of the Product Liability Fairness Act,\(^7\) as well as the substance of Council Draft No. 1 of the Products Liability Restatement.

II. PRODUCT LIABILITY FAIRNESS ACT OF 1993 (S. 687)

A. Introduction

Sponsored by Senator John D. Rockefeller IV (D., W. Va.), S. 687 is described as "[a] bill to regulate interstate commerce by providing for a uniform product liability law, and for other purposes."\(^8\) The Fairness Act would reform product liability significantly in such areas as the availability of compensatory damages for commercial and economic loss, the level of proof sufficient for an award of punitive damages, the burden of proof to recover compensatory damages against a nonmanufacturing seller, preemption, alternative dispute resolution, expedited judgments, and the admissibility of evidence of collateral benefits as an offset to compensatory damages.

B. Applicability

The Act applies to "any civil action brought against the manufacturer or products seller, on any theory, for harm caused by a product."\(^9\) However, claims "for loss or damage to a product itself or for commercial loss [are] not subject to [the] Act."\(^10\) The Act indicates that such claims are to be "governed by applicable commercial or contract law."\(^11\) It is not clear what effect the authors anticipate from the last-mentioned clause; in view of the Fairness Act's preemption clause,\(^12\) it would seem that a conclusion that the Act does not apply to a certain claim would permit a court to apply any appropriate doctrine, be it tort, contract, or otherwise.

In any event, by excising from the Fairness Act's coverage claims for commercial loss and for product disappointment not involving harm to other property, the congressional authors chose the widely followed rule that such claims sound properly

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6. See infra part V.
7. The substantial similarity between the House and the Senate versions of the Fairness Acts invites the convenience of describing the Senate version, S. 687, as representative of the three bills.
10. Id.
11. Id.
12. Fairness Act § 4(b) provides, in pertinent part, that the Act "supersedes any state law regarding recovery for harm caused by a product only to the extent that this Act establishes a rule of law applicable to any such recovery." Id. § 4(b).
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in warranty, not tort. The provision does not recognize the exception, adopted in several states but scourged by the Supreme Court in *East River Steamship Corp. v. Transamerica Delaval, Inc.* that permits tort recovery for accidents not involving harm to persons or property other than the subject product when the accident itself is of such a sudden and dangerous character that the absence of harm to other property or persons is a mere fortuity.

C. Preemption

Section 4(b) states that the Act "supersedes any State law regarding recovery for harm caused by a product only to the extent that [the] Act establishes a rule of law applicable to any such recovery." Section 4(c) specifically excludes preemptive effect for a variety of issues, including state choice of law rules, state statutory or common-law claims regarding nuisance, and cost recovery actions arising under the Comprehensive Environmental Response, Compensation and Liability Act of 1980. However, the Fairness Act does afford sweeping dispositive effect to decisions of the federal courts of appeal, stating that such decisions interpreting or applying the Fairness Act "shall be considered a controlling precedent and followed by each Federal and State court within the geographical boundaries of the circuit[]." It is unlikely that such a provision could be given effect, however, as no existing preemption doctrine permits Congress to assign or delegate preemptive effect binding state courts to legal interpretations reached by an intermediate federal court.

D. Expedited Judgments and Alternative Dispute Resolution

Title I of the Fairness Act, entitled "Expedited Judgments and Alternative Dispute Resolution Procedures," provides a detailed framework for early resolution of covered controversies.

1. Expedited Judgments

Section 101 of Title I ("Expedited Product Liability Judgment") is intended to encourage both parties to settle before trial. It provides that the claimant in a products liability action may include in the complaint an offer of judgment, in any specific dollar amount, "as complete satisfaction of the claim." Likewise, the

13. *Acord Council Draft*, supra note 5, § 101 cmt. r, at 43 ("Liability for harm caused by product defects imposed by the rules stated in this Chapter is tort liability, not liability for breach of warranty under the Uniform Commercial Code.").
17. Id. § 4(c).
18. Id. § 4(e).
19. Id. §§ 101-102.
20. Id. § 101.
21. Id. § 101(a).
section also provides that the defendant may "serve an offer to allow judgment to be entered against that defendant for a specific dollar amount as complete satisfaction of the claim." The time permitted for defendant to make this offer is the longer of (1) the time allowed for responsive pleading under applicable state law or (2) sixty days.

If, after defendant receives claimant's offer, defendant does not accept claimant's offer and suffers a final judgment in a dollar amount larger than the offer, "the court shall modify the judgment against that defendant by including in the judgment an amount for the claimant's reasonable attorney's fees and costs, not to exceed $50,000." If a claimant who receives and does not accept a defendant's offer receives a judgment that is less than the defendant's offer, "the court shall reduce the amount of the final judgment in such action by that portion of the judgment which is allocable to economic loss for which the claimant has received or is entitled to receive collateral benefits." Because the claimant's risk, while material, will not exceed the amount of collateral benefits he or she has received, proponents of S. 687 observe correctly that its inducements to accept reasonable settlement offers do not levy decimating consequences upon a claimant who improvidently declines defendant's offer.

