SYMPOSIUM ISSUE

RESTATEMENT (THIRD) OF TORTS:
PRODUCTS LIABILITY
IS THE BEST DEFENSE REDEFINING THE OFFENSE?

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On February 6, 1999, the Northern Kentucky Law Review sponsored a symposium on the Restatement (Third) of Torts: Products Liability (hereinafter Third Restatement), which was recently released by the American Law Institute ("ALI"). The ALI "is a private body of judges, practicing attorneys, and legal scholars that drafts and publishes the Restatements of various fields of law." Many of our symposium speakers and article contributors participated in drafting the Third Restatement.

It has been said that the ALI's mission "is not to reform the law, but rather to rationalize it... to reconcile conflicting state standards... and to create a unified presentation of products liability law..." The goal is to articulate a uniform rule of law that "might, as the hypothesis goes, prompt a state high court in a jurisdiction that had not ruled on the matter to adopt the Restatement position as the optimum rule of law."

In 1965, the ALI promulgated the Restatement (Second) of Torts § 402A (hereinafter Second Restatement), which proposed a set of rules and comments pertaining to the liability of commercial sellers for injuries caused by their products. Section 402A was adopted in numerous jurisdictions and today dominates the field of products liability law. It has received both praise and criticism from scholars, judges and practicing attorneys.

In the early 1990s, the ALI appointed professors James Henderson, of Cornell Law School, and Aaron Twerski, of Brooklyn

1. Assistant Professor of Law, Salmon P. Chase College of Law, Northern Kentucky University.
2. The Law Review would like to express its gratitude to Professor David Elder for his help and assistance in planning and executing the symposium.
4. Id.
5. Id.
7. See id.
Law School, as Reporters for the project of drafting a *Third Restatement* for products liability. The Revision project was finished in 1998 when the ALI published the final version of the new Restatement on products liability. The final draft was almost four hundred pages long and consisted of twenty-one numbered sections.

Like the *Second Restatement*, the *Third Restatement* has sparked considerate interest (and, again, criticism and praise) by the academy, the bench and the bar. While some commentators have expressed approval of the *Third Restatement* and its proposed changes in products liability law, others have severely criticized it as being too influenced by the so-called “tort-reform” movement. It has also been noted that there was a great deal of partisan lobbying of the ALI by both plaintiff and defense attorneys. Our symposium speakers and writers were chosen because of their expertise in the products liability field, their participation in the ALI project, and their divergent views.

Specifically, the symposium contributors debated the impact of the *Third Restatement* on four important areas of tort law: (1) the post-sale duty to warn; (2) liability of component parts manufacturers and raw materials sellers; (3) the relationship between warnings and design defects; and (4) the interplay between the *Third Restatement* and regulatory agencies' controls on product defectiveness.

The symposium participants contributed a series of articles that form this special edition of the *Northern Kentucky Law Review*. Professor Stuart Madden's article discusses important changes in the *Third Restatement* regarding the duties of component parts and raw material sellers. Professor Madden asserts that the *Third Restatement*'s position in this area is well founded under either a corrective justice or economic efficiency analysis.

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8. See id.
9. See id. at 2.
10. See id. at 3-6.
11. See id. at 5.
12. Professor Madden is the Charles A. Freaufl Research Professor and Distinguished Professor of Law at Pace University School of Law in New York.
14. Id. at 555.
Professors Jerry Phillips and Richard Ausness provide divergent viewpoints regarding the question whether manufacturers should ever be permitted to warn their way out of design defects. Following the approach taken by the Third Restatement, Professor Phillips contends that the adequacy of a product's design should be resolved by use of a risk-utility test and that a factor in this assessment should be whether the product had an adequate warning. By contrast, Professor Ausness argues that the Third Restatement's position is too sweeping and that giving large damages awards to consumers who fail to heed clear warning is not socially or economically desirable.

Professor Kenneth Ross writes on the post-sale duty to warn and its treatment by the Third Restatement. Professor Ross notes that while the possibility of burdening manufacturers with a post-sale duty to warn generated a good deal of debate, the drafters ultimately decided that there was sufficient common law precedent for such a duty and thus included it in the final draft. Professor Ross' article provides an overview of the Third Restatement's post-sale duty sections and suggests ways in which manufacturers might comply with the new provisions.

Finally, Professor James O'Reilly writes regarding the interplay of regulatory product safety agencies and the Third Restatement. Professor O'Reilly argues that there needs to be greater coordination between the common law tort system and the governmental safety

15. Professor Phillips is the W. P. Thomas Professor of Law at the University of Tennessee School of Law in Knoxville.
16. Professor Ausness is the Ashland Oil Professor of Law at the University of Kentucky School of Law in Lexington.
18. See id. at 628.
19. Professor Ross is the Distinguished Practitioner in Residence at William Mitchell College of Law in St. Paul, Minnesota.
21. See id. at 573.
22. See id. at 587.
23. Visiting Professor of Law, University of Cincinnati College of Law.
regulation systems. He contends that such coordination will result in
greater protective deterrents and hopefully safer product designs.

We are hopeful that this edition of the *Northern Kentucky Law
Review* will make a meaningful and lasting contribution to the field of
products liability law generally, and to the emerging debate over the
*Third Restatement* in particular.

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25. See id. at 567-58.
26. See id. at 655.
COMPONENT PARTS AND RAW MATERIALS SELLERS:
FROM THE TITANIC TO THE NEW RESTATEMENT

by M. Stuart Madden

ABSTRACT

Professor Madden evaluates the treatment of potential design and informational obligation liability for raw materials and component parts manufacturers under the Products Liability Restatement. Following an introduction to the approach taken under the Restatement (Second) of Torts: Products Liability, and the congruent approach of the new the Restatement (Third) of Torts: Products Liability (hereinafter Third Restatement), the author evaluates the Third Restatement and the limited number of decisions that have employed it. Further to the goal of evaluating the bona fides of the Third Restatement rule, the author describes the two principal approaches to modern Tort law. The first approach is the venerable corrective justice-morality model. The second model is that of economic efficiency-deterrence. Professor Madden concludes that the Third Restatement's synthesis in terms of warnings and design duties of raw materials or component parts suppliers proves up favorably under either construct, and that as respects these somewhat commingled issues represents a valuable contribution to Products Liability law.

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1. Professor Madden is Charles A. Frueauff Research Professor and Distinguished Professor of Law, Pace University School of Law, New York.
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INTRODUCTION

Imagine that the powers of Madison Avenue have at last persuaded you that you really would rather have a Buick. You buy one, and before the odometer registers 2000 miles, at a bend in the road and at a normal speed, the axle breaks. Your Buick stutters to a stop and you find yourself as a stimulus for a multi-car chain collision.

From your lap top modem at your hospital bed, you learn that the axle, part of Buick's original equipment, was manufactured not by General Motors, but by Acme Metal Works, a small but reputable manufacturer of axles for several automobile manufacturers. Your attorney, a graduate of the Salmon P. Chase School of Law, suggests that you bring a suit against Acme, since it appears that they manufactured an axle that was flawed in the manufacturing or inspection process, or was improperly designed. She suggests further that you sue Buick. You ask: "Why Buick?" The response is twofold. First, if the bank robber Willie Sutton had been a plaintiff's lawyer, he might say: "Because that's where the money is." Buick is solvent, and is not likely to repatriate to a foreign country during the pendency of the suit. Second, and in an insight that fills attorneys with a sense of deja vu, or more specifically a recollection of MacPherson v. Buick Motor Co.,\(^2\) you remember that if the overall product is marketed as a Buick, and if buyers have the reasonable perception that they are buying a Buick, then Buick has a nondelegable duty to sell a duly safe vehicle.\(^3\)

In a new scenario, a middle-aged man has suffered bone damage to his jaw. His surgeon informs him that all or most of his condition can be eliminated by implantation of a temporomandibular joint (TMJ), made of Teflon (TM). Teflon is a proprietary product of E.I. DuPont de NeMours. Such joints are manufactured by a company named Vitek. DuPont sells its product in bulk to a large number of purchasers, who use it for a multitude of purposes. While DuPont knows of many applications of its product, such as the popular cooking device coating, it neither knows of, nor does it take steps to inquire as to, the universe of Teflon's potential uses or misuses.

DuPont does know that Teflon has not been approved as safe for application in Type III medical devices, and the literature accompanying

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2. 111 N.E. 1050 (N.Y. 1916).
3. See id. at 1053.
its sale makes no representation as to its suitability for such use. When Teflon is found to be unsuitable for human implantation, should DuPont be liable in products liability? 4

A manufacturer sells truck chassis to which downstream assemblers will thereafter affix commercial truck bodies, ranging from beverage truck bodies to garbage truck bodies. Query: Is the component part manufacturer of the rear-view windows for such chassis charged with a duty to anticipate, and design for, rear vision mirrors suited to all potential uses? 5

A final hypothetical is based upon the venerable Cub Scout Pinewood Derby competition. The miniature pine cars, fashioned by Cub Scouts and their moms or dads, formerly were accompanied by miniature driver figurines, approximately LEGO (TM)-sized. The assembly kit now announces that the driver figurines are no longer included. Perhaps the reason for the change is that the driver figurines posed a small parts hazard. Query: Would the driver figurine manufacturer have warnings or design duties regarding the inclusion of its otherwise non-defective stamped plastic figurines sold as a component part of a hobby kit principally manufactured by, and sold under the name of, the Pinewood Derby trademark?


[T]he fabricator of a component part that is not inherently dangerous has no control over whether the purchaser properly installs the component part into the final system. Where a finished product is the result of work by more than one party, a court must examine at what stage installation of safety devices is feasible and practicable. In many jurisdictions, responsibility for installing a safety device is determined by reference to three criteria: (1) the trade custom indicating the party that normally would install the safety device; (2) the relative expertise of the parties, looking to which party is best acquainted with the design problems and safety techniques in question; and (3) practicality, focusing on the stage at which installation of the device is most feasible.

For a suggested answer, see Verge v. Ford Motor Co., 582 F.2d 384 (3d Cir. 1978), in which the court found not feasible the installation of safety devices by the competent manufacturer.
A. Generally

Component parts, raw materials and ingredients, and the responsibilities of sellers of such products, have long been treated as a special subcategory in products liability. The rationale has consistently been that component parts, raw materials, or ingredients enjoy one more, or all of these qualities that differentiate them from ordinary consumer products:

1. They often do not reach the final vendee or user in a form substantially unchanged and do not deserve strict products liability treatment under Restatement (Second) of Torts: Products Liability (hereinafter Second Restatement) Section 402A; 6
2. The upstream supplier may in fact have sold a duly safe and perfectly merchantable product that only thereafter, by dint of design, formulation, application, warnings or other initiatives taken by others, became a part of a defective end product; 7
3. The component part, raw materials or ingredient supplier often has no practical or efficient means of overseeing the use of its product by a large population of vendees, and thus cannot reasonably be expected to either foresee all potential hazards

6. The court in Zaza held that
[a] further requirement for the imposition of strict liability on a component part fabricator is that the component part reach the user without substantial change. Where a component part is subject to further processing, or where the causing of the injury is not directly attributable to any defect in the component part, the fabricator is typically not subject to strict liability.
675 A.2d at 629 (citations omitted).

7. Commenting upon the implications of an alternative rule, the Third Restatement section 5, comment (a) states in part: "[i]f the component is not itself defective, it would be unjust and inefficient to impose liability solely on the ground that the manufacturer of the integrated product utilized the component in a manner that renders the integrated product defective." Restatement (Third) of Torts: Products Liability § 5 cmt. a (1998).
inhering in various finished products, nor take steps to remedy those flaws; 8
(4) With regard to raw materials and design duties at the least, absent adulteration or another production defect, 9 there is no such thing as a misdesigned raw material, i.e., sand is sand, hydrochloric acid is hydrochloric acid; 10
(5) Even without recourse against the component manufacturer, the injured party may proceed against the ultimate fabricator; 11 and
(6) It is the downstream fabricator whom we want to encourage to pursue risk reducing manufacturing decisions, 12 and who can most readily and inexpensively detect and remedy avoidable product risks. 13

8. The Third Restatement explains that “[i]mposing liability would require the component seller to scrutinize another's product which the component seller has no role in developing. This would require the component seller to develop sufficient sophistication to review the decisions of a business entity that is already charged with responsibility for the integrated product.” Id.
9. One example occurred when sheet steel with an unacceptable level of internal imperfections was rendered brittle and unsuitable for fabrication into automobile radiator fan blades. See Pouncey v. Ford Motor Co., 464 F.2d 957 (5th Cir. 1972).
10. “Regarding the seller's exposure to liability for defective design, a basic raw material such as sand, gravel, or kerosene cannot be defectively designed. Inappropriate decisions regarding the use of such materials are not attributable to the supplier of the raw materials but rather to the fabricator who puts them to improper use.” RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 5 cmt. c (1998).
11. Comment e to the Third Restatement notes that it is the final fabricator that makes the germane safety-related “decisions” regarding the final product, and it is that fabricator that is “the business entity that is already charged with responsibility for the integrated product.” Id. § 5 cmt. a.
12. See id. § 5 cmt. a.
13. Regarding raw materials integrated into other products, the Third Restatement explains that:

The manufacturer of the integrated product has a significant comparative advantage regarding selection of materials to be used. Accordingly, raw-materials sellers are not subject to liability for harm caused by defective design of the end-product. The same considerations apply to failure-to-warn claims against sellers of raw materials. To impose a duty to warn would require the seller to develop expertise regarding a multitude of different end-products and to investigate the actual use of raw materials by manufacturers over whom the seller has no control. Courts uniformly refuse to impose
The American Law Institute's (hereinafter ALI) effort to accommodate this cluster of practical considerations is set out at section 5 to the Third Restatement. Contemplating component parts, raw materials and product ingredients, that section provides:

§ 5. Liability of Commercial Seller or Distributor of Product Components for Harm Caused by Products Into Which Components Are Integrated

One engaged in the business of selling or otherwise distributing product components who sells or distributes a component is subject to liability for harm to persons or property caused by a product into which the component is integrated if:

(a) the component is defective in itself, as defined in this Chapter, and the defect causes the harm; or
(b)(1) the seller or distributor of the component substantially participates in the integration of the component into the design of the product; and
(2) the integration of the component causes the product to be defective, as defined in this Chapter; and
(3) the defect in the product causes the harm.14

My goal in this essay is to examine both the premises of this new provision, and also to gauge preliminarily whether the Third Restatement section 5 conduces to identified tort objectives that have achieved greater or lesser following over the years. The doctrinal objectives that I have sketched out are these:

1. **Reduction in Avoidable Accident Costs**

Principal goals of accident law are the deterrence of harmful conduct and the encouragement of beneficial conduct. An accident law rule that provides in some measure both deterrence of risk-creating behavior and incentives for the actor to take affirmative steps to reduce such an onerous duty to warn.

**Id.** § 5 cmt. c.

14. **Id.** § 5.
avoidable accident advances these twin objectives.