2. Alternative Dispute Resolution Procedures

Fairness Act section 102 ("Alternative Dispute Resolution Procedures") provides that within time periods tracking those for offers of judgment under section 101 a claimant or defendant may "serve upon an adverse party an offer to proceed pursuant to any voluntary, nonbinding alternative dispute resolution procedure established or recognized under the law of the State in which the civil action is brought or under the rules of the court in which such action is maintained." This section provides penalties of "reasonable attorney's fees" for a defendant's "unreasonable" refusal to proceed when, after trial, "final judgment is entered against the defendant for [the] harm caused by a product." Section 102 provides no reciprocal penalty or disincentive for a claimant's refusal to use alternative dispute resolution.

22. Id. § 101(b).
23. Id. The time period may be extended by court order upon motion of either party. Id. § 101(c).
24. Id. § 101(d).
25. Id. § 101(e).
26. As Victor E. Schwartz testified before the Senate Commerce, Science and Transportation Committee (September 23, 1993):

Any objective person would see that there is a significant imbalance of punishment with regard to sanctions for turning down reasonable offers, but the approach comports with the fact that most claimants cannot afford to pay a defendant's legal fees. This new approach [of S. 687] gives claimants a new and important weapon to foster settlement[.]

27. Fairness Act, supra note 1, § 102(a).
28. Id. § 102(b). In determining whether refusal to proceed was in "good faith," the "court shall consider such factors as the court deems appropriate." Id. § 102(c).
E. Liability Standards for Nonmanufacturing Sellers

Fairness Act Title II,29 entitled “Standards for Civil Actions,” adopts two liability standards—the first in negligence and the second in express warranty—for nonmanufacturing product sellers. Section 202(a) states that liability attaches when the claimant establishes “by a preponderance of the evidence” that:

(1)(A) the individual product unit which allegedly caused the harm complained of was sold by the defendant; (B) the product seller failed to exercise reasonable care with respect to the product; and (C) such failure to exercise reasonable care was a proximate cause of the claimant’s harm; or

(2)(A) the product seller made an express warranty, independent of any express warranty made by a manufacturer as to the same product; (B) the product failed to conform to the product seller’s warranty; and (C) the failure of the product to conform to the product seller’s warranty caused the claimant’s harm.30

Section 202(b) authorizes the trier of fact to evaluate the conduct of the nonmanufacturing product seller, including conduct concerning the “construction, inspection, or condition of the product, and any failure of the product seller to pass on adequate warnings or instructions from the product’s manufacturer about the dangers and proper use of the product.”31 With its explicit negligence standard for liability of the nonmanufacturing seller, the Fairness Act reflects a marked departure from the still-prevailing rule applying strict products liability to nonpharmaceutical product retailers.32 To ameliorate the harshness befalling a claimant who finds the product manufacturer is either insolvent or not amenable to in personam jurisdiction, the Act allows product sellers to be treated as manufacturers for the purpose of civil liability when “the manufacturer is not subject to service of process” or “the court

29. Id. §§ 201–207.
30. Id. § 202(a).
31. Id. § 202(b)(1). However, a product seller would not incur liability “based upon an alleged failure to provide warnings or instructions unless the claimant establishes that, when the product left the possession and control of the product seller,” the product seller failed to provide to its vendee “pamphlets, booklets, labels, inserts, or other written warnings or instructions” that it received from the manufacturer, or failed “to make reasonable efforts to provide users with the warnings” it received after the sale. Id. § 202(b)(2).
32. For example, the Council Draft of the Products Liability Restatement, discussed in the second part of this Article, preserves retailer strict liability. See Council Draft, supra note 5, § 101. Reporters Henderson and Twerski explain:

A widely shared justification for holding wholesalers and retailers strictly liable for harm caused by manufacturing defects is that, as between them and innocent victims who suffer harm because of defective products, the product sellers as business entities are in a better position than are individual users and consumers to insure against such losses.

Id. cmt. b, at 8. The Reporters observe that such a rule recognizes that retailers may seek indemnity from their vendors and that retention of strict tort liability operates as an incentive for wholesalers and retailers “to deal only with reputable, financially responsible manufacturers and distributors[.]” Id. at 9.
determines that the claimant would be unable to enforce a judgment against the manufacturer.\textsuperscript{13}

F. Punitive Damages

The Fairness Act also sets standards for punitive damage awards. It provides that punitive damages “if otherwise permitted by applicable law” may be awarded to claimants who establish that the harm suffered was “the result of conduct manifesting a manufacturer’s or products seller’s conscious, flagrant indifference to the safety of those persons who might be harmed by the product.”\textsuperscript{34} A simple failure “to exercise reasonable care in choosing among alternative product designs, formulations, instructions, or warnings is not of itself such conduct.”\textsuperscript{35} Further, a compensatory damage award is an explicit prerequisite of any punitive award.\textsuperscript{36} The Fairness Act also sets a “clear and convincing” standard for punitive damages, a rule that finds growing support in state products liability statutes,\textsuperscript{37} as does the requirement of an award of compensatory damages.\textsuperscript{38}