2. **Cost Spreading**

A premise of accident law liability rules is that a seller will be able to liquidate a fairly predictable loss future into a dollar amount that it will pay for third-party liability insurance. The cost of such insurance, and other internal costs of liability defense, will therefore be spread among consumers of the subject product in the form of higher consumer prices. An optimal liability rule will permit an insured to meet with its insurance carrier and describe with some particularity its potential future liability exposure. In contrast, an accident law rule that leaves a seller with indeterminate liability undermines the objective of cost spreading.

3. **Justice**

A general rule imposing joint liability upon component suppliers and final fabricators alike for the sale of defective finished products would, one acknowledges, achieve certain efficiencies in judicial administration. However, whatever the efficiency gains of such a rule, they would be dwarfed by various practical considerations. In this setting, a joint liability rule would be oblivious to tort considerations of justice. A tort rule that achieves the zenith of efficiency but which disregards justice or practical consequences will be rejected as irrational, otherwise wasteful, or, as the comments to the *Second and Third Restatements* suggest, both. Omnibus component or raw material seller liability would be unjust as it would impose an irrational burden upon sellers to superintend, which is to say, to be hall monitors, regarding myriad potential downstream applications of their otherwise non-defective products. Such a burden would, it is seen, impose social costs, in the form of elevated product costs, or even total unavailability of valuable

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16. Should accident incidence or other factors make it infeasible to transfer insurance costs to consumers, or render insurance unavailable, the actor must necessarily evaluate the practicality of continuing the conduct, i.e., in the current context, the manufacture and sale of products.
18. *Id.* § 5 cmt. a.
products, that would occlude whatever deterrence attributes or administrative efficiencies that might be achieved.19

4. Reasonable Foreseeability

Within the shortest period of time, it now seems in retrospect, the so-called "strict liability" standard of the Second Restatement section 402A was pulled back into the gravitational field of the reasonableness standards of negligence.20 Applying such a standard of reasonableness and reasonable foreseeability to a component seller's design and warning obligations does not, proponents of the Third Restatement rule might say, place a premium on ignorance.21 No modern accident law rules create incentives for ignorance. Rather, limitations on liability for component, raw materials and ingredient sellers simply and clearly recognize important distinctions between the component supplier's role and that of the final fabricator.22 A manufacturer remains responsible for being an expert in the field of the pertinent manufacturing endeavor.23 A chair manufacturer is presumed to be an expert in the load strength and ergonomics of a duly safe chair, in both its intended use (sitting) and, at least with regard to load strength, a reasonably foreseeable "off label" use such as to support a person attempting to replace a light bulb.

Likewise, a seller of sand is held to the standard of an expert in the production of sand. We might suppose that such responsibility would run to such matters as making certain that your playground sand did not contain any dangerous level of adulteration, such as mineral radium or chrysotile asbestos. The sand seller is not expected to be an expert in the use of its product in the manufacture of glass since there are no identifiable perimeters around the potential end users of sand, or for that matter teflon, silicon, sheet metal or pig iron. Thus, a "reasonable

19. See id. § 2 cmt. a.
20. Consistent therewith, under the Third Restatement, only manufacturing defects are evaluated under a truly strict liability standard. Design and informational obligations are based upon reasonableness and foreseeability. Id. § 1 cmt. a.
21. See id. § 1 cmt. a.
22. See id.
foreseeability" predicate to the component seller's design or warning duties will, in the majority of circumstances, preclude a finding of liability.24

B. Section 402A's Strategic and Successful Distortion of the Standards for a Conventional Restatement

The objective of the Third Restatement, in keeping with25 tradition, is not to reform the law, but rather to rationalize it. It does so by reconciling to the extent possible conflicting state standards and creating a unified presentation of products liability law that might prompt a state high court in a jurisdiction that had not ruled on the matter to adopt the Third Restatement position as the optimal rule of law.26

The Second Restatement section 402A, published in 1965, was more of a law reform initiative than a typical Restatement. Nevertheless, it became enormously influential because (a) at the time of its publication, Products Liability law was a substantially incoherent welter of divergent voices, a Tower of Babel;27 and (b) section 402A gave language that courts could understand, at least initially.

C. The Decisional Law Under Section 402A

I. Generally

Neither the Second Restatement section 402A nor its successor, Third Restatement, affect liability for the truly defective component part.

24. A liability prerequisite of reasonable foreseeability is therefore essential (1) preservation of incentives for reasonable user caution; (2) for harmonization with risk/utility analysis employed elsewhere in personal injury law, and in products liability law particularly; (3) as the cornerstone for judicious identification of substandard conduct; (4) is central to optimal evaluation of economic efficiency; and (5) is necessary to any reasonable expectation that tort rules will encourage beneficial conduct and deter wasteful or harmful conduct.
25. The American Law Institute is a private body of judges, practicing attorneys, and legal scholars that drafts and publishes the Restatements of various fields of the law.
In comment p to the *Second Restatement* section 402A, the ALI states:

It seems reasonably clear that the mere fact that the product is to undergo processing, or other substantial change, will not in all cases relieve the seller of liability under the rule stated in this Section. If, for example, raw coffee beans are sold to a buyer who roasts and packs them for sale to the ultimate consumer, it cannot be supposed that the seller will be relieved of all liability when the raw beans are contaminated with arsenic, or some other poison . . . . On the other hand, the manufacturer of pigiron, which is capable of a wide variety of uses, is not so likely to be held to strict liability when it turns out to be unsuitable for the child’s tricycle into which it is finally made by a remote buyer.28

A harmonious note is added in the *Third Restatement* where the ALI confirms:

[I]f a cut-off switch is sold in a defective condition due to loosely connected wiring, the seller of the switch is subject to liability for harm to persons or property caused by the improper wiring after the switch is integrated into another product. Similarly, if aluminum that departs from the aluminum manufacturer's specifications due to the presence of foreign particles is utilized in the manufacture of airplane engines, the seller of the defective aluminum is subject to liability for harm to persons or property caused by the defects in the aluminum.29

Putting aside circumstances in which the component, raw material, or ingredient is defective, under the *Second Restatement* section 402A a component seller's warning duties extend only to such risks as were foreseeable at the time of the seller’s initial introduction of the product into commerce.30 Where such risks are foreseeable, the decisions

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30. Zaza, 675 A.2d at 632-33. The court stated: The general rule is that a manufacturer of
commend a manufacturer's duty in strict tort liability to provide warnings as to risks inhering in the use of its product as a component of another product only when the component supplier actually participated in the creation of the specifications for the end product, and in effect "signed off" on the suitability of its part or material for integration into such an end use. Departures from this approach seem localized to circumstances in which even ordinary end use of the product could cause death or serious bodily injury, or where the component supplier, in contrast to its vendee, was in a clearly superior situation from which to evaluate and reduce the risk.

With the passage of years following the 1965 publication of the so-called "strict liability" rule of the Second Restatement section 402A, the section 402A design and warning duties, when compared to the duties that had been assigned under negligence principles, grew to be interpreted so similarly as to become nearly indistinguishable. One California court, relying upon the Second Restatement sections 388 and 394 described the standard for that state in these words:

[T]he manufacturer has a duty to use reasonable care to give warning of the dangerous condition of the product or of facts which make it likely to be dangerous to those whom he should expect to use the product or be

a component part will not be held strictly liable for failure to warn where the danger involved is not foreseeable. See, e.g., Cropper v. Rego Distribution Center, Inc., 542 F. Supp. 1142, 1156 (D. Del. 1982) (holding that component part manufacturer was not liable for failing to place in its catalog warning of dangers involved in using component part in connection with unloading riser, on ground that manufacturer could not be expected to foresee every possible misuse to which part might be put); Mayberry v. Akron Rubber Machinery Corp., 483 F. Supp. 407, 413-14 (N.D. Okla. 1979) (holding that supplier of component parts which were not defective did not have duty to warn subsequent product manufacturer and employees of danger that might arise after components were assembled according to manufacturer's exclusive design).

31. Cf. Restatement (Third) of Torts: Products Liability § 5 cmt. a (1998) (stating that the decisional law has not imposed liability upon component suppliers who did not participate in the integration of the component into the design of the final product).

endangered by its probable use, if the manufacturer has reason to believe that they will not realize its dangerous condition.33

Accordingly, decisional law under both the negligent failure to warn and the strict liability failure to warn approaches of the Second Restatement has confirmed repeatedly that component and raw materials sellers of merchantable products should not, as a general proposition, be exposed to warning duties. Considerations of both fairness and financial burden have figured conspicuously in such conclusions. As one court stated:

Making suppliers of inherently safe raw materials and component parts pay for the mistakes of the finished product manufacturer would not only be unfair, but it also would impose an intolerable burden on the business world . . . . Suppliers of versatile materials like chains, valves, sand, gravel, etc., cannot be expected to become experts in the infinite number of finished products that might conceivably incorporate their multi-use raw materials or components.34

Like considerations guided a widely referenced 1980 decision of a Pennsylvania federal trial court, Orion Ins. Co. v. United Technologies Corp.35 which involved a manufacturer who built a component part to specification.36 Absent a defect in the part, and upon a showing that it was reasonable for the component manufacturer to rely upon said specifications, the Orion court concluded:

[N]o public policy can be served by imposing a civil penalty on a manufacturer of specialized parts for a highly

36. Id. at 174.
technical machine according to the specifications supplied by one who is expert at assembling these technical machines, who does so without questioning the plans or warning of the ultimate user. The effect of such a decision on component parts manufacturers would be enormous. They would be forced to retain private experts to review an assembler's plans and to evaluate the soundness of the proposed use of the manufacturer's parts. The added cost of such a procedure both financially and in terms of stifled innovation outweighs the public benefit of giving plaintiffs an additional pocket to look to for recovery. I believe the better view is to leave the liability for design defects where it belongs and where it now is—with the originator and implemener of the design—the assembler of the finished product. 37

In reasoning similar to that of courts evaluating claims against sellers of component parts, harmonious conclusions have been reached consistently in claims brought against sellers of raw materials. For example, a seller's incapacity to anticipate, and therefore to affect end use risks, provided the basis for defendant's judgment in Pennwalt Corp. v. Superior Court. 38 That suit arose from injuries an eighteen year old plaintiff suffered while attempting to compound chemicals, including sodium chlorate, aluminum powder, and sulfur, 39 at home to create fireworks. Plaintiff brought suit against the manufacturer, distributor, and retailer of each chemical. 40 The appellate court held that the manufacturer of the chemicals should not be liable to plaintiff for the sale of a chemical that had been repackaged, relabeled, and distributed through a retailer over which the manufacturer had no control. 41 The court explained:

Sodium chlorate has many legitimate uses, some of which involve using it in conjunction with other chemicals. Pennwalt cannot be expected to anticipate every possible

37. Id. at 178.
39. Id.
40. Id. at 677.
41. Id.
use and issue warnings of any potential danger involved in each such use. To hold otherwise would place an impossible burden on a bulk manufacturer which would be tantamount to imposing absolute liability for injury resulting from the use of a product not claimed to be otherwise defective.\(^{42}\)

Another California case, *Walker v. Stauffer Chemical Corp.*,\(^ {43}\) involved a plaintiff who was injured seriously by an explosion of drain cleaner that contained sulfuric acid.\(^ {44}\) With respect to the mismarketing claim brought against the supplier of the sulfuric acid, the court observed: "We are referred to no California case, nor has independent research revealed any such, extending the strict liability of the manufacturer (seller) to the supplier of a substance to be used in compounding or formulating the product which eventually causes injury to an ultimate consumer."\(^ {45}\)

The *Walker* court explained further:

We see no compelling reason for an extension [of strict liability] to a situation such as presented in the instant case . . . . We do not believe it realistically feasible or necessary to the protection of the public to require the manufacturer and supplier of a standard chemical ingredient . . . not having control over the subsequent compounding, packaging or marketing of an item eventually causing injury to the ultimate consumer, to bear the responsibility for that injury. The manufacturer (seller) of the product causing the injury is so situated as to afford the necessary protection.\(^ {46}\)

Read together, *Pennwalt, Orion, Walker* and *Stauffer* invite the conclusion that under comment p to the *Second Restatement* section 402A, no liability should attach to the seller of component parts, raw materials or ingredients having multiple end uses, the selection of which is beyond the

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42. *Id.*
44. *Id.*
45. *Id.* at 805-06.
46. *Id.* at 806.
seller's control.

THE PRODUCTS LIABILITY RESTATEMENT TREATMENT OF COMPONENT PART SUPPLIER AND RAW MATERIAL SELLERS' DUTIES

A. Generally

Commentary to section 2 (c) of the *Third Restatement* makes plain the ALI's conclusion, subject to an exception for the supplier who is substantially involved in the design of the eventual product, that absent a defect in the component, the raw material, or the ingredient, liability should not attach to component sellers whose product is integrated into a defective end product. Comment a thereto states:

As a general rule, component sellers should not be liable when the component itself is not defective as defined in this Chapter. If the component is not itself defective, it would be unjust and inefficient to impose liability solely on the ground that the manufacturer of the integrated product utilizes the component in a manner that renders the integrated product defective. Imposing liability would require the component seller to scrutinize another's product which the component seller has no role in developing. This would require the component seller to develop sufficient sophistication to review the decisions of the business entity that is already charged with responsibility for the integrated product.

The *Third Restatement* provides further support and illustration, stating: "[A] basic raw material such as sand, gravel, or kerosene cannot be defectively designed . . . . Accordingly, raw-materials sellers are not subject to liability for harm caused by defective design of the end-product."

Should an employee of the downstream manufacturer or fabricator

48. Id. § 2 cmt. a.
49. Id. § 5 cmt. c.
be put at an unreasonable risk by virtue of a misapplication of the component vendor’s product, guidance as to the vendor’s warnings obligations is found in the more general warnings provisions of the Third Restatement. Regarding sales to informed intermediaries under the Third Restatement, the conventional rule regarding a seller’s informational obligation to the ultimate user is stated as follows:

There is no general rule as to whether one supplying a product for the use of others through an intermediary has a duty to warn the ultimate product user directly or may rely on the intermediary to relay warnings. The standard is one of reasonableness in the circumstances. Among the factors to be considered are the gravity of the risks posed by the product, the likelihood that the intermediary will convey the information to the ultimate user, and the feasibility and effectiveness of giving a warning directly to the user.50

B. The Early Decisional Response

Because of the yet novel quality reality of the Third Restatement, it would not be realistic to expect a groundswell of judicial reaction, be it favorable or unfavorable. Nevertheless, the early decisions seem to suggest that courts find both the articulation and the application of the new rule appealing.

One example is a New Jersey Supreme Court case that involved injuries sustained by one Gerardo Zaza, an employee of Maxwell House Coffee (Maxwell House), a division of General Foods.51 Upon discovering a clog in a quench tank, Zaza was burned severely by scalding hot liquids while attempting to repair the malfunction.52 The defendant had bid to build the quench tank to the specifications of the buyer, and these specifications did not require any of the safety devices that might have prevented the injury.53 Instead, the specifications merely

50. Id. § 2(c) cmt. i.
52. Id.
53. Id.
required defendant to cut holes for any such safety devices. 54

Reviewing the trial court's grant of summary judgment, 55 the New Jersey Supreme Court quoted, with approval, an earlier draft of comment a to the Third Restatement referenced above. Affirming the judgment below, the state high court wrote:

The majority of courts from other jurisdictions have held that a manufacturer of a component part, which is not dangerous until it is integrated by the owner into a larger system, cannot be held strictly liable to an injured employee for the failure of the owner and/or assembler to install safety devices, so long as the specifications provided are not so obviously dangerous that it would be unreasonable to follow them. 56

The court in Zaza explained:

Holding defendant liable would impose on a component part fabricator, whose products were built in accordance with the designer's specifications and whose part when it left defendant's plant was not defective, the duty to investigate whether the use of its non-defective product would be made dangerous by the integration of that product into the complex system designed and installed

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54. Id.
55. The trial court stated:
   The plaintiff says the defendant failed to provide warnings. There was no way that the fabricator could even know what the final looks of that machine would be or what type of use the machine would entail or what component parts would be added to that tank in order to make it into a manufacturing instrument, into an operative working unit. 
Id. at 626.
by experts. Component fabricators would become insurers for the mistakes and failures of the owners and installers to follow their own plans. Defendant would have to retain an expert to determine whether each and every integrated manufacturing system that incorporates one of its sheet metal products is reasonably safe for its intended use . . . . Even if defendant wanted to provide a warning, there is no suitable location on the quench tank for a warning. The quench tank is not a single unit designed to come into contact with workers. Moreover, plaintiff did not produce any evidence that the tank was so obviously dangerous that International had an obligation to warn the users of the trecar-carbon regeneration system. Maxwell House's plans called for the installation of safety devices, and professionals were hired to ensure that the plans were followed . . . . The duty to warn does not extend to the speculative anticipation of how component parts that are not defective can become potentially dangerous, depending on the nature of their integration into a complex system designed and assembled by another. 57

Another recent obeisance to the *Third Restatement* component seller rule is *Artiglio v. General Electric Co.*, 58 a silicon breast implant suit before a California Appeals Court, in which appellant appealed a summary judgment. 59 The underlying claim was that the silicon supplier breached a duty to warn customers about the claimed potential hazards of silicon in these medical devices. 60 The facts showed that General Electric (GE), the manufacturer of the silicon, supplied it in fifty-five gallon drums to McGhan Medical Corp., which manufactured the implants. 61 On appeal, GE argued the rectitude of the verdict, stating that:

[B]ecause it supplied silicone materials which are used in

57. *Id.* at 634-35.
59. *Id.* at 818.
60. *Id.*
61. *Id.*
a number of other products, because the silicone materials it provided were subject to further processing by the actual manufacturers of breast implants and because the implant manufacturers themselves had the ability to determine the suitability and safety of the implants, it owed no duty of care to the eventual recipients of the silicone breast implants.62

After turning to what may eventually become an obligatory reference to the Third Restatement section 5 comment c, the appellate court continued by relying upon comment b, which addresses "sophisticated buyers" and states:

[W]hen a sophisticated buyer integrates a component into another product, the component seller owes no duty to warn either the immediate buyer or ultimate consumers of dangers arising because the component is unsuited for the special purpose to which the buyer puts it. To impose a duty to warn in such a circumstance would require that component sellers monitor the development of products and systems into which their components are to be integrated.63

Affirming the court below, the appellate division summarized:

Taken together, [authority establishes] that component and raw material suppliers are not liable to ultimate consumers when the goods or material they supply are not inherently dangerous, they sell goods or material in bulk to a sophisticated buyer, the material is substantially changed during the manufacturing process and the supplier has a limited role in developing and designing

62. Id. GE's chemical "building block" for the manufacture of silicon was polydimethylsiloxane (PDMS). Id. GE used PDMS manufacturing "a host of silicone materials for use by the manufacturers of everything from bed pads to electronic circuit boards to food additives to other medical devices." Id.

63. Id. at 822 (The Proposed Final Draft of the Restatement Third of Torts, Products Liability, § 5, approved on May 20, 1997).
the end product. When these factors exist, the social cost of imposing a duty to the ultimate consumers far exceeds any additional protection provided to consumers.64

THE TORT GOALS OF CORRECTIVE JUSTICE AND EFFICIENCY

A. Generally

One court wrote recently: "Products liability law is based on concepts of fairness, feasibility, practicality and functional responsibility. [Courts] have always stressed the public's interest in motivating individuals and commercial enterprises to invest in safety..."65

In the above review of the liability rules and the decisional law thereunder, the courts, the ALI authors of the comments to the Second Restatement (Second) of Torts section 402A, and the Third Restatement frequently invoke expressions such as "just," or "unjust," or "efficient," or "social cost." These terms have broadly understood common colloquial meanings, so that an "inefficient" tort rule is interpreted as one that wastes money. I would like now to think in terms of economic efficiency-deterrence, and corrective justice-morality, in a more particularized way.

There are today two contrasting schools of tort philosophy.66 The older of the two approaches is commonly termed corrective justice, and its influential group of scholars hew to the position that the original and

64. Id. See also In re TMJ Implants Products Liability Litigation, 97 F.3d 1050, 1057 (8th Cir. 1996).
66. Gary T. Schwartz, Mixed Theories of Tort Law: Affirming Both Deterrence and Corrective Justice, 75 Tex. L. Rev. 1801 (1997). Mr. Schwartz stated that: "currently there are two major camps of tort scholars. One understands tort liability as an instrument aimed largely at the goal of deterrence, commonly explained within the framework of economics. The other looks at tort law as a way of achieving corrective justice between the parties." Id. See generally John Borgo, Causal Paradigms in Tort Law, 8 J. Legal Stud. 419, 454-55 (1979) (commending "conception of tort law that rivals the dominant economic one," employing "notions of individual moral responsibility...logically excluded from the latter"); Matthew S. O’Connel, Correcting Corrective Justice: Unscrambling the Mixed Conception of Tort Law, 85 Geo. L.J. 1717 (1997). The article stated that generally accepted theories of tort law can be divided into two classes: instrumental theories, which view social cost and efficiency as the essential factors in evaluating rights and duties under the law, and noninstrumental theories, which view law as the vindication of a scheme of moral responsibility. Id.
primary goal of tort law, including the law of products liability, is righting wrongs caused by tortious behavior. With its strong overlay of moral obligation, and the annulment of a wrongdoer's unjust enrichment, the corrective justice approach posits that tort's principal raison d'être is to return parties suffering personal physical injury or property damage due to another's tortious conduct to the status quo ante, at least insofar as money damages can do so. The more recently developed approach is one of economic efficiency, an evaluation that seeks to demonstrate that the appropriate measure of the success, or failure, of tort law ought to proceed under an economic analysis, emphasizing evaluation of such considerations as wealth maximization, avoidance of waste, and overdeterrence.

B. Corrective Justice-Morality

As a corollary to the corrective justice rectificatory goal of setting matters straight between the parties, the corrective justice model sets forth the broader societal objective of reducing the occurrence of similar wrongs in the future. The corrective justice objective of deterrence is evidenced in such early writings as that of one academic author, who in 1890 wrote of the goals of the negligence action in these words: "The really important matter is to adjust the dispute between the parties by a rule of conduct which shall do justice if possible in the particular case, but which shall also be suitable to the needs of the community, and tend to prevent like accidents from happening in the future." The Supreme Court, in

68. See id. (noting that one of two ways of "understanding tort law ... emphasizes its role in rectifying for wrong done").
70. See id.
71. William Schofield, Davies v. Mann: Theory of Contributory Negligence, 3 HARV. L. REV. 263, 269 (1890); accord Barrett v. Superior Court (Paul Hubbs Constr. Corp.), 272 Cal. Rptr. 304 (Cal. Ct. App. 1990) (interpreting term "wrongful act" in wrongful death statute to mean tortious act). The Barrett court commented further that by choosing not to limit the measure of damages, "California has chosen to strengthen the deterrent aspect of the civil sanction: "the sting of unlimited recovery . . . more effectively penalize[s] the culpable defendant and deter[s] it and others similarly situated from such future conduct" . . .
Cipollone v. Liggett Group, 72 implicitly recognized the deterrence role of an award of tort damages, i.e., that a tort judgment equates to a "requirement or prohibition" in that such tort judgments force actors to make behavioral modifications upon pain of paying large money awards. 73  

Corrective justice principles in tort are intended to minimize not only the personal physical injury effect of accidents, but also to lessen the intrusions such accidents work upon others' autonomy and liberty interests. Personal autonomy is stated repeatedly to be part of that bundle of modern citizenship rights, the perimeters of which law should mediate. 74 A dictionary defines "autonomy" as "independence or freedom."75 If the correlative right of "liberty," which has been defined as "freedom from external control or interference, obligations, etc.; freedom to choose,"76 is added to freedom, then the freedom to choose and the informed choice rationale of a seller's warnings obligations are inextricably related.  

C. Efficiency-Deterrence  

Economic analysis of tort law is not limited to one analytical construct. More than one vantage point from which an economic observation of products liability rules may be made. The "utilitarian theory" invites the assessment of the relative social cost associated with favoring one course of conduct over another. Coase, with his example of the physician and the confectioner,77 prompts application of utilitarian...
theory to the products liability context, in which the question might be posed this way: To what extent is it worthwhile to restrict or encumber product availability in order to achieve marginally safer products, or, considering social cost, is it preferable to ensure a broader range of products, conceding that more products with marginally higher potential for harm will exist in the market? Thus, a utilitarian or social cost model measures a tort rule's practical effect on plaintiffs and defendants as a whole, and considers how much social and economic cost we are prepared to incur in order to maintain product availability.

Another perspective that has played an ascendant role in modern economic analysis of tort law involves the concepts of "wealth maximization" and "efficiency," and the relationship between them. Michael D. Green describes the "wealth maximization"--"economic efficiency" relationship in these terms: "By economic efficiency [is meant] maximizing total societal resources, without concern for the distribution of those resources among members of society."78 One of the efficiency school's most noteworthy constructs has been to "emphasize [tort law's] role in substituting for efficient contractual exchange."79 To Posner, apart from the corrective justice, moral and fairness attributes of tort liability, the law and economics argument is that any intentional tort or accident law doctrine should "dete[r] persons from engaging in activities that a reasonable person would view ahead of time to be socially wasteful."80

In Posner's words, such torts, i.e., unconsented to harmful acts, "involve . . . a coerced transfer of wealth to the defendant occurring in a setting of low transaction costs. Such conduct is inefficient because it violates the principle . . . that where market transaction costs are low, people should be required to use the market if they can and to desist from the conduct if they can't."81 Posner concludes that such bypassing of the market is inefficient and therefore should create liability in tort.82

whether social costs and gains are best served by preservation of status quo, by cessation of confectioner's activities, or by cessation of physician's activities).
79. COLEMAN, supra note 67 at 197.
82. Id. at 207-09.
Transferred to a products liability context, what of the seller of a defective product that causes personal physical injury or property damage?

Economists might recast the corrective justice goals of encouraging individual autonomy and liberty to efficiency-based objectives phrased in terms of discouraging involuntary transfers of wealth, market avoidance, or imposition of negative externalities. A product purchaser has a societally-countenanced expectation, the argument goes, that the product will not create an unreasonable risk of harm if used for its reasonably foreseeable purpose. Should the product prove dangerously defective, and should the purchaser be injured or his property damaged, the manufacturer has, in a sense, subverted the market and created accident costs that might have been avoided had the

83. See Alan Schwartz, Proposals for Products Liability Reform: A Theoretical Synthesis, 97 Yale L.J. 353, 355 (1988) (supposing consumer sovereignty as dominant objective in transactions between contracting parties, under which norm: "the law should reflect the preferences of competent, informed consumers regarding risk allocation."). See also Kathryn Dix Sowle, Toward a Synthesis of Product Liability Principles: Schwartz's Model and the Cost-Minimization Alternative, 46 U. Miami L. Rev. 1, 9 (1991). Werner Z. Hirsch has observed that: "broadly speaking, a tort is a civil (seldom a criminal) wrong. Such a wrong occurs when one party, usually unintentionally, destroys another party's initial entitlement by imposing a negative externality on him. The courts can then provide a remedy in the form of damages. When externalities result in the forcible taking of initial entitlements—for example, when a slaughterhouse pollutes the air of the surrounding neighborhood—liability rules can be invoked. Concomitantly government assumes responsibility for the imposition of objectively determined compensation and its prompt payment to the party harmed." Werner Z. Hirsch, Law and Economics: An Introductory Analysis 127 (1979).

84. See Restatement (Third) of Torts: Products Liability § 2 cmt. a (1998) (Reporters' Note). The comment states that "[S]trict liability has been justified on fairness grounds because the product containing a hidden manufacturing defect that causes harm disappoints the consumer's or user's reasonable expectations with regard to safety." (citing, inter alia, F. Patrick Hubbard, Reasonable Human Expectations: A Normative Model for Imposing Strict Liability for Defective Products, 29 Mercer L. Rev. 465 (1978); Marshall S. Shapo, A Representational Theory of Consumer Protection: Doctrine, Function and Legal Liability for Product Disappointment, 60 Va. L. Rev. 1109 (1974)).

85. See Guido Calabresi, The Costs of Accidents: A Legal and Economic Analysis 129 (1970) (discussing loss spreading, general deterrence, and specific deterrence approaches to accident cost reduction). Stephen Sugarman has summarized Calabresi's cost-avoidance philosophy:

In [The Costs of Accidents], Calabresi argued that society's policy towards accidents should be to minimize the sum of primary, secondary, and tertiary accident costs. Reducing primary costs concerns
manufacturer simply bargained for pertinent product-related rights.

Perhaps the best substitute for an actual bargained for exchange is a circumstance in which a buyer, fully apprised of pertinent safety-related information and instructions for the safe operation of a product, makes an informed decision to purchase the product for the buyer's use or for devotion to the use of others. Such a knowledgeable consent or choice model for sale of a product with a high risk level means, in a proto-contractual sense, that the seller has bargained for the right to sell it. In essence, the seller preserves the transaction within the market by conveying warnings sufficient to permit the purchasers to make informed choices of whether or not to expose themselves to the risk. Absent a bargain struck with an informed purchaser, the sale of a product defective for want of adequate warnings, and that proximately causes plaintiff's harm, represents an involuntary or coerced transfer of wealth from the injured party to the injurer.

A primitive but persuasive evaluative standard was offered in a negligence context by Judge Learned Hand in the opinions in United States v. Carroll Towing Co., and Conway v. O'Brien. In those two cases, the Second Circuit held that the degree of care appropriate to a given action or omission to act should be the result of a three-factor promoting safety (while not discouraging, if possible, socially desirable innovation). Reducing secondary costs concerns spreading the costs of compensation paid to accident victims. Tertiary costs are the transactions costs; these costs include the costs of lawyers' fees, insurance administration, the parties' time, and court costs.