Section 203 of the Fairness Act sets forth a protocol for the measurement of punitive damages, authorizing the trier of fact to consider “all relevant evidence,” including the financial condition of the defendant; the severity of the harm caused by the defendant’s conduct; the duration of the conduct or any concealment of it by the defendant; the profitability of the conduct to the defendant; the number of products sold by the defendant; awards of compensatory, punitive, or exemplary damages to similarly situated persons; any criminal penalties imposed on the defendant as a result of the conduct in question; and the amount of any civil fines assessed against the defendant as a result of the conduct in question.\textsuperscript{39}

While similar in substantial ways to punitive damages criteria adopted by many courts and legislatures, this seemingly innocuous recitation of factors that the trier of fact sees fit. For example, in Haslip v. Pacific Mutual
Insurance Co. the Supreme Court found unobjectionable Alabama punitive damages standards that included most of the Fairness Act factors (although not the prospective civil award factor), but identified only two—imposition of criminal sanctions and existence of other civil awards—as appropriate for consideration in mitigation. 41

For claims involving prescription drugs and medical devices, the Fairness Act states that punitive damages are not to be awarded against manufacturers or product sellers if the drug or device in question was subjected to FDA premarket approval or "is generally recognized as safe and effective pursuant to conditions established by" the FDA. A similar conditional immunity is afforded manufacturers of aircraft or aircraft components who have received FAA certification and have satisfied postapproval reporting obligations. 43

G. Apportionment of Noneconomic Loss

Lastly and significantly, section 206 of the Fairness Act provides that a defendant's liability for noneconomic loss is to be several only, with judgment to be entered in proportion to the defendant's "percentage of responsibility." 44

III. COUNCIL DRAFT NO. 1, RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY

A. Introduction

The subjects of Council Draft No. 1 are "Product Defectiveness," "Causation," and "Affirmative Defenses." Like S. 687, the draft Restatement addresses only a subpart of the many legal issues affecting products liability. Unlike S. 687, however, there is no political impediment to the Institute's plan to return to the subject over the next decade, reconciling and rationalizing tort doctrine one step at a time.

B. Manufacturing, Design, and Informational Defects

Sections 101, 102, and 103 of the Council Draft establish standards for product defectiveness. The authors state that "[r]ather than perpetuating confusion spawned by existing doctrinal categories [i.e., strict liability, warranty, and negligence], Sec-

42. Fairness Act, supra note 1, § 203(b)(1).
43. Id. § 203(c).
44. Id. § 206(a).
45. Council Draft No. 1 was preceded by an April 20, 1993, Preliminary Draft. See generally Preliminary Draft, supra note 4. A Preliminary Draft and a Council Draft each play a role in the maturation of an eventual Restatement. The Preliminary Draft of a potential Restatement is, in every sense, preliminary. It represents the work, synthesis, and approach of its authors and is exclusively the work of the reporters. It is the first of many stages of an eventual Restatement.

In the months following distribution of the Products Liability Preliminary Draft the Reporters and
tion 101 defines the liability for each form of defect in functional terms. These "functional terms" are familiar: manufacturing defect, design defect, and failure to instruct or warn. Section 101, entitled "Commercial Seller's Liability for Harm Caused by Defective Products," states:

(a) One engaged in the business of selling products who sells a product in a defective condition is subject to liability for harm to persons or property caused by the product defect.

(b) Liability under Subsection (a) may be based on: (1) a manufacturing defect . . .

though all possible care was exercised in the preparation and marketing of the product; (2) a design defect if the foreseeable risks of harm posed by the product could have been reduced by the adoption of a reasonable alternative design . . . or (3) a defect consisting of failure to instruct or warn if the foreseeable risks of harm posed by the product could have been reduced by the adoption of reasonable instructions and warnings . . .

Comment a to section 101, while acknowledging that liability for each form of defect is defined in functional terms, recognizes that many courts insist upon using "strict liability" language in design and failure to warn cases. According to the Reporters, there are several reasons for this preference. First, in the area of design defect, "if a product causes injury while being put to a reasonably foreseeable use, the seller is held to have known of the risks that attend such use." Also, some courts have tried to limit the defense of comparative fault by characterizing the liability test as being "strict," rather than based in negligence, thereby applying comparative or contributory fault "in a more restrictive fashion." Moreover, a negligence standard might preclude a finding of liability against a small manufacturer if the factfinder believed that it was "too burdensome for [the manufacturer] to discover some risks or to design or warn against them." Finally, the Reporters explain that courts' "rhetorical preference" for "strict liability" accurately reflects that the liability of nonmanufacturing sellers is and remains "strict" because it is "no defense that they acted reasonably and were not aware of a defect in the product, be it manufacturing, design, or failure to warn." The Reporters conclude that courts (and presumably legislatures) "can choose to employ existing doctrinal

47. See id. § 101(b).
48. Id. § 101.
49. Id. cmt. a, at 5.
50. Id.
51. Id. at 5–6.
52. Id. at 6.
53. Id. at 5–6.
structure or simply define liability in the functional terms set forth in the black letter.\textsuperscript{54}