Stephen D. Sugarman, A Restatement of Torts, 44 STAN. L. REV. 1163, 1167 (1992) (review essay). Jules Coleman further explains the three types of costs attributable to personal injury or property damage torts:

Primary costs are the dollar equivalent of the damages caused by accidents. Secondary costs are the costs of bearing the costs of accidents. These are the costs associated with the various schemes for distributing the primary (and tertiary) costs of accidents. Secondary costs are reduced when they are spread maximally over persons and time, or when they are borne by those individuals in the best position to bear them. Tertiary costs are the administrative costs of any system, including the tort system, for determining who should bear the costs of accidents.

COLEMAN, supra note 67 at 204.

86. 159 F.2d 169, 173 (2d Cir. 1947).
87. 111 F.2d 611, 612 (2d Cir. 1940), rev'd on other grounds, 312 U.S. 492 (1941).
calculus: (1) the likelihood that the conduct will injure others; (2) multiplied by the seriousness of the risk if it happens; (3) balanced against the burden of taking precautions against the risk. In formula, the calculation is known as B (Burden) < P (Probability of Harm) X L (Magnitude of Loss Should It Occur). The Learned Hand approach can be conformed to a more modern utilitarian analysis by visualizing B, or the Burden upon the actor, as encompassing not only the particular burden of precautionary measures upon the actor, but also the burden upon society if the conduct must either be eliminated due to liability rules, or made more expensive if the precautionary measures are undertaken.

Posner machined the Hand formulation into an efficiency principle by explaining that:

Hand was adumbrating, perhaps unwittingly, an economic meaning of negligence. Discounting (multiplying) the cost of an accident if it occurs by the probability of occurrence yields a measure of the economic benefit to be anticipated from incurring the costs necessary to prevent the accident. If the cost of safety measures [including, perhaps, eliminating the activity] or of curtailment--whichever cost is lower--exceeds the benefit in accident avoidance to be gained by incurring that cost, society would be better off, in economic terms, to forgo accident prevention.

88. Carroll Towing, 159 F.2d at 173; Conway 111 F.2d at 612.
89. Carroll Towing, 159 F.2d at 173.
90. Likewise, in keeping with a utilitarian economic view that transcends the concerns of the individual plaintiff and defendant, consideration of the factors P (Probability of Harm) and the L (Magnitude of the Loss should it occur) would be enlarged to contemplate the likelihood of harm to others identically or similarly situated, and the magnitude of the potential harm, not only in terms of the individual plaintiff but also to the population exposed to the risk.

When the cost of accidents is less than the cost of prevention, a rational profit-maximizing enterprise will pay tort judgments rather than incur the larger cost of avoiding liability. Furthermore, overall economic value or welfare would be diminished rather than increased by incurring a higher accident-prevention cost in order to avoid a lower accident cost. Perhaps, then, the dominant function of the fault
1. **Least Cost Avoider**

A leading exponent of the efficiency role of the common law of tort has been Guido Calabresi, who has argued persuasively that in matters of compensation for accidents, civil liability should ordinarily be laid at the door of the "cheapest cost avoider," the actor who could most easily discover and inexpensively remediate the hazard. Together with A. Douglas Melamed, and employing the setting of environmental harm, Calabresi asserts that considerations of economic efficiency dictate placing the costs of accidents "on the party or activity which can most cheaply avoid them." Posner's harmonious observation has been that in

system is to generate rules of liability that if followed will bring about, at least approximately, the efficient--the cost-justified--level of accidents and safety . . . . Because we do not like to see resources squandered, a judgment of negligence has inescapable overtones of moral disapproval, for it implies that there was a cheaper alternative to the accident . . . . Where, [alternatively,] the measures necessary to avert the accident would have consumed excessive resources, there is no occasion to condemn the defendant for not having taken them.

*Id.* at 33.


93. Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules and Inalienability: One View of the Cathedral*, 85 *Harv. L. Rev.* 1089, 1108-09 (1972); see also Mark C. Rahdert, *Covering Accident Costs: Insurance, Liability, and Tort Reform* 29, 32-33 (1995) (analyzing rationale for insurance and addressing concern that cost-spreading function will divert compensatory responsibility away from least cost avoider). One frequently-referenced validation of the "least cost avoider" can be found in *Union Oil Co. v. Oppen*, 501 F.2d 558 (9th Cir. 1974), a California coastal oil spill case in which the court allowed commercial fishermen to recover from defendant their business losses caused by lost fishing opportunity during a period of pollution. *Id.* The court found justice and efficiency were served by placing responsibility for the loss on the "best cost avoider" (in this setting the defendant oil company), reasoning: "[T]he loss should be allocated to that party who can best correct any error in allocation, if such there be, by acquiring the activity to which the party has been made liable . . . . The capacity "to buy out" the plaintiffs if the burden is too great is, in essence, the real focus of Calabresi's approach. On this basis there is no contest--the defendants' capacity is superior." *Id.* at 570. (citing Guido Calabresi, *The Cost of Accidents: A Legal and Economic Analysis*, 50–52 (1970)). Calabresi and Hirschoff provide a concise description of what the least cost avoider approach requires, both of private parties and of the government:

The strict liability test we suggest does not require that a governmental
the so called alternative care - indemnity damage shifting scenario, "we do not want both tortfeasors to take precautions; we want the lower cost accident avoider to do so." It is seen readily that a cheapest cost avoider leads us to the conclusion that the component parts supplier, or a raw materials supplier, is not ordinarily the entity that can most readily detect risks posed by a completed product, or reduce such risks to a reasonable level.

2. Pareto Efficiency

From another, yet still efficiency-influenced, perspective a products liability doctrine that passes efficiency muster probably would result also in a Pareto superior or even a Pareto optimal resolution. A rule is Pareto optimal when its effects benefit all parties, in essence, a win-win proposition. As summarized by Mark Seidenfeld: "An economic change institution make ... a cost-benefit analysis. It requires ... only a decision as to which of the parties to the accident is in the best position to make a cost-benefit analysis between accident costs and accident avoidance costs and to act on the decision once it is made. The question for the court reduces to a search for the cheapest cost avoider.


94. PosNFK, supra, note 81 at 189. In some settings defendants themselves have sought to employ the cheapest cost avoider rationale to promote a finding of no liability when a consumer aware of product risks is, the argument goes, the party that can most cheaply avoid the accident costs. See Dewey v. R.J. Reynolds Tobacco Co., 577 A.2d 1239, 1254 (N.J. 1990) (discussing defendant's argument that cigarette consumers are cheapest cost avoiders).

95. The Pareto criteria for wealth maximization analysis are summarized in The Economic Analysis of Tort Law which states:

The first application of the Pareto criteria is to evaluate the desirability of changes in the distribution of goods. Pareto's system allows that evaluation without regard to the desirability of the initial distribution among individuals of either their abilities to pay or enjoy and without the need for interpersonal utility comparisons. Imagine a society in which all resources have already been allocated to particular individuals. Now imagine a change in allocations that left at least one person better off and no one worse off. Surely that change is desirable from any perspective. Economists refer to such a change in the allocation of resources as a Pareto superior change.


96. Id. at 12. Richard A. Posner further elaborated upon the principle by stating:
is considered a Pareto improvement [or Pareto superior] if it makes some individuals better off without making any person worse off. A state of the economic system is Pareto optimal [or Pareto efficient] if there is no Pareto superior state that society can reach. If we are using the Pareto criterion to evaluate our economic system, we say that a Pareto optimal state is "economically efficient." A liability rule that creates burdens upon one participant with no correlative benefits to other participants would be denominated Pareto inefficient.

V. COMPONENT PART AND RAW MATERIAL SELLERS' DUTIES ANALYZED IN TERMS OF CORRECTIVE JUSTICE AND EFFICIENCY

A. Corrective Justice-Morality

With regard to warnings obligations particularly, the "informed consent" rationale reflects the societal judgment that a product user or consumer is entitled to make his own choice as to whether the product's utility or benefits justify exposing himself to the risk of harm. From the standpoint of corrective justice, warnings adequate to permit a product user to make an informed decision as to whether to expose himself or others to the risk are central to preservation of a product user's autonomy interests. From an efficiency perspective, informed decision making by a


98. See, e.g., Borel v. Fibreboard Paper Prod. Corp., 493 F.2d 1076 (5th Cir. 1973). The court stated that "a true choice situation arises, and a duty to warn attaches, whenever a reasonable man would want to be informed of the risk in order to decide whether to expose himself to it." Id. at 1089; Graham v. Wyeth Lab., 666 F. Supp. 1483, 1498 (D. Kan. 1987) (holding that consumer has right to know risks so that he can make informed decision).

99. Conversely, a risk creator's interest in self autonomy diminishes to the extent that he has "already injected himself into the plaintiff's realm." Andrulonis v. United States, 724 F.
plaintiff permits the buyer-seller transaction to be fairly characterized as an agreement that avoids the extracontractual inefficiencies of involuntary wealth transfers.\textsuperscript{100}

In the context of hypothesized warnings that might be required of a seller of, to employ an earlier example, Teflon (TM), there is no practicable means for a seller to communicate cautionary information to the ultimate user or consumer. There is an accepted doctrine in the law of product warnings that permits a bulk seller to discharge its warning obligations by its provision to the immediate vendee, ordinarily the injured party's employer, sufficient safety related information to permit the vendee to provide adequate warnings to users.\textsuperscript{101} This approach fails in the setting of raw materials and components parts sellers for this reason: The accepted doctrine is premised on the seller's ascertainment that the vendee is sufficiently sophisticated and responsible to convey such information to the users. This predicate is arguably workable when the product is established and its accepted use fairly well defined. An example might be an industrial solvent, and the risks to be communicated might logically focus on ventilation, inhalation, dermal exposure and flammability. For newer synthetic products, in contrast, the boundless and growing potential applications and misapplications, effectively preclude a seller's confident transmittal of safety information to its vendee. Due to the new and dynamic uses to which the raw material might be put, a seller might not yet know of either the potential risks or the capacity of the vendee to responsibly communicate them to either employees or consumers.

A representative expression of the "informed consent" rationale of warnings analysis has been put this way: The duty to warn arises "whenever a reasonable man would want to be informed of the risk in order to decide whether to expose himself to it."\textsuperscript{102} Thus, a core attribute of the Reporters' approach is one of vindicating the personal autonomy interest that underpins corrective justice.

\textsuperscript{100} Moran v. Johns-Manville Sales Corp., 691 F.2d 811, 814 (6th Cir. 1982) (citing Borel v. Fibreboard Paper Prods. Corp., 493 F.2d 1076, 1089 (5th Cir. 1973)). The Borel case stated that a product must not be made available to the public without disclosure of the dangers that the application of reasonable foresight would reveal. Borel, 493 F.2d at 1089.

\textsuperscript{101} RESTATEMENT (THIRD) OF PRODUCTS LIABILITY § 2 cmt. i (1998).

\textsuperscript{102} Borel, 493 F.2d at 1089.
With respect to warning obligations to intermediaries, no hardship is worked upon corrective justice principles by continuation of the nearly universal rule that a warning only to an intermediary will satisfy a seller's obligations when, in the totality of the circumstances, it can be predicted that pertinent safety-related information will be effectively conveyed to the end user. In a scenario often involving risks of personal injury to workplace users of the product, the Third Restatement preserves the conventional rule regarding a seller's informational obligation to remote users by stating: "The standard is one of reasonableness in the circumstances. Among the factors to be considered are the gravity of the risks posed by the product, the likelihood that the intermediary will convey the information to the ultimate user, and the feasibility and effectiveness of giving a warning directly to the user." This approach is in no material way unlike that suggested by the earlier Second Restatement section 388, comment n and it is consistent with the protocol described in the leading case law.

A like conclusion can be reached in claims arising from use of, or contact with, raw materials. In terms of corrective justice, the sellers of raw materials, many of which are transformed into a seemingly limitless array of applications by downstream participants in the commercial chain, have not, in any meaningful way, caused a plaintiff's harm. As a plaintiff may pursue a remedy against the distributive participant who did work the allegedly harmful change or modification in the material that triggered a warning obligation, the principles of corrective justice likewise are preserved.

B. Efficiency-Deterrence

In the context of component part suppliers or the sellers of raw materials that will be transformed into a part of a multitude of products, the developed Hand formulation, supports the conclusion under the Third Restatement that neither warning nor design duties should ordinarily attach to the supplier. Apart from the rare instance in which the supplier knows specifically of, or has actually participated in the judgment to utilize the component part or raw material in an application that entails excess preventable risk, the supplier will not have the expertise to appreciate, and

104. Id.
as a practical matter has no means to accurately foresee, the uses to which
the product will be put. The burden, therefore, of assuming this
responsibility (acquisition of staff, micro-inquiries into the proposed uses
to which vendees will put the product) will therefore be quite large. Even
at its extremity such a burden could not be confidently discharged, as the
potential incautious uses to which a component part or a raw material may
be put are bordered only by the human imagination. Thus, definitionally
the burden of such precautionary measures is potentially boundless, and
therefore in most instances greater than the probability of a harm (again
unquantifiable) times the magnitude of the loss should it occur (again
unquantifiable).

In the main, the Third Restatement's treatment of warnings can be
harmonized readily with both Posner's market efficiency and Calabresi's
least cost avoider approaches. By declining to take a position that suggests
that a warning should be given even where the risk and the means of its
avoidance are abundantly clear, the Reporters avoid adding unnecessary
precautionary costs to the marketing of products of utility by stating that:

From a fairness perspective, requiring individual users
and consumers to bear appropriate responsibility for
proper product use prevents careless users and consumers
from being subsidized by more careful users and
consumers, when the former are paid damages out of
funds to which the latter are forced to contribute through
higher product prices.\footnote{105}

While phrased in terms of fairness, this assertion speaks with
equal persuasiveness in terms of efficiency.\footnote{106} In addition, a sketch of

\footnote{105. \textit{Id.} § 2 cmt. a.}
[The Reporters suggest] that courts should avoid requiring warnings
about "obvious product" risks. However, courts often disagree about
which particular product hazards are obvious, and the Reporters offer
no guidance on just how obvious a risk must be before courts should
hold as a matter of law that warnings need not mention the risk. A
hazard obvious to 80 percent of product users would not be evident to
the other 20 percent, and the costs of providing a more complete
warning to this minority group may be justified in comparison with the}
Pareto efficient application to a component seller’s warning duties readily reveals that warning duties create a cost to the seller, which will be passed along to vendees, with no commensurate benefit in terms of reducing avoidable accident costs. As it is the downstream formulator or fabricator that can most readily and inexpensively anticipate and ameliorate risk, placement of informational obligations upon the vendee can be considered Pareto efficient, while application of warnings duties upon the component seller would be Pareto inefficient.

Regarding the Third Restatement’s approach to warnings to intermediaries and with respect to raw materials, the influence of efficiency considerations is even more apparent. In confirming that the objective of the Third Restatement § 2(c) comment i is indistinguishable from that of the Second Restatement section 388 comment n, 107 the Reporters emphasize the Third Restatement’s goal of lowering accident costs by recognizing that it is ordinarily the workplace supervisor who can most efficiently and effectively communicate risk information, particularly in settings involving bulk sales of potentially hazardous materials. 108 Thus, the Third Restatement promotes an efficient rule that would relieve the component or ingredient supplier of liability when the component or ingredient is not itself defective. In such circumstances, the component or ingredient supplier ordinarily has no meaningful control over the hazard level, if any, of the finished product. 109 As between the ingredient supplier

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107. Comment i of § 2(c) of the Third Restatement and comment n of § 388 of the Second Restatement both pertain to warning duties to third persons.

108. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2(c) cmt. i, no. 5 (1998) (Reporters’ Note).

109. Any substance can be hazardous. As the 16th century physician Paracelsus stated: “What is not a poison? All things are poison and none without poison. Only the dose determines that a thing is not a poison.” Charles E. Erway, III, The Ingredient Supplier Defense, 16 J. PROD. & TOXICS LIAB. 269, 273 & n.15 (1994) (quoting AMERICAN CONFERENCE OF GOVERNMENTAL INDUS. HYGENISTS, THRESHOLD LIMIT VALUES—DISCUSSION AND THIRTY-FIVE YEAR INDEX WITH RECOMMENDATIONS 332 (1984)).
and the downstream assembler or formulator, the proper conclusion is that the downstream formulator, with its superior (and often exclusive) knowledge of the product's end use, and which is responsible for ultimate design, formulation, packaging, risk information and marketing, should remain the principal locus of potential liability.\textsuperscript{110}

The tort goal of deterrence is in no way compromised by application of a "no duty" rule to mere suppliers of merchantable raw materials. A residual duty of reasonableness exists in the supplier's duty to supply what has been ordered. If a standard grade of copper is ordered and what is supplied is contaminated or a different grade and an injury results, the raw material supplier should be subject to liability. Likewise, if a raw material supplier goes beyond its traditional role and actively participates in the manufacturing process, its conduct should be judged on the basis of a reasonableness standard. Both of the aforementioned duties provide the raw materials supplier with an incentive to conduct its business consistent with a standard of reasonableness, and to avoid harmful behavior.

Deterrence only works if behavior exists that can be encouraged or prevented. Case law ranging from the most inchoate early rules to the most modern analyses have suggested that the manufacturer of the product, and not the raw material supplier, is in the best position to prevent

\textsuperscript{110} Illuminating in this regard is \textit{Shell Oil Co. v. Harrison}, 425 So. 2d 67, 70 (Fla. Dist. Ct. App. 1982), a suit brought against the manufacturer of the chemical DBCP, which was sold to a formulator who used it as an ingredient of a fumigant claimed to have injured farm workers. \textit{Id.} at 68. As the court stated: "[L]abeling and packaging requirements necessarily differ depending on the particular [end product] formulation and, thus, place the responsibility on the formulator for providing adequate warning to the public . . . ." \textit{Id.} at 70. Similarly, and illustrative of application of the least cost avoider approach, is \textit{Beauchamp v. Russell}, 547 F. Supp. 1191 (N.D. Ga. 1982), involving the issue of the connection, if any, between an air valve component in a pneumatically-run pelletizer and the injury of plaintiff's spouse. \textit{Id.} at 1193. The court suggested that the duty to warn should properly be placed upon the participant in manufacture with the greatest access to information and the easiest means of its dissemination. \textit{Id.} at 1197. In the words of the court:

The responsibility for information collection and dissemination should rest on the party who has the greatest access to the information and who can make it available at the lowest cost. Where a component part is incorporated into another product, without material change, the manufacturer of the part is in the best position to bear this responsibility.

\textit{Id.}
an accident or injury. First, the manufacturer is a knowledgeable purchaser, usually industrial, and is aware of the problems that a raw material can cause. Second, the manufacturer alone knows about its products, as well as who is likely to use them. The manufacturer is in the appropriate position to formulate warnings and to design its product so as to prevent injury. If it is impossible to prevent some risks, the *Third Restatement* requires manufacturers to warn about them, unless they involve hazards that everybody knows about.

The TMJ cases are significant because they have made it clear that knowledge of how a raw material will be used does not, by itself, create a duty to investigate the risks posed by the final product.111

A *Third Restatement* "no duty" rule governing sales of merchantable component parts, raw materials, and ingredients, represents sound policy. If those who mined copper, lead, or fabricated steel were strictly liable for harms caused by end-use products, insurance would be either unavailable or enormously costly. Those saddled with the task of actuarially determining a proper rate would be faced with indeterminate liability because they would not know what products would eventually be made. Delineating a rational starting point for, or cessation of potential liability, would be impossible. By way of contrast, an insurer for the end-use product producer can look at, and evaluate, based on history and rational projections, insurance risks of end-use products. Information on liability costs, past and projected, is crucial to carriers seeking to make coverage decisions and to set premiums. This information is available to the manufacturer of the end product, while it is normally unavailable to the supplier of raw materials potentially suited to a large number of potential end uses. Thus, the raw materials manufacturer, if subject to potential liability for harms caused by products in which the material ultimately was an ingredient, could never procure liability insurance in an informed and cost effective way. In terms of efficiency, insurance becomes less expensive, and the raw materials supplier and the end use manufacturer avoid duplicating insurance coverage.

111. See, e.g., *In re TMJ Implants Products Liability Litigation*, 97 F.3d 1050 (8th Cir. 1996).
CONCLUSION

Liability issues pertaining to component part, raw material and ingredient suppliers are both longstanding and pervasive in the purchase and sale of products. These questions concerned transactions ranging from the sale of behemoth turbines for ocean-going vessels in East River Steamship Corp. v. Transamerica Delaval,\textsuperscript{112} where the Supreme Court applied the economic loss doctrine, and the Supreme Court observed that virtually every product has components,\textsuperscript{113} to the more prosaic, for example, fiber binding tape that a hypothetical business, "Boxes Are Us", might use to secure cardboard boxes used in shipping countless types of items.\textsuperscript{114} The longstanding nature of these questions was highlighted recently in a newspaper article I read that speculated that the reason the iceberg damaged the Titanic so mortally was because the rivets employed to bind together the hull plates had a level of internal metallurgical imperfections far exceeding what would be expected even in that era.

To borrow from Max Weber, Restatements float or sink on the moving stream of judicial acceptance. The rules expressed in the Third Restatement will either be validated as a material contribution to the rationalization of this field by a swell of favorable references in judicial opinions, or it will atrophy. Some, such as Guido Calabrese, have suggested that the Third Restatement will not be successful. With temerity, I think the great Yale scholar, and now federal judge, is in error. As suggested earlier, no new treatment of products liability will overrun judicial and statutory thinking as did the Second Restatement Section 402A. But in its introductory commentary, the ALI recognizes that habit and acculturation may militate against abandonment of the classical doctrinal labels, such as strict tort liability or negligence.\textsuperscript{115} Even when that proves true, the Third Restatement Reporters and the ALI agree, the venerable doctrinal categories can coexist with the functional definitions of manufacturing defects, design defects and warning/instructions defects. And, when used as a means of evaluating products liability claims, whether bonded with a doctrinal title or standing alone, the Third

\textsuperscript{112} 476 U.S. 858 (1986).
\textsuperscript{113} Id. at 867.
\textsuperscript{114} Such tape, we might imagine, would be suitable for securing boxes containing quilts, but a broken foot waiting to happen if used to secure a cast iron anvil.
Restatement, including its provisions for sellers of component parts, raw materials and product ingredients, represents a work product satisfying the highest and best purposes of the American Law Institute.
POST-SALE DUTY TO WARN: A CRITICAL CAUSE OF ACTION

by Kenneth Ross

INTRODUCTION

Merely manufacturing, designing and selling safe products may not satisfy a product manufacturer’s legal duties. A few courts, starting many years ago, held that manufacturers have a duty to warn product users when they learn of risks in their product after sale, even if the product was not defective when sold. Likewise, a number of courts held that there was no such duty.

The American Law Institute recently considered the status of product liability law in the United States. This culminated in the publishing of the new Restatement (Third) of Torts: Products Liability (hereinafter Third Restatement). The Institute had to decide whether there was enough precedence to include the post-sale duty to warn in this new enunciation of product liability law.

The law professors who served as the drafters of the Third Restatement (hereinafter Reporters) studied all of the cases and felt, while there was some split of authority, that there were enough cases in support and that common sense dictated that this duty should be included. This proposed inclusion resulted in lots of debate. The plaintiff-oriented members of the Institute wanted this section included.

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1. Kenneth Ross was a Distinguished Practitioner in Residence at William Mitchell College of Law in St. Paul, Minnesota for the Spring 1999 semester. He is a partner in the Minneapolis law firm of Bowman and Brooke LLP.

2. See Cover v. Cohen, 461 N.E.2d 864, 871 (N.Y. App. Div. 1984) (“[a]lthough a product [may] be reasonably safe when manufactured and sold and involve no then known risks of which warning need be given, risks thereafter revealed by user operation and brought to the attention of the manufacturer or vendor may impose upon one or both a duty to warn.”). See also Comstock and Zurich Ins. Co. v. General Motors Corp., 99 N.W. 2d 627 (Mich. 1959); Walton v. Avco Corp., 610 A.2d 454 (Pa. 1992).


while some of the defense-oriented members wanted it omitted or severely limited.  

Post-sale duty to warn was ultimately included in the final Third Restatement. The Third Restatement and case law require, in certain instances, manufacturers or product suppliers to provide post-sale warnings, or possibly to recall or repair products in a variety of circumstances. In analyzing possible post-sale liability, it is important that manufacturers and product suppliers be aware of the factors that may trigger a post-sale duty. Armed with this knowledge, they can establish procedures to identify the existence of the duty and to implement appropriate post-sale remedial measures to prevent or limit exposure based on post-sale conduct.

This article provides an overview of the Third Restatement's post-sale duty sections. In addition, the article highlights key issues for manufacturers and focuses upon case law that illustrates the Third Restatement's sections. Finally, suggestions are provided which will help manufacturers comply with post-sale requirements.

THIRD RESTATEMENT: SECTIONS 10, 11, AND 13

The Restatement (Second) of Torts: Products Liability (hereinafter Second Restatement), which created product liability in 1965 by adopting Section 402A, did not contain post-sale duty provisions. Warnings were required only if a risk associated with a product was known or should have been known at the time of sale. The post-sale duty section in Third Restatement is truly new, not merely a revision of Section 388. It provides as follows:

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6. Id.
8. Id. §§ 10-11, 13.
10. See id. § 388.
§ 10. Liability of Commercial Product Seller or Distributor for Harm Caused by Post-Sale Failure to Warn

(a) One engaged in the business of selling or otherwise distributing products is subject to liability for harm to persons or property caused by the seller’s failure to provide a warning after the time of sale or distribution of a product if a reasonable person in the seller’s position would provide such a warning.

(b) A reasonable person in the seller’s position would provide a warning after the time of sale if:

(1) the seller knows or reasonably should know that the product poses a substantial risk of harm to persons or property; and

(2) those to whom a warning might be provided can be identified and can reasonably be assumed to be unaware of the risk of harm; and

(3) a warning can be effectively communicated to and acted on by those to whom a warning might be provided; and

(4) the risk of harm is sufficiently great to justify the burden of providing a warning.\(^{11}\)

Section 10 does not include a duty to do anything other than warn.\(^{12}\) However, since there was case law holding that, in certain narrow instances, a manufacturer may have a duty to recall or retrofit a product, the Institute dealt with this precedent.\(^{13}\) Given the great burden of any post-sale activities, especially recall, the Institute included a section severely limiting the duty to recall a product. Section 11 of the *Third Restatement* provides as follows:

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12. Id.

§11. Liability of Commercial Product Seller or Distributor for Harm Caused by Post-Sale Failure to Recall Product

One engaged in the business of selling or otherwise distributing products is subject to liability for harm to persons or property caused by the seller's failure to recall a product after the time of (a)(1) a governmental directive issued pursuant to a statute or other governmental administrative regulation specifically requires the seller or distributor to recall the product; or;

(2) the seller or distributor, in the absence of a recall requirement under Subsection (a)(1), undertakes to recall the product; and

(B) the seller or distributor fails to act as a reasonable person in recalling the product. 14

Section 11 basically provides that the seller or distributor is not liable for a failure to recall the product unless the recall is required by statute or regulation or the seller or distributor voluntarily undertakes to recall the product and does so negligently. 15 The main reason for including section 11 was to make it clear that section 10 does not include a duty to recall the product. However, it also included the so-called "Good Samaritan" doctrine where liability can attach for a negligent recall, even if it is voluntary. 16

The last section pertaining to the post-sale duty to warn is section 13. 17 This section, which concerns a successor's liability for a failure to issue a post-sale warning, states in part:

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15. Id.
17. Id. § 13.
§13: Liability of Successor for Harm Caused by Successor’s Own Post-Sale Failure to Warn

(a) A successor corporation or other business entity that acquires assets of a predecessor corporation or other business entity, whether or not liable under the rule stated in §12, is subject to liability for harm to persons or property caused by the successor’s failure to warn of a risk created by a product sold by the predecessor if:

(1) the successor undertakes or agrees to provide services for maintenance or repair of the product or enters into a similar relationship with purchasers of the predecessor’s products giving rise to actual or potential economic advantage to the successor, and

(2) a reasonable person in the position of the successor would provide a warning.

The section goes on to say that a reasonable person in the successor’s position would provide such a warning if the four above conditions in section 10 are met.

Case law supports the inclusion of section 13 into the Third Restatement’s post-sale duty sections and emphasizes the same important factors for finding successor liability.

18. Id. § 12. Section 12 provides for liability for a successor manufacturer even if a predecessor manufacturer sold the product in a defective condition. Id.
19. Id.
20. Id.
21. See Sherlock v. Quality Control Equip. Co., 79 F.3d 731, 734 (8th Cir. 1996) (the critical element is a continuing relationship between the successor and the predecessor’s customers for the successor’s benefit); Patton v. TIC United Corp., 77 F.3d 1235, 1240 (10th Cir. 1996) (a successor entity may incur a duty to warn if it has knowledge of the defective condition and has a more than causal relationship with the predecessor’s customers).
DISTINGUISHING POST-SALE DUTY FROM PRE-SALE DUTY

In examining the prior case law, it became apparent to the Reporters that there was great confusion by juries, judges and scholars. Many of the cases were unclear as to whether the jury or judge believed that the product was defective when sold or was not defective when sold but thereafter became defective.

If it was defective when sold, then it was judged under Section 402A (or now Section 2 of the Third Restatement). Since the Second Restatement did not have a post-sale duty section, courts that discussed this new theory of liability simply assumed that the defect became known after sale without considering whether it was defective when sold.

The Third Restatement makes it clear that this post-sale duty is independent of a time-of-sale defect and therefore selling a defective product can result in claims of time-of-sale defect and also post-sale failure to warn. In addition, the Third Restatement makes it clear that if the product was defective when sold, the manufacturer cannot be absolved of liability by issuing a post-sale warning.