1. Manufacturing Defects

The Council Draft definition of a manufacturing defect is expanded over that of the Preliminary Draft. A manufacturing defect in both is defined as "a departure from a product unit's design specifications."\textsuperscript{55} Both also impute liability to a down-the-chain seller for defects that arise after manufacture, for example, during shipment or storage. However, the Council Draft makes it clear that "[w]hen the manufacturer delegates some aspect of the manufacture, such as final assembly or inspection, to a down-the-chain seller, the manufacturer may be subject to liability under rules of vicarious liability for a defect that was introduced into the product after it left the hands of the manufacturer."\textsuperscript{56}

The Reporters specifically rejected any requirement that a claimant prove a manufacturing defect be "unreasonably dangerous."\textsuperscript{57} The reasons given are that (1) the imposition of such a requirement "would place a needless burden on plaintiff"; (2) there are virtually no cases "where a product contains a manufacturing defect that is the cause of the plaintiff's injury but is not 'unreasonably dangerous'"; and (3) the functional definition of manufacturing defect adopted in section 101(b)(1) "has been utilized by courts and has caused no difficulty in application."\textsuperscript{58}

Section 102 of the Council Draft was completely rewritten to provide for an inference of defect only in the context of manufacturing defects.\textsuperscript{59} It states: "When a product malfunctions and causes harm under circumstances where it is more probable than not that the malfunction was caused by a manufacturing defect, the trier of fact may infer that such a defect caused the harm and plaintiff need not specify the nature of such defect."\textsuperscript{60} Preliminary Draft section 102 contained no such limitation to manufacturing defects. The policy reason for allowing an inference of defect is to permit recovery when the product is destroyed or consumed, thus inhibiting a finding of what specifically went wrong with the product.\textsuperscript{61} Limiting the inference to manufacturing defects is sensible, the Reporters explain, for two reasons: (1) "[n]umerous commentators [note that it is] impossible to conjure up a failure-to-warn case that would fall within the requisites of Section 102[.]",\textsuperscript{62} and (2) design defect cases are not cases where evidence of defect is unavailable[.]

\textsuperscript{54} Id. at 7.
\textsuperscript{55} Id. § 101 cmt. f, at 14; Preliminary Draft, supra note 4, § 101 cmt. f, at 17.
\textsuperscript{56} Council Draft, supra note 5, § 101 cmt. f, at 14 (emphasis added).
\textsuperscript{57} Reporters' Guide to Revisions Made to Preliminary Draft No. 1, Restatement (Third) of Torts: Products Liability, at ii (Sept. 10, 1993) [hereinafter Guide].
\textsuperscript{58} Id.
\textsuperscript{59} Id. at v.
\textsuperscript{60} Council Draft, supra note 5, § 102.
\textsuperscript{61} See id. cmt. a, at 118.
\textsuperscript{62} Guide, supra note 57, at v.
2. Design Defects

Section 101 of the Preliminary Draft provided that a case for design defect liability would be established "if the foreseeable risks of harm presented by the product could have been reduced by the adoption of a reasonable, safer design."\(^6^4\) The Council Draft instead reads: "if the foreseeable risks of harm posed by the product could have been reduced by the adoption of a reasonable alternative design."\(^6^5\) Explaining the revision, the Reporters state that "reasonable alternative design" is the phrase most frequently used by the courts\(^6^6\) and that use of the term "safer" would be redundant, for "if the alternative design reduces the foreseeable risks of the harm posed by the product, it is by definition safer."\(^6^7\) Finally, the Reporters note that the design offered by the plaintiff must be a "reasonable alternative" to the design in question.\(^6^8\) Although "[t]he proffered design may be safer[,] it may not be a 'reasonable alternative to the defendant's product.'"\(^6^9\)

The Reporters emphasize that the well-known "consumer expectations" test is "not an independent standard for judging the defectiveness of product designs."\(^7^0\) In their words, the test for design defect properly employs a "'risk-utility' balancing" to determine defectiveness in the context of design.\(^7^1\) This test is "the standard for judging the defectiveness of product designs"\(^7^2\) and obligates "plaintiff[s] prove that the seller or a predecessor in the distributive chain failed to adopt a reasonable alternative design that would, at acceptable cost, have reduced the foreseeable risks of harm posed by the product."\(^7^3\)

A risk-utility balancing test is unmistakably the test for determining the reasonableness of a "reasonable alternative design." The Council Draft discusses the restrictions of "reasonable alternative design" more fully than had the Preliminary Draft. In evaluating any proposed alternative design, consideration must be given to the cost of designing the alternative and whether the alternative would provide greater overall safety.\(^7^4\) The Reporters explain: "It is not sufficient that the alterna-

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63. Id. at vi.
64. Preliminary Draft, supra note 4, § 101(2)(b) (emphasis added).
67. Id.
68. Id.
69. Id. at ii; see also Council Draft, supra note 5, § 101 cmt. h ("Design defect: Reasonable Alternative Design").
70. Council Draft, supra note 5, § 101 cmt. i, at 27. However, the Reporters state that "the nature and strength of consumer expectations," inter alia, may be considered when deciding the reasonableness of a product design. Id. § 101 cmt. h, at 22.
71. Id. § 101 cmt. g, at 16.
72. Id.
73. Id. at 16-17.
74. See generally id. § 101 cmt. h.
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Tive design would have reduced or prevented the harm suffered by the plaintiff if it would also introduce into the product other dangers of equal or greater magnitude. Such an alternative design could not be considered to be reasonable.\textsuperscript{75} Cost and consumer preference may be considered as well. An alternative design may provide greater safety, "but only by substantially increasing the monetary cost of the product or by significantly reducing its attractiveness to consumers by decreasing the benefits of use and consumption."\textsuperscript{76}