While the Third Restatement is generally viewed as favorable to manufacturers and product sellers, this section clearly establishes a cause of action that creates lots of opportunity for plaintiffs to argue for more discovery of post-sale actions, more admissibility of post-sale accidents, and more allegations of punitive damages. In addition, by stating that a manufacturer cannot cut off liability no matter how good the post-sale warning program, this section almost creates absolute liability if someone is injured by a product defect that was known after sale and the manufacturer undertakes a less than reasonable post-sale...
warning program.\textsuperscript{27} Plaintiff will argue that a program that was not successful in warning them was not reasonable.

A CAUSE OF ACTION BASED ON POST-SALE DUTY SOUNDS IN NEGLIGENCE

While synthesizing years of judicial consideration of post-sale issues, section 10 still raises many questions that surely will be litigated for years. However, one aspect of section 10 is clear. A cause of action based on post-sale duties must sound in negligence, since the reasonableness of a product suppliers’ conduct is the focus of the post-sale inquiry.\textsuperscript{28}

According to section 10(b), a seller can only be subject to post-sale duties if a “reasonable” person would have supplied such a warning.\textsuperscript{29} The four factors are fact-based, making the reasonableness of supplying a post-sale warning the key to establishing a post-sale duty.\textsuperscript{30}

Judging post-sale conduct through the lens of negligence is consistent with previous case law. Actual or constructive knowledge of a post-sale risk is necessary to impose a post-sale duty.\textsuperscript{31} Also, negligence is the correct legal theory when a manufacturer’s conduct is at issue\textsuperscript{32} and, as such, application of a post-sale duty depends on the reasonableness of the manufacturer’s conduct.\textsuperscript{33} Consequently, a product supplier cannot be strictly liable for post-sale conduct under section 10.

ACQUISITION OF POST-SALE KNOWLEDGE

Section 10 may create an affirmative duty for product suppliers to exercise reasonable care to learn of post-sale problems with their products. Section 10(a) bases a post-sale duty, in part, on suppliers who

\begin{itemize}
\item \textsuperscript{27} See \textit{RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY} § 10 cmt. j (1998).
\item \textsuperscript{28} Id. § 10 cmt. b (1998).
\item \textsuperscript{29} Id. § 10(a).
\item \textsuperscript{30} Id. § 10(b).
\item \textsuperscript{32} See Hutchinson Wil-Rich Mfg., 861 P.2d at 1310.
\item \textsuperscript{33} See Crowston v. Goodyear Tire & Rubber Co., 521 N.W.2d 401, 409 (N.D. 1994).
\end{itemize}
know or reasonably should know their products pose a substantial risk of harm to persons or property.\textsuperscript{34} In addition, comment \textit{c} states that the general duty of reasonable care may require manufacturers to investigate when reasonable grounds exist for the seller to suspect that a hitherto unknown risk exists.\textsuperscript{35}

However, comment \textit{c} also makes it clear that, except for prescription drugs and medical devices, "constantly monitoring product performance in the field" is usually too burdensome and will not support a post-sale duty.\textsuperscript{36} Despite this language, section 10 and comment \textit{c} may impose a broader duty on product suppliers than recent case law to establish systems to obtain information from the field. The failure of a manufacturer to set up an information gathering system and then claim a lack of knowledge may appear unreasonable to a jury, especially when one could be set up with little effort and expense.

Many courts, however, mimic the language of the \textit{Third Restatement}, and are concerned about imposing too heavy of a burden on manufacturers to monitor field performance. In \textit{Patton v. Hutchinson Wil-Rich Manufacturing Company}, the Kansas Supreme Court held that plaintiffs who allege post-sale duty claims must prove that manufacturers "acquired knowledge of a [post-sale] defect."\textsuperscript{37} \textit{Patton} did not impose an affirmative duty on suppliers to take reasonable steps to learn of post-sale problems not brought to their attention. This is consistent with earlier opinions.\textsuperscript{38}

In contrast to the \textit{Third Restatement}'s post-sale duty to warn section, the Court of Appeals for the Seventh Circuit recently stated that "the well established and generally accepted law in Illinois is that manufacturers do not have a continuing duty to warn."\textsuperscript{39} The plaintiff in

\begin{footnotesize}
\begin{enumerate}
\item See \textit{Restatement (Third) of Torts: Products Liability § 10(a)} (1998).
\item \textit{Id.} at cmt. \textit{c}.
\item \textit{Id}.
\item \textit{Hutchinson Wil-Rich Mfg.}, 861 P.2d at 1314.
\item See also \textit{Cover v. Cohen}, 461 N.E.2d 864, 871 (N.Y. 1984) (post-sale duty triggered by knowledge "brought to the attention of" manufacturers and vendors); \textit{Comstock v. General Motors Corp.}, 99 N.W.2d 627, 634 (Mich. 1959) (duty triggered when knowledge of post-sale risk "becomes known" to manufacturers); \textit{McAlpin v. Leeds & Northrup Co.}, 912 F. Supp. 207, 210 (W.D. Va. 1996) (ends of justice require a manufacturer to warn if the manufacturer is made aware of the defect (citing \textit{Island Creek Coal Co. v. Lake Shore, Inc.}, 832 F.2d 274, 280 (4th Cir. 1987))).
\item \textit{Birchler v. Gehl Co.}, 88 F.3d 518, 521 (7th Cir. 1996).
\end{enumerate}
\end{footnotesize}
Birchler v. Gehl Company was injured while working with a hay baler manufactured by the defendant. He brought suit against the defendant alleging that because the defendant knew of three other accidents similar to his accident, the defendant was under a duty to warn the plaintiff of the supposed risk of injury. The court, however, did not agree. The decision clearly states there is no post-sale duty.

On the other hand, there is a rule that requires drug manufacturers to keep informed of scientific developments and provide the medical profession with information about risks of drugs already on the market. This affirmative duty for drug manufacturers is consistent with the language in section 10 and may also be imposed by Federal Regulations for other products.

The language in section 10 could extend the scope of other manufacturers' and suppliers' legal duties by requiring reasonable affirmative actions to learn of post-sale product risks. Regardless of the legal duty, affirmatively trying to learn of post-sale risks is a beneficial activity for enhancing product safety and preventing accidents.

EXISTENCE OF THE DEFECT: A QUESTION OF TIMING

Section 10(a) obviously contemplates that knowledge of a risk or defect acquired by a supplier must be obtained after the sale. The section is less clear about when the defect must actually come into existence. Comment a to section 10 explains that a post-sale duty may be imposed "...whether or not the product is defective at the time of original sale . . . ." The Institute also acknowledges in comment a that imposing a post-sale duty, even if the product was not defective when sold, is relatively new. They are quick to point out, however, that

40. Id.
42. Id.
44. See discussion supra pp. 574-81.
46. Id.
satisfaction of section 10's four factors should prevent "unbounded" and "onerous" post-sale burdens on product sellers.47

The position of section 10 -- that it is immaterial whether the defect existed at the time of sale -- contrasts with many decisions where courts have refused to impose post-sale duties when products were not defective when sold.48 Recently, for example, the Michigan Supreme Court refused to recognize a duty to repair or recall where a product not defective at the time of sale becomes obsolete or unreasonably dangerous due to post-sale technological advances.49 The Michigan court reasoned that:

imposing a duty to update technology would place an unreasonable burden on manufacturers. It would discourage manufacturers from developing new designs if this could form the basis for suits or result in costly repair and recall campaigns.50

This holding is consistent with many other opinions.51

PRODUCT USERS: CAN THEY BE IDENTIFIED

Section 10(b) requires proof that people to whom a post-sale warning should be provided can be identified before a post-sale duty is triggered.52 This case-specific inquiry will depend on a number of factors including the type of product, the number of units sold, the

47. Id.
50. Id. at 337.
number of potential users, the availability of records and the available means of tracing product users. Comment e makes it clear that when no records identifying the customers are available, a post-sale duty will not arise.

These factors formed the basis for the Wisconsin Supreme Court’s holding that the manufacturer of a sausage stuffing machine had a duty to provide users with information about a new safety by-pass valve. The machines were sold to a limited market where the manufacturer knew all of the product’s owners. The Wisconsin court made it clear, however, that it was not crafting a continuing duty for all manufacturers to warn of safety improvements, since many products are mass produced and tracing users to warn of safety improvements would place an undue burden on manufacturers.

Similarly, the North Dakota Supreme Court has held that it would be difficult to require the manufacturer of mass-produced tire rims to trace individual users if the rims were not unique or sold to a specialized group of customers. While recognizing the problem of providing individual notice to the original purchasers, this court nevertheless held that the defendant had a duty to warn foreseeable users about the potential dangers of using the product discovered after the product was sold.

An interesting question remains as to how far a manufacturer must go to identify its customers. What would a reasonable manufacturer concerned about safety do? Establishing a “traceability” system before the product is sold is the most effective way to find customers. However, such systems take planning, considerable effort, and substantial cost. The question of whether a particular defendant’s

53. See id. at § 10 (Reporters’ Note to comment a).
54. See id. § 10 cmt. e.
55. See Kozlowski v. John E. Smith’s Sons Co., 275 N.W.2d 915 (Wis. 1979).
56. Id. at 923.
57. Id. at 924-25.
59. Id. at 409. See also Hodder v. Goodyear Tire and Rubber Co., 426 N.W.2d 826, 832 (Minn. 1988) (tire rim manufacturer had a post-sale duty to instruct and warn, so that potential users of its product would be apprised of safety hazards which, at an earlier time, were not fully appreciated).
60. See AMERICAN SOCIETY FOR QUALITY, THE PRODUCT RECALL PLANNING GUIDE (1999).
actions are "reasonable" will be case-specific and decided by the jury. The Institute continually stresses in comments to section 10 that this duty should not be "unbounded" and "onerous" and that courts need to be careful before imposing such a duty.61

The federal government has jurisdiction over many products and may "raise the bar" in this area. In March 1999, the U.S. Consumer Product Safety Commission convened a meeting of manufacturers to discuss ways in which recalls can be made more effective.62 These discussions included ways in which manufacturers could be required to better ascertain and maintain the identities of purchasers of certain consumer products.63 Product registration and warranty card returns are among the methods being considered.64 The federal government already mandates customer tracking for products such as car seats65 and medical devices.66

DUTY TO INFORM OF SAFETY IMPROVEMENTS

Manufacturers should always strive to improve the safety of their products. But does the manufacturer have a duty to inform prior customers of each safety improvement made in similar products manufactured after the sale of the less safe product? Some courts have found it reasonable to impose a duty to inform purchasers of safety improvements when:

1. There is a continuing relationship between the manufacturer and the purchaser;
2. The market is limited; and
3. The cost of providing notice of the safety improvement is negligible.67

61. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 10, cmt. a, d (1998). There are also several federal guidelines as well as industry guidelines describing what might be considered a reasonable program. For a recent example of an industry produced guideline, see AMERICAN SOCIETY FOR QUALITY, THE PRODUCT RECALL PLANNING GUIDE (1999).
64. Id. at 6052.
65. See 49 C.F.R. § 588.5-6 (1999).
Most courts, however, have found that there is no post-sale duty to inform customers of safety improvements when the original product has been properly designed and manufactured.68

Section 10 does not foreclose a finding of a failure to issue a post-sale warning of safety improvements but makes it clear that the four factors in section 10 must be met.69 However, it says that “...in most cases it will be difficult to establish each of the four § 10 factors that are a necessary predicate for a post-sale duty to warn if the warning is merely to inform of the availability of a product-safety improvement.”70

To date, a duty to inform product users about safety improvements has only been required by a few courts and only in limited factual circumstances.71

This might be a difficult area for manufacturers to make a reasonable decision. A plaintiff might argue that the original product is defective without the safety improvement and use the improvement as proof of a time-of-sale defect. Since it is sometimes difficult to decide whether a jury will accept this argument, a manufacturer must carefully consider whether it is reasonable and prudent to notify prior customers of safety improvements.

The manufacturer should perform the kind of analysis that is done in deciding whether a duty arises in the first place using section 10. If the manufacturer's post-sale improvement significantly improves safety and the manufacturer can easily find its customers, the manufacturer should consider informing its prior customers about the safety improvement.

For example, if a manufacturer were to significantly improve the warning labels on its product or add labels where none initially existed, it is a good idea to provide the labels, at cost or free of charge, to

70. Id. § 10 (Reporters’ Note to comment a).
71. See Kozlowski, 275 N.W.2d at 924 (duty to inform users of machine of post-sale safety improvements where users were traceable); Bell Helicopter Co. v. Bradshaw, 594 S.W.2d 519 (Tex. Civ. App. 1979) (duty to retrofit where manufacturer assumed duty to notify users of safety improvements).
purchasers of prior products. Labels are usually very inexpensive and easy to disseminate. As a result, a jury might feel that a product was defective without the improved labels or feel that the manufacturer should have disseminated the labels to its prior customers.

On the other hand, if the manufacturer creates a safety improvement that would double the price of the original product, it would not be necessary for a manufacturer to provide the safety improvement free of charge to prior customers. The argument would be that the customer would have paid for the improvement in the original price of the product. If the safety improvement significantly improves safety, it might be advisable for the manufacturer to inform prior purchasers of the improvement and allow them to purchase it if they wish.

Decisions in this area are difficult to make and can have unfortunate consequences. If the manufacturer makes the wrong decision, it could result in significant liability.

POST-SALE DUTY TO RECALL

Section 11 sets forth a limited duty to recall a defective product.Comment a makes it clear that this duty is different from the post-sale duty in section 10. This comment also says that improvements in product safety do not trigger a duty to recall or retrofit a product. Manufacturers would be discouraged from making products safer.

This limited duty is based mostly on a governmental directive specifically requiring the manufacturer to recall the product. The Michigan Supreme Court recently declined an invitation to impose a duty to recall or repair in a negligent design claim where a plaintiff

73. Id. at cmt. a ("[t]he duty to recall or repair should be distinguished from a post-sale duty to warn about product hazards discovered after sale").
74. Id.
75. Id.
76. See id. ("[m]oreover, even when a product is defective within the meaning of §2, §3, or §4, an involuntary duty to recall should be imposed on the seller only by a governmental directive issued pursuant to statute or regulation."). See also 15 U.S.C.A. § 2061(b)(1) (West 1998).
alleges that a manufacturer knew or should have known of a defect at the
time of sale.\textsuperscript{77} While Michigan required a warning in such
circumstances, the court concluded that “the duty to repair or recall is
more properly a consideration for administrative agencies and
legislatures . . .”\textsuperscript{78}

Unfortunately, the Institute incorporated the “Good Samaritan”
or “volunteer” rule that one who undertakes a rescue must act reasonably
so as not to put the rescued party in worse shape than before.\textsuperscript{79} This
rule, in the context of product liability, comes from the belief that
voluntary recalls are typically undertaken in the anticipation that a
governmental agency will require one anyway.\textsuperscript{80}

This belief, by the Institute and some courts, may be correct in a
general sense. However, there are many voluntary recalls, retrofits, or
even post-sale warning programs that are done to enhance safety and
would not constitute a post-sale duty under section 10. With this
doctrine incorporated into the \textit{Third Restatement}, some manufacturers
may not undertake what they truly believe are voluntary programs unless
they are prepared to do so in a way that would not be considered
negligent. This determination is difficult and case-specific.