The Reporters' proposed liability standards reject the "open and obvious" or "patent danger" rule as a total bar to a design defect claim, relegating "obviousness" to the role of "one factor among many to consider as to whether a product design meets risk-utility norms."\textsuperscript{77} However, the Reporters state that there is no duty to warn about obvious dangers.\textsuperscript{78} Explaining the compatibility of a rule that obviousness is no automatic bar to a design defect claim with one that preserves obviousness as an exculpatory factor in warning cases, Professors Henderson and Twerski cite their own earlier commentary:

\begin{quote}
\textit{The argument for abandoning the patent danger rule in warning cases, simply because the rule has been abandoned in design cases, makes no sense. In the design case, the obviousness of the danger does not necessarily preclude the possibility that an alternative design could reduce the risk cost-effectively. By contrast, assuming that some risks are patently obvious, the obviousness of a product-related risk invariably serves the same function as a warning that the risk is present. Thus, nothing is to be gained by adding a warning of the danger already telegraphed by the product itself.}\textsuperscript{79}
\end{quote}

3. Informational Defects (Warnings and Instructions)

Section 101(b)(3) adopts a reasonableness test in judging the adequacy of warnings\textsuperscript{80} similar to the reasonableness test of section 101(b)(2) for design defects.\textsuperscript{81} The Council Draft emphasizes the difficulty of applying this standard in the context of failure to instruct or warn, recognizing, inter alia, that the effectiveness of a warning may be reduced by (1) the existence of too many warnings (which increases the likelihood that they will be ignored), (2) an inappropriate degree of intensity in the transmission of the warning, and (3) the inclusion of "trivial or far-fetched risks."\textsuperscript{82}

Liability for design defect and failure to warn claims will attach only when the

\begin{footnotes}
73. Id. at 22.
74. Id. at 21.
75. Id. § 101 reporters' notes, at 69. A majority of the courts have rejected the "open and obvious" or "patent danger" rule. Id. at 69-70.
76. Id. § 101 cmt. k, at 31.
78. See id. § 101 101(b)(3).
79. Id. § 101 cmt. j, at 29.
80. Id.
81. Id.
82. Id.
\end{footnotes}
product has been put to a reasonably foreseeable use. The Council Draft reflects one substantive change from the Preliminary Draft in this area. The Preliminary Draft took the position that if a use of a product (excluding prescription drugs and toxic products) is foreseeable, the manufacturer is charged with the knowledge of risks arising therefrom. Recognizing that imputing knowledge to the manufacturer in all cases has little judicial and scholarly support, the Council Draft places upon plaintiff the burden of showing that the risks of harm were known or should have been known at the time of manufacture. However, the Reporters make an exception in the case of mechanical products, providing that if plaintiff establishes that a mechanical product was put to a reasonably foreseeable use, it is not necessary for the plaintiff to prove that the seller knew or should have known of the risks that would arise from such foreseeable use. The Reporters explain: "We see no good reason to burden plaintiffs with proving the foreseeability of risks arising from foreseeable uses of mechanical products. The reality is that, almost by definition, once the use [of a mechanical product] is foreseeable, the risks which attend such use are foreseeable."

C. Prescription Drugs and Medical Devices

Section 103 of the Council Draft pertains to liability for prescription drugs and medical devices and posits that the plaintiff should prevail only if (1) there was a "manufacturing defect"; or (2) "reasonable instructions and warnings . . . were not provided to prescribing and other medical providers . . ."; or (3) "reasonable instructions and warnings regarding foreseeable risks of harm . . . were not provided directly to the patient when: (i) the manufacturer knew or had reason to know that no medical provider was in the position [to reduce the risk of harm]," or (ii) FDA regulations require direct warnings, or (iii) "the manufacturer advertised or otherwise promoted the drug or medical device directly to users and consumers;" or (4) the "reasonably foreseeable risks of harm posed by the drug or medical device were sufficiently great in relation to its therapeutic benefits that a reasonable medical provider . . . would not prescribe the drug or medical device . . . ." Cognizant of the nearly uniform adoption of comment k to Restatement (Second) of Torts section 402A, the Council Draft "specifically exclude[s] prescription drugs, chemicals and toxics from imputed knowledge."
Section 103 of the Council Draft contains several important changes in the black letter rule as originally written in the Preliminary Draft. Most importantly, while the Reporters preserve the orthodox rule that the manufacturer's informational obligation for prescription products is satisfied by providing adequate warnings to the medical profession, they have included several exceptions. Comments received by the Reporters indicated that both plaintiffs and defendants were unhappy with the original text of the Preliminary Draft, which simply included a "caveat" at the end of the black letter rule stating that the "[American Law] Institute takes no position as to whether persons other than the medical providers should receive instructions and warnings about the risks presented by prescription drugs or medical devices." Plaintiffs' lawyers, among others, wanted acknowledgment that in some instances even sellers of prescription drugs should be required to convey warning information directly to the patient. Those arguing the interests of defendants were equally dissatisfied because the subject was left wide open and without guidance.