Hopefully, more manufacturers will “do the right thing” and try
to improve the safety of their products and try to anticipate what might
be considered reasonable. Unfortunately, the fact that an accident
happened means, by definition, that the post-sale remedial program was
arguably ineffective for the injured party.

\textbf{LEGAL COMPLIANCE AND GOOD BUSINESS PRACTICES}

\textbf{A. Management of a Post-Sale Program}

\textbf{1. Product safety policy and post-manufacture action plan}

A manufacturer should be guided in its implementation of a
post-sale program by a formal product safety policy. The policy serves

\textsuperscript{77} Gregory, 538 N.W.2d at 333-34.
\textsuperscript{78} Id. at 334. \textit{Accord Hutchinson Wil-Rich Mfg.}, 861 P.2d at 1315; Morrison v.
Kubota Tractor Corp., 891 S.W.2d 422, 429-30 (Mo. Ct. App. 1994).
\textsuperscript{79} See supra note 16.
\textsuperscript{80} \textit{RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY} \$ 11 cmt. c (1998).
as a guidepost for overall product safety. In addition to this general statement of product safety, a manufacturer should consider having a post-sale action plan. This document establishes procedures for analyzing the need for post-sale action and for implementing whatever action is determined to be appropriate.

Both of these documents are part of good business practices and could be helpful in defending any litigation that might arise. It is important to point to a document, endorsed by the Board of Directors, the Chief Executive Officer, the President, or General Manager which confirms a manufacturer's desire to market safe products and to identify and remedy any post-sale problems that come to their attention.

2. Information network

The foundation of a post-sale program is established in an information network that will allow a company to determine how its product is performing in the marketplace. This information is necessary for the manufacturer to ultimately make decisions about what, if any, post-sale action might be necessary.

A manufacturer has a number of readily available sources of information. For example, notices of claims or accidents might provide information on the types of products that are failing, the mode of failure, and possible misuse of the product. Lawsuits will provide the same information, as well as reports from plaintiffs' experts that may provide further insight into how the product could be made safer. Customer complaints and warranty returns are fertile sources of information. A pattern of complaints and returns may indicate that a product is failing in a particular mode on a regular basis.

An inordinate number of sales of a particular component part may indicate that a part is failing prematurely. Of course, observations by sales personnel and by service personnel who are actually out in the field talking to customers are also invaluable sources of information. Post-sale information can also come from competitors at trade shows or as part of membership in a trade association. Lastly, post-sale information, albeit some of it unsubstantiated or even incorrect, is now on the Internet. Some companies monitor the Internet, especially sites where customers might visit, to see what is being said about their products.
3. **Analyzing the information**

Once a manufacturer has obtained all relevant information, it must determine whether post-sale action is necessary. Good business practices and good litigation planning require that someone be in charge of the post-sale program. Juries want to know that some person or specific group has the responsibility of managing this problem.

Generally, some form of product safety committee should analyze the information. This committee should be made up of representatives from various areas of the company, including engineering, service, sales, marketing, and legal. It is also very important that the lawyer who is advising the committee be experienced in product liability and regulatory law.

The committee analyzing the post-sale information should hold regular meetings. This is important, both to make certain that information is being reviewed on a timely basis, and to show a jury that the company is acting reasonably in how it handles its post-sale analysis. The number of persons who are allowed to attend should be limited and those who take notes at these meetings should write them carefully.

Determining whether post-sale action is necessary under the common law requires applying the factors identified in case law and section 10 above to the facts learned through the information gathering network. If there are a number of injuries involving the same product, with the same basic failure mode, it most likely will be necessary to take some type of post-sale remedial action.

If the network reveals one incident involving property damage out of many products in the field, it may be important to take note of the incident, but no post-sale action may be necessary. A manufacturer must simply apply the factors to the information gathered, keeping in mind that the primary objective is to make safe products, prevent accidents, and, if necessary, present itself as a responsible company to the jury.

Determining whether post-sale action is necessary also involves an analysis of any applicable government laws or regulations that provide criteria for making this decision. The U.S. Consumer Product Safety Commission [hereinafter CPSC] provides criteria for determining
the existence of a substantial product hazard.\textsuperscript{81} The criteria to be considered are the pattern of defect, the number of defective products distributed in commerce and the severity of risk to consumers.\textsuperscript{82} Using these criteria will provide guidance to the manufacturer about what information to gather and how to analyze the information. The CPSC provides little further guidance on this threshold question and expects the manufacturer to report a substantial product hazard or any suspicion that the product contains such a hazard to the CPSC.\textsuperscript{83} In that event, the staff of the CPSC will help the manufacturer analyze the information and decide what, if any, appropriate post-sale remedial measures are necessary.

4. Determining the appropriate post-sale action

Once the manufacturer has identified a post-sale hazard that should be remedied, it must decide what post-sale action to take. There are a number of available options. The most appropriate action will depend upon the previously used factors such as the severity of the harm and the likelihood of personal injury or property damage. For example, the problem may be corrected by simply sending a safety notice to distributors/retailers. If there is concern about the notice reaching the ultimate user/purchaser of the product, the safety notice should be sent directly to the users/purchasers. Of course, a manufacturer's ability to do this will depend on its ability to locate its purchasers and product users.

If the severity of the harm and the likelihood of the injury are significant and a warning is insufficient, a manufacturer might go to the field and retrofit the allegedly defective product.\textsuperscript{84} Depending upon the ease with which the product can be returned to the manufacturer, a retrofit in the plant might be appropriate. If retrofitting the product does not result in the elimination of the hazard, or if a retrofit is simply not feasible for the product, it may be necessary to recall the product.

\textsuperscript{82} Id.
\textsuperscript{83} Id.
\textsuperscript{84} While this is not required under the common law, it still may be appropriate when considering safety and may be required by some government agency.
As previously discussed, the manufacturer needs to consider the available post-sale options under the common law and also identify any government laws or regulations that apply. Many federal government agencies, once they learn of a problem, will classify the level of risk. Once the level is classified, the manufacturer can identify regulations that define the extent of the post-sale activities.

For example, the CPSC has established a hazard priority system defining hazards as Class A, Class B or Class C. A Class A hazard exists when a risk of death or grievous injury or illness is likely or very likely, or serious injury or illness is very likely. Class A hazards warrant the highest level of company and CPSC action and immediate, comprehensive and imaginative corrective action measures are required. Class B and Class C hazards are lesser hazards and less immediate and comprehensive corrective action measures are necessary.

The Food and Drug Administration assigns a classification to a recall to indicate the degree of health hazard presented by the product. These are listed as Class I, Class II and Class III. Class I is defined as a situation in which there is a strong likelihood that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death. Class II and Class III are lesser levels of severity and require less comprehensive post-sale programs.

Under the CPSC guidelines, the kinds of corrective measures to be considered include joint news releases; sending out safety notices with bills; purchasing advertisements in national and/or regional newspapers and magazines; installation of a toll-free telephone line to receive calls from consumers; using incentives to encourage users to return the product; distributing point-of-purchase posters to alert consumers to a recall; using warranty cards to identify users of the

85. See U.S. CONSUMER PRODUCT SAFETY COMMISSION, CORRECTIVE ACTION HANDBOOK (October 1988).
86. Id.
87. Id.
88. Id.
89. See FOOD AND DRUG ADMINISTRATION REGULATORY PROCEDURES MANUAL, PART 5, CH. 5-00, RECALL PROCEDURES (May 1988).
90. Id.
91. Id.
product; and notifying trade associations and other groups for whom the recall may have particular concern. 92

5. Adequacy of post-sale remedial measures

Whether a manufacturer decides to warn, retrofit, or recall, it is very important that the initial notice of the post-sale action be properly written and contain the appropriate message. Any communication made by a manufacturer to a dealer or customer will be judged according to the same adequacy standards as warnings are generally judged. This means that a letter notifying a dealer or customer of a product problem must describe the hazard, the consequences of the hazard, and how to avoid the hazard. 93 The best information gathering network in the world and the best safety committee is useless if the communication that is ultimately sent is inadequate to promote any action.

Letters to dealers or customers notifying them of potential post-sale problems should be written very clearly and be very explicit. This means that if a manufacturer has experienced prior accidents or prior injuries, it should probably say so in the letter, describing the general nature of the problem and the types of injuries. A manufacturer should be careful not to understate the problem.

The letter should be written keeping in mind that it will be read by potential future plaintiffs who will challenge its adequacy in future litigation if they are injured. This should not preclude a manufacturer from writing the letter, but should encourage them to write it in a way that will be helpful in defending any litigation that might arise. The manufacturer may even want to perform a small focus group survey to confirm that the reader understands the communication and is inclined to follow its instructions.

92. See U.S. CONSUMER PRODUCT SAFETY COMMISSION, CORRECTIVE ACTION HANDBOOK (October 1988).
93. See Burch v. Amsterdam Corp., 366 A.2d 1079, 1086 (D.C. 1976) ("[t]he seller or manufacturer of a product whose use could result in foreseeable harm has a duty to give a warning which adequately advises the user of attendant risks and which provides specific directions for safe use." (citing Buffington v. Amchem Prods., Inc., 489 F.2d 1053,1055 (8th Cir. 1974)). See also 29 C.F.R. § 1910.1200 (1999) (OSHA standards for hazard communication); 16 C.F.R. § 1500.121 (1999) (U.S. Consumer Product Safety Commission labeling requirements for hazardous substances).
Under the common law and sections 10 and 13 of the Third Restatement, there is little guidance on how to adequately communicate a post-sale program. The cases also are not particularly helpful in determining whether a post-sale program has been performed adequately. Government guidelines do provide some guidance, and they should be considered, even if the manufacturer's product does not fall under the jurisdiction of these agencies.  

For example, the CPSC provides clear guidelines for implementing product safety recalls. Certainly, if the manufacturer's product is a consumer product, these guidelines should be followed. However, even if the products are not consumer products, and do not fall under another agency's jurisdiction, the guidelines should still be considered.

The CPSC guidelines provide specific suggestions for communicating recall messages. They suggest that on notices to consumers, distributors and retailers, the words "Important Safety Notice" or a heading such as "Recall Notice" appear in the lower left-hand corner of the envelope and at the beginning of each letter. If there are press releases, the CPSC says that the release must contain information such as a description of the products and its intended use, a description of the specific product hazard, and directions as to how consumers may obtain refunds, replacement or repair of the product. The press release should contain a glossy black and white photograph or line drawing of the product and the defect.

Guidelines are also provided by other federal government agencies, and they might be considered in identifying the best post-sale remedial program for a particular manufacturer.

In determining the adequacy of the program, the manufacturer must consider what percentage of success is adequate. Anything less than a 100% success rate leaves the possibility that there is a hazardous

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94. See U.S. CONSUMER PRODUCT SAFETY COMMISSION, CORRECTIVE ACTION HANDBOOK (October 1988); 16 C.F.R. § 1115.20.
95. Id.
96. Id.
97. Id.
98. Id.
99. See FOOD AND DRUG ADMINISTRATION REGULATORY PROCEDURES MANUAL, PART 5, CH. 5-00, RECALL PROCEDURES (May 1988).
product still in the hands of consumers or users and that such a defect could cause injury and result in a lawsuit. In many situations, particularly involving the mass distribution of consumer products, the manufacturer would never expect to or achieve anything close to a 100% success rate. In the consumer product area, product safety experts consider a 25% response rate for a recall program to be excellent.

For a recall of medical devices, the Food and Drug Administration has established effectiveness levels ranging from 100% of the customers who received the recall notice down to 2% of these customers.\textsuperscript{100} The levels correspond to the severity of the product hazard.

It is possible for a jury to believe that the manufacturer engaged in an adequate post-sale program and find the manufacturer not liable for an injury suffered by a user of the defective product. Juries expect manufacturers to engage in comprehensive post-sale programs, but do not expect a 100% success rate. Unfortunately, while a jury might feel that the manufacturer's post-sale program was reasonable and adequate, it would still be possible for them to hold the manufacturer liable for selling a defective product in the first place. In other words, initial liability for selling a defective product cannot be cut off by undertaking a post-sale remedial program that is not 100% effective.\textsuperscript{101}

CONCLUSION

Post-sale duties have been expanding in the United States by court decision and legislative action. The \textit{Third Restatement} affirms this expansion and, in some respects, broadens the post-sale responsibilities of manufacturers. Manufacturers must act now to put into place an appropriate information gathering network and establish appropriate committees or trained personnel who can analyze the gathered information to determine whether post-sale actions might be appropriate. A failure to take timely and adequate remedial actions could result in huge liability, including punitive damages, that could eventually result in large numbers of injured people and lead to the demise of the manufacturer.

\textsuperscript{100} Id.

\textsuperscript{101} See \textit{Restatement (Third) of Torts: Products Liability} § 10 cmt. j (1998).
PRODUCTS LIABILITY: BEYOND WARNINGS

by Jerry J. Phillips

INTRODUCTION

Much of the debate over the adoption of the Restatement (Third) of Torts: Products Liability [hereinafter the Third Restatement] centered on the section 2(b) standard, which requires proof by the plaintiff of a reasonable alternative design before there can be recovery for design defectiveness. It was thought that this provision unduly ratcheted up the standard of proof for the plaintiff in design defect cases over that which exists under a consumer expectation standard, or a risk-utility standard, which may consider, but does not require, proof of an alternative design.

The concern evidenced by this debate may be misplaced, since probably the majority of the states had firmly established their standards for proof of defectiveness before adoption of the Third Restatement. Some had done so by statute, and others by judicial decision. The state of New York and the state of Connecticut, while aware of the Third Restatement, adopted their own distinct standards. The Court of Appeals of New York in Denny v. Ford Motor Company held that a product may be defectively designed either if it fails to meet a general risk utility test, or if it fails to meet consumer expectations as established by defendant's marketing and advertising practices. The Supreme Court of Connecticut in Potter v. Chicago Pneumatic Tool Company held that a product may be defectively designed if it fails to meet the ordinary consumer or the risk-utility test, regardless of whether a reasonable alternative design is shown. The Potter court noted that its position represented the majority view. It held that the plaintiff may recover on the basis of a consumer expectations test when

4. Id.
5. 694 A.2d 1319 (Conn. 1997).
6. Id.
7. Id. at 1331.
“everyday experience indicates that a product’s design does not meet "minimum safety expectations.""8

The real long-term effect of the *Third Restatement* may lie in some of its less controversial provisions, which received relatively little discussion in the American Law Institute. One such provision is comment *l* to section 2, which states:

1. **Relationship between design and instruction or warning.**

Reasonable designs and instructions or warnings both play important roles in the production and distribution of reasonably safe products. In general, when a safer design can reasonably be implemented and risks can reasonably be designed out of a product, adoption of the safer design is required over a warning that leaves a significant residuum of such risks. For example, instructions and warnings may be ineffective because users of the product may not be adequately reached, may be likely to be inattentive, or may be insufficiently motivated to follow the instructions or heed the warnings. However, when an alternative design to avoid risks cannot reasonably be implemented, adequate instructions and warnings will normally be sufficient to render the product reasonably safe. Compare Comment. Warnings are not, however, a substitute for the provision of a reasonably safe design.