The Reporters responded to these criticisms with a rule that attempts to reflect "the instances in which courts have justifiably allowed inroads into the learned intermediary' rule." Section 103(a)(3) of the Council Draft thus recognizes that direct warnings or instructions to patients are warranted for drugs or medical devices that are dispensed to patients by prescription (a) when "the manufacturer knew or had reason to know that no medical provider was in the position [to receive the warnings and reduce the risk of harm]"; (b) when FDA regulations require direct warnings; or (c) when "the manufacturer advertised or otherwise promoted the drug or medical device directly to users and consumers . . . ." In another change from the Preliminary Draft, the standard for defective design of a prescription drug or medical device, originally articulated in the Reporters' comments, now appears in the black letter text. Under section 103(a)(4) the

91. See id. § 103 cmt. d.
93. Preliminary Draft, supra note 4, § 103 caveat, at 108.
94. Guide, supra note 57, at vi; see, e.g., Reyes v. Wyeth Labs., 498 F.2d 1264 (5th Cir. 1974) (manufacturer of polio vaccination had duty to convey risk warnings directly to population to be vaccinated when circumstances of vaccination of large numbers of persons eliminated presumption of individualized treatment and communication that underlies informed intermediary doctrine); Macdonald v. Ortho Pharmaceutical Corp., 475 N.E.2d 65 (Mass.), cert. denied, 474 U.S. 920 (1985) (manufacturer of oral contraceptives had duty to provide warnings directly to patients due to distinctive nature of physician-patient relationship for such prescriptions, the substantial risks associated with the product's use, and the feasibility of direct warnings).
96. Id.
97. Council Draft, supra note 5, § 103(a)(3). The Reporters note that judicial authority supports the requirement of direct warning in cases (a) and (b). Id. § 103 reportes' notes, at 146-47. They concede, however, that there is no judicial authority supporting direct warning in case (c), but assert that "common sense notions of fairness" support their position. Id. at 147.
98. See Preliminary Draft, supra note 4, § 103 cmt. e, at 113.
drug or device must "have so little merit compared with its risks that no reasonable medical provider, possessing knowledge of risks that were known or reasonably should have been known to the drug or device manufacturer, would have prescribed the drug or device to any class of patients." The Reporters explain:

The thrust of the rule is that a drug design cannot be declared defective as long as there are patients for whom the drug can and should be prescribed. No ascertainable class of patients should be deprived of a drug merely because some medical providers may misprescribe the drug... To [hold the drug defective] would effectively deny the drug to patients for whom it is, appropriately, the drug of choice.

D. Causation

Council Draft section 104 states that whether a product defect caused a claimant's harm is to be determined by the rules and principles governing causation in tort, subject to an exception for enhanced harm/crashworthiness causation questions treated in section 105.

1. Proportional Causation

The Preliminary Draft included a "caveat" that left open for discussion the issue of proportional liability (including, inter alia, market share liability). The Council Draft similarly leaves the question open by not taking a firm position on proportional liability. However, the comments identify factors for a court to consider when deciding whether to adopt such a rule. These include: (a) the generic nature of the defect; (b) the long latency period of the injury; (c) the inability of plaintiffs to discover the identity of the defendant even after exhaustive discovery; (d) the clarity of the causal connection between the defective product and the injury suffered by plaintiffs; (e) the absence of medical or environmental factors that could have caused or materially contributed to the injury; and (f) the availability of sufficient market share data to allow a rational apportionment of liability. The Reporters make it clear that "the [American Law] Institute leaves to developing case law the question of whether, given the appropriate factors, a rule of proportional liability should be adopted," but suggest strongly that "should a court adopt some form of proportional liability, the liability should be several, reflecting only the individual defendant's share of the market.

2. Concurrent Causation

Council Draft section 105 treats an issue often raised in crashworthiness cases: whether the injured claimant or the defendant manufacturer must satisfy the burden.

100. Id. § 103 cmt. b, at 132.
103. Preliminary Draft, supra note 4, § 104 caveat, at 125.
104. Council Draft, supra note 5, § 104 cmt. c, at 159-60.
105. Id. at 160.
106. Id.
of proving the actual apportionment of damages when the manufacturer's defective product enhances an injury caused by a third party and/or the claimant. Specifically, the Reporters resolve the conflict between the Third Circuit rule, established in *Huddell v. Levin,*107 and decisions such as Oklahoma's *Lee v. Volkswagenwerk of America.*108 Council Draft section 105 states:

(a) When a product is found to be defective within the meaning of Section 101 and the defect increases the harm suffered by a victim as a result of other causes, the product seller is subject to liability for increasing the harm. The plaintiff is not required to prove the extent of the defect-caused increase, but only that such an increase occurred.

(b) When the plaintiff proves defect-caused increase in harm, the product seller is liable for all of the harm suffered by the victim from both the defect and the other causes unless the seller proves the extent of the defect-caused increase, in which event the seller's liability is limited to the extent of such increase.

(c) In connection with determining the extent of the defect-related increase in harm under subsection (b), the court should make such rulings regarding the admissibility and sufficiency of evidence as will, consistent with considerations of fairness to all concerned, facilitate apportionment.

(d) When a seller of a defective product is held liable for part or all the harm suffered by the victim under the rule stated in subsection (b), the liability is joint and several with all other parties who bear responsibility for causing the harm, determined by applicable rules of joint and several liability.109

Significantly, section 105(b) places upon plaintiff the initial burden of proving that the product was defective and that the defect was the cause of enhanced injuries. Upon such a showing, "the product seller is subject to liability for all the harm suffered by the victim from both the defect and other causes unless the seller proves the extent of the defect-caused increase."110 This provision would encourage a holding similar to the majority position in *Lee* and discourage results following *Huddell,* which required the plaintiff to prove the extent of enhancement damages.111 While some support for the *Huddell* view exists,112 the Reporters note that most writers support placing this burden on defendants.113

Subsection (c) of section 105 is a new addition to the Preliminary Draft version. This subsection urges courts to allow apportionment when feasible by lessening

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107. 537 F.2d 726 (3d Cir. 1976).
110. Id. cmt. c, at 177 (emphasis added).
111. See *Huddell,* 537 F.2d at 738.
113. Id. at 203 (citing, inter alia, Stanton P. Beck, *Enhanced Injury: A Direction for Washington,* 61 Wash. L. Rev. 571 (1986)).
the evidentiary burden. Courts are asked "to listen to apportionment evidence and to let the jury decide the apportionment issue whenever it is feasible." 114

E. Affirmative Defenses


When the conduct of the plaintiff combines with a product defect to cause harm to the plaintiff's person or property and the plaintiff's conduct fails to conform to an applicable standard of care, responsibility for harm to the plaintiff shall be apportioned between the plaintiff and the seller of the defective product pursuant to the applicable rules governing apportionment of responsibility. 115

Section 106 is substantively unchanged from the Preliminary Draft and reflects a policy conclusion that "[i]t would be unfair to impose the costs of substandard plaintiff conduct on manufacturers, who will be impelled to pass on those costs to all users and consumers, including those who use and consume products safely and reasonably." 116 The Preliminary Draft left open the questions whether any forms of plaintiff conduct should be considered in comparative fault and whether any exceptions should be made immunizing plaintiffs from comparative fault based on the type of product defect involved. 117 While not a panacea to problems involving plaintiff fault, section 106 now addresses these concerns by stating that "all forms of plaintiff's failure to conform to applicable standards of care should be presented to the trier of fact for the purpose of apportioning responsibility between the plaintiff and the product seller." 118 In the view of the Reporters, however, "the relative innocence or seriousness of plaintiff's fault . . . should not serve automatically to absolve the plaintiff from fault or bar the plaintiff from recovery." 119

In the final section of the proposed Products Liability Restatement, the Reporters suggest that sellers should not be able to rely upon disclaimers and waivers in connection with products liability claims involving personal physical injury. Council Draft section 107 states:

Disclaimers and limitations of remedies by product sellers, waivers by product purchasers, and other similar contractual exculpations, oral or written, do not bar or reduce otherwise valid products liability claims for harm to persons. 120

116. Id. cmn. a, at 216.
117. See Preliminary Draft, supra note 4, § 106 cmn. d, at 174.
119. Id.
120. Id. § 107.
This section, following the influential warranty decision of *Henningsen v. Bloomfield Motor, Inc.* \(^{121}\) provides an irrebuttable presumption that the "plaintiff lacked sufficient information, bargaining power, or bargaining position necessary to execute a fair contractual limitation of rights to recover." \(^{122}\)

**IV. CONCLUSION**

Victor E. Schwanz, a leading private-sector proponent of federalization of products liability law, recently testified: "In the past dozen years, over a dozen states have passed some form of product liability legislation. All this legislation is different and has continued the Tower of Babel style product liability law we have in the United States." \(^{123}\) Product liability legislation of varying stripes has been introduced in Congress annually for over a decade.

S. 687 reveals several strategic compromises presumably based upon criticism of earlier bills. The claimant who refuses to participate in ADR cannot be penalized, while the defendant who refuses ADR in bad faith can be penalized in the amount of the claimant's attorneys' fees occasioned thereby, a decidedly consumer-favorable amendment. The expedited product liability claim procedure in a previous bill, S. 640, \(^{124}\) was interpreted by critics as placing a penalty in the amount of defendant's legal costs upon a claimant who refused an offer of settlement and thereafter received a judgment for less than the settlement offer. \(^{125}\) S. 687 would confine such a plaintiff's penalty to the amount of collateral benefits the plaintiff received, while preserving a penalty of up to $50,000 of the plaintiff's legal costs for a defendant who, following rejection of plaintiff's offer, fails to do better at trial. Lastly, S. 687 manifests greater sensitivity to consumer concerns in its punitive damages provisions providing immunity from punitive damages to pharmaceutical companies and aircraft manufacturers who have received federal approval to market their products. S. 687 makes clear that even following agency approval, drug companies and aircraft makers have a continuing duty to report safety-related information to their governing agencies. \(^{126}\)

The proposed legislation reconciles competing societal, tort policy, and legal interest-group objectives in ways unachieved by its predecessors. Its punitive damages provisions are basically sound, and its flaws can be remedied by simple delineation of factors that should be considered only in mitigation or only in aggravation. The immunization from punitive damage vulnerability of products with prior FDA or FAA approval simply recognizes the de facto approach adopted in leading judicial...
opinions throughout the country. Its adoption of a negligence standard for products liability involving nonmanufacturing sellers, although a departure from the current majority rule preserving strict tort liability, preserves a plaintiff's strict liability claim when the manufacturer cannot be served successfully. In this sense the Fairness Act is more favorable to plaintiffs than the many state statutes that have endeavored to protect retailers from strict products liability through such devices as "closed container" and "no duty to inspect" rules, but provide no exception for manufacturer unavailability.

If there is to be a federal products liability law, S. 687 stands out as being measured and moderate. Seemingly free of the politicization that affected earlier efforts, it addresses only those matters most critical to its proponents and does so with proposed law that fairly reflects the better rule throughout the states. Moreover, its expedited judgment and dispute resolution rules can only create economies for courts and litigants alike, with the savings passed on to consumers and shareholders. These latter provisions should become models for state legislatures throughout the country.

A Restatement represents the consensus of its reporters, the ALI Council, and the ALI membership that its black letter provisions and accompanying Reporter's Notes reflect the best rule of law, consistent with decided cases, on a particular subject. The Institute's goals have been described as the rationalization or reconciliation of incompatible decisional law and the explanation of superior rules and their rationales in such a way that a state high court considering an issue as a matter of first impression would be stimulated to adopt the Restatement position.

In the main, Council Draft No. 1 has accomplished this. Observers cannot realistically expect material departure from core provisions of the Council Draft upon their statement of how the law should be, absent a showing that the Reporters have misinterpreted modern decisional authority.

Congress and the ALI seem to have constructed quite divergent realities. What is one to make of the different legislative and ALI initiatives? The ALI, responsible for promulgation of the enormously influential Restatement (Second) of Torts section 402A, now embarks upon a Restatement (Third) of Torts: Products Liability without apparent recognition of at least eight years of congressional effort in products liability reform. The House and the Senate, in turn, serve up new draft Fairness Acts that cast no more than a sideways glance at the developing common law.

128. E.g., Sam Shainberg Co. v. Barlow, 258 So. 2d 242 (Miss. 1972) ("We are unwilling to extend the rule of strict products liability in tort to the wholesaler and retailer . . . [when the] shoes were never out of their [original container] until the retailer transferred them from the box to a [store rack]."); Padron v. Goodyear Tire & Rubber Co., 662 P.2d 67, 70 (Wash. Ct. App. 1983) ("[T]he duty to inspect or test for defects lies with the manufacturer rather than the retailer.").
129. See, e.g., RESTATEMENT OF TORTS introduction, at iii-iv (student ed. 1934). In products liability this archetype is increasingly rare, as the highest courts in most jurisdictions have reviewed and decided most elements of products liability claims and defenses.
including empirical demonstrations that plaintiff judgments already are in a downward swing in such bellwether jurisdictions as California.

The principal reason for the distinct realities is that Congress and the ALI have altogether different aims and purposes. Congress is charged with effecting, in legislation, and within constitutional limitations, the urges and needs of its individual members' constituents. This, of course, is not its only charge. The ALI has a different mandate. It was formed and continues to aspire to rationalize, synthesize, and make more effective and progressive existing common law or bodies of law represented, as is products liability, by both common law and statutes. Thus the ALI is restrained from introducing dynamic, even untested experiments in the civil justice system. It is a limitation that cedes to Congress the role of promulgating devices such as alternative dispute resolution mechanisms and settlement when such devices, at least for now, have no widespread presence in state statutes or decisional law. The tort bar and the judiciary can expect Congress to continue to use tort reform as a laboratory, and substantive products liability law as the Petri dish, for its experiments in economic and judicial efficiency.

V. POSTSCRIPT

Council draft 1A was published January 4, 1994, and approved by the ALI Council at its meeting on March 4 with revisions. The Reporters are incorporating the requested revisions and plan to publish a Tentative Draft before the May 1994 ALI meeting, when a discussion of the draft Restatement is scheduled.

The most significant changes in Council Draft 1A were:

In section 101, new section 1, the black letter now states that to prove defective design or defect due to inadequate warnings or instructions, plaintiff must establish that the omission of reasonable alternative warnings or instructions renders the product "not reasonably safe."

In comment language the Draft recognizes that some narrow categories or products, such as certain hazardous toys, may be defined as "'not reasonably safe' whether or not an alternative design is suggested."

Council Draft 1A deleted from the black letter language proposing an exception to the learned intermediary rule for prescription products advertised directly to patients.

Finally, Draft 1A's "enhanced injury" rule now states that the "defect must be a substantial factor in causing increasing harm beyond that which would have been suffered by the plaintiff from non-defect related causes." In addition, Draft 1A does not formally shift to the defendant the burden to prove the extent of the enhanced harm. Nevertheless, when the proof does not support apportionment, the defendant is jointly and severally liable.