The fact that a risk is obvious or generally known often serves the same function as a warning. See Comment *j*. However, obviousness of risk does not necessarily obviate a duty to provide a safer design. Just as warnings may be ignored, so may obvious or generally known risks be ignored, leaving a residuum of risk great enough to require adopting a safer design. See Comment *d*. Illustration:

14. Jeremy’s foot was severed when caught between the blade and compaction chamber of a garbage truck on which he was working. The injury occurred when

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8. *Id.* at 1334.
he lost his balance while jumping on the back step of the garbage truck as it was moving from one stop to the next. The garbage truck, manufactured by XYZ Motor Co., has a warning in large red letters on both the left and right rear panels that reads, "DANGER—DO NOT INSERT ANY OBJECT WHILE COMPACTION CHAMBER IS WORKING—KEEP HANDS AND FEET AWAY." The fact that an adequate warning was given does not preclude Jeremy from seeking to establish a design defect under Subsection (b). The possibility that an employee might lose his balance and thus encounter the shear point was a risk that a warning could not eliminate and that might require a safety guard. Whether a design defect can be established is governed by Subsection (b).9

Comment 1 is not a new concept in products liability law. But its imprimatur by the American Law Institute may give that concept new vitality. Moreover, the implications of the concept are far-reaching throughout products law, wherever warnings presently play a significant role in determining liability.

THE RELATION OF WARNING TO DESIGN IN GENERAL

The received dogma has been that a product may be defective owing to a manufacturing flaw, a design defect, failure to warn, or misrepresentation.10 While it is generally assumed that a product can be defectively designed regardless of whether there is a manufacturing flaw or misrepresentation, the rule has been less clear regarding the relation of design and warning. It is well accepted that a product can be defective for lack of warning even if properly designed.11 A poison, for example, may be the best poison made but the manufacturer can nevertheless be liable if it

10. See JERRY J. PHILLIPS, PRODUCTS LIABILITY IN A NUTSHELL 5 (5th ed. 1998). The Third Restatement lists misrepresentation separately from its categories of product defect, see §§ 1, 2, and 9, but a misrepresentation is as much a product defect as a failure to warn since both are based on misrepresentations that may be either attached to, or separate from, the product.
fails to warn regarding the dangerous properties of the product. What is less well accepted is whether the product supplier can be liable for defective design even though the relevant danger has been adequately warned against. Is it enough, for example, to warn clearly that a rat poison should not be swallowed by humans, instead of redesigning the poison so that a human (although not a rat) would regurgitate the poison on swallowing it?

The Restatement (Second) of Torts [hereinafter the Second Restatement] takes the position that an adequate warning would suffice to relieve the supplier from liability. Comment j to section 402A provides: "Where warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous."13

The Third Restatement reverses this assumption at least where design is concerned, stating in comment l to section 2 that "[w]arnings are not . . . a substitute for the provision of a reasonably safe design."14 As the comment notes, "obviousness of risk does not necessarily obviate a duty to provide a safer design," and the "fact that a risk is obvious or generally known often serves the same function as a warning."15 In those jurisdictions where obviousness is not a legal bar to recovery, warnings should ordinarily not be such a bar either.

The proposition stated in comment l is not new to the law. It is well-accepted by design engineers.16 The Illustration to this comment is based on the 1978 Massachusetts case of Uloth v. City Tank Corp.,17 which held that a product may be defectively designed even if "there are warnings found to be adequate, or if the dangers are obvious."18

Uloth has been followed by several courts,19 but there is a division

13. Id.
15. Id.
18. Id. at 1193.
of authority on the issue. Comment I may inspire a developing trend toward the adoption of the Ulloth rationale. Two recent cases relying on comment I, Rogers v. Ingersoll-Rand Co. \(^{21}\) and Uniroyal Goodrich Tire Co. v. Martinez, \(^{22}\) indicate just such a trend.

In Rogers, the plaintiff was severely injured by a milling machine that ran over her as it was backing up. \(^{23}\) She sued the manufacturer of the machine, alleging that it was defectively designed. \(^{24}\) Sustaining a verdict for


21. 144 F.3d 841 (D.C. Cir. 1998).

22. 977 S.W.2d 328 (Tex. 1998).


24. Id. Kenneth Ross thinks the defendant in Rogers may have lost the design claim owing to inadequate documentation of its design research:

Concerning the alternative safety features, the defendant’s engineering services manager testified about various safety features that some of its competitors had in use at the time the machine involved in this case was in production. When asked about some specific safety features proposed by the plaintiff, this manager said that Ingersoll-Rand decided not to use them on this model, and that it did no testing of any additional safety features, calling such testing a “complete waste of time.”

The court either ignored or did not understand testimony offered by the defendant concerning its design process. There are many alternative designs and safety features that might be available for manufacturers to consider or test. Most experienced engineers or product safety experts can quickly, and without testing, analyze these various alternatives and decide whether they might be appropriate or inappropriate to consider for use on a particular product.

In its appellate brief, the defendant said its engineers rejected the alternative safety devices after consulting with a human factors expert and pointed out that these devices would actually increase the hazards. The brief, however, did not detail why no tests were done and why better documentation did not exist on some of these crucial points.

It is not necessary to test every alternative design or safety feature that might be available, even if used by competitors. However,
the plaintiff, the appellate court relied on *Third Restatement*, comment 1, to affirm the trial court’s refusal to give to the jury the following charge, requested by Ingersoll-Rand:

*If you find that the milling machine was accompanied by adequate warning which made the milling machine safe for use if the warnings are followed, then the milling machine was not unreasonably dangerous and was not defective, and you should find for defendant Ingersoll-Rand.*

Thus, *Rogers* makes clear that an adequate warning will not automatically discharge the defendant manufacturer’s duty to design a safer product.

In a five to four decision of the Texas Supreme Court affirmation of the proposition stated in comment 1 was not so clear. There the plaintiff employee was injured by an explosion which resulted when he mismounted a 16-inch tire on a 16.5-inch wheel. He sued the tire manufacturer, alleging that an alternative bead design on the tire would have prevented the injury. A label on the tire stated conspicuously: “NEVER MOUNT A 16" SIZE DIAMETER TIRE ON A 16.5" RIM.” The label also warned against mounting the tire on a flat surface instead of using a tire-mounting machine; it warned against inflating a tire “to seat beads without using an extension hose with gauge and chip-on chuck;” and it warned never to “stand, lean or reach over the assembly during inflation .... Martinez ignored every one of these warnings.”

The jury awarded $5.5 million compensatory damages and $11.5

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it would have been prudent for the manufacturer, in this instance, to create documentation as to why these alternative safety features or reasonable alternative designs were not appropriate and why testing was unnecessary. A jury may not believe the manufacturer if it fails to have documentation of things that were done or of things that were considered and not done.


26. *Id.*

27. *See* Uniroyal Goodrich Tire Co. v. Martinez, 977 S.W.2d 328, 331 (Tex. 1998).

28. *Id.* at 331-32.

29. *Id.* at 332.

30. *Id.*

31. *Id.*
million punitive damages. The compensatory award was reduced to the amount of $4.1 million by the trial court "pursuant to a settlement agreement," and the punitive award was reduced to a like amount by the court. The state supreme court, affirming the appellate court, sustained the trial court decision relying on comment l to section 2 of the Third Restatement.

The dissent argued for reversal, contending that evidence of injuries from thirty-four other claims over fifteen years, caused by attempts to mount 16" Goodrich tires on 16.5" rims, should not have been admitted "without proof that any of the claims were valid . . . or that they arose out of accidents similar to Martinez's;" that the wheel manufacturer "bore some responsibility for Martinez's accident as a matter of law;" that Martinez acted deliberately rather than inadvertently, and should have been assigned some degree of fault; and that "[w]hen the undisputed evidence is that the magnitude and probability of a risk are low, an alternative design could reduce but not eliminate that risk, and the instructions and warnings given do eliminate the risk, the product should be determined not to be defective as a matter of law."

The Martinez case points up a number of likely qualifications to the principle stated in comment l to section 2 of the Third Restatement. The plaintiff's careless conduct in ignoring clear warnings will often reduce damages under comparative fault, and that conduct can bar recovery entirely in a modified comparative fault jurisdiction where the plaintiff's fault is 50% or more. The plaintiff may also be barred if her conduct is equatable with consent, or if her conduct or that of another constitutes unforeseeable

33. Id.
34. Martinez, 977 S.W.2d at 331.
35. Id. at 344 (Hecht, J., dissenting).
36. Id. at 352.
37. Id. at 354.
38. Id. at 344.
39. Under pure comparative fault the plaintiff can recover as long as she is not 100% at fault, while under modified comparative fault she can recover if she is less than 50% (or 51% in some jurisdictions) at fault. The overwhelming majority of jurisdictions have adopted some form of comparative fault. See JERRY J. PHILLIPS ET AL., TORT LAW – CASES, MATERIALS, PROBLEMS 639-40 (2d ed. 1997).
misuse in ignoring clear warnings.\footnote{See \textit{Simpson v. Standard Container Co.}, 527 A.2d 1337 (Md. App. Ct. 1987).} In those jurisdictions where obviousness of danger bars recovery,\footnote{See \textit{Phillips et al.}, supra note 20, at 739-40.} adequate warnings may also continue to bar recovery regardless of whether a reasonably safer design would have prevented the injury. And of course a warning may be adequate in any case where it does not leave "a residuum of risk great enough to justify adopting a safer design."\footnote{\textit{Restatement (Third) of Torts: Products Liability} § 2 cmt. 1 (1998).} Nevertheless, the principle of comment\footnote{It is widely held, that the only duty generally owed by a product supplier "to allergic users is one of warning, and then only when the plaintiff is a member of a substantial or appreciable number of persons subject to the allergy, where the defendant should have known of the risk." \textit{Phillips, supra} note 10, at 232.} to section 2 of the \textit{Third Restatement} stands as a substantial retrenchment on the idea of adequate warnings as a legal bar to recovery.\footnote{\textit{Restatement (Third) of Torts: Products Liability} § 2 cmt. 1 (1998).} Some may lament the apparent retreat from individual responsibility that comment I indicates.\footnote{See Richard C. Ausness, \textit{When a Warning Just Won't Do: A Reply to Professor Phillips}, 26 \textit{Northern Ky. L. Rev.} 627 (1999 this issue, under heading B.3., \textit{Moral Responsibility}).} It seems too late, however, to return to an unbridled doctrine of laissez faire or caveat emptor, in the modern-day world of complex products, advertising blandishments, and clearly foreseeable human frailty. It seems more responsible to put the loss on the generally better accident-avoider, the manufacturer, with discretion in the jury, except in the clearest (matter-of-law) cases, to determine what, if any, percentage of fault should be allocated to the plaintiff, or to others under a several (rather than joint) liability regime.
THE PRESCRIPTION DRUG

The Reporters state in section 6 of the *Third Restatement*:

§ 6. Liability of Commercial Seller or Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices

(a) A manufacturer of a prescription drug or medical device who sells or otherwise distributes a defective drug or medical device is subject to liability for harm to persons caused by the defect. A prescription drug or medical device is one that may be legally sold or otherwise distributed only pursuant to a health-care provider's prescription.

(b) For purposes of liability under Subsection (a), a prescription drug or medical device is defective if at the time of sale or other distribution the drug or medical device:

(1) contains a manufacturing defect as defined in § 2(a); or

(2) is not reasonably safe due to defective design as defined in Subsection (c); or

(3) is not reasonably safe due to inadequate instructions or warnings as defined in Subsection (d).

(c) A prescription drug or medical device is not reasonably safe due to a defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.

(d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

(1) prescribing and other health-care providers
who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or

(2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

(e) A retail seller or other distributor of a prescription drug or medical device is subject to liability for harm caused by the drug or device if:

(1) at the time of sale or other distribution the drug or medical device contains a manufacturing defect as defined in § 2(a); or

(2) at or before the time of sale or other distribution of the drug or medical device the retail seller or other distributor fails to exercise reasonable care and such failure causes harm to persons.46

A major thrust of this section is to eliminate potential design liability for manufacturers of prescription drugs47 except in those situations where no “reasonable health care provider [ ] . . . knowing of [the] foreseeable risks and therapeutic benefits” of a prescription drug, would prescribe that drug “for any class of patients.”48 This provision lacks any precedent in case law. It is filled with ambiguities, and will probably prove unworkable.

The Reporters apparently intended to carry forward the idea of the “unavoidably unsafe” product, as set for in commentk to section 402A of the Second Restatement, which itself created many ambiguities.49 Comment k stated that there “are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and

47. Professor James O’Reilly (this issue) states that there are very few prescription medical devices, which are also covered by section 6.
ordinary use." Such products are "especially common in the field of drugs." A manufacturer is justified in marketing such "apparently useful and desirable" products without liability provided they are "properly prepared and marketed" and accompanied by "proper directions and warning . . . where the situation calls for it." This comment was widely interpreted as imposing only a negligence duty to warn on the manufacturer, provided the product was "unavoidably unsafe" and apparently useful and desirable.

The Reporters did not carry forward the protections of comment k in the Third Restatement. Instead, they sought in section 6 to limit the category of protected products to prescription drugs and medical devices, which are presumably "useful and desirable" within the meaning of comment k. The responsibility for deciding whether such products should be marketed (are unavoidably unsafe?) is curiously placed with the health care provider, the prescribing doctor, or learned intermediary - rather than with the manufacturer itself.

The Reporters apparently wanted to protect the availability of drugs that are useful for some purposes, but not for others, by placing on the prescribing doctor the duty to properly choose such uses, and to warn patients against improper use. They probably had in mind drugs such as thalidomide, recently approved for marketing by the FDA. The drug is useful for the treatment of leprosy, chronic myelogenous leukemia and severe rheumatoid arthritis, but may have disastrous teratogenic effects on the offspring of pregnant women who take the drug. It will be up to the learned intermediary to insure that the drug is not taken by pregnant women.

But suppose thalidomide could reasonably be redesigned so as to eliminate its teratogenic effects, or suppose a substitute drug would provide more effective treatment for rheumatoid arthritis. Would not the reasonable doctor choose the redesigned drug to treat pregnant women with rheumatoid

50. Restatement (Second) of Torts § 402A cmt. k (1965).
51. Id.
52. Id.
55. Id.
56. Id.
57. See Sally Squires, Thalidomide May Reduce Some Cancer Tumors: Multiple Myeloma Sufferers Treated With Sedative Linked to Birth Defects, Milwaukee Jour. & Sent. 5, Jan. 11, 1999.
arthritis, or the substitute drug to treat all cases of rheumatoid arthritis?

It is possible that a doctor would stick with the old drug as a result of HMO pressures to prescribe a less expensive drug, or as a result of

58. See Nancy K. Plant, The Learned Intermediary Doctrine: Some New Medicine for an Old Ailment, 81 Iowa L. Rev. 1007, 1024-29 (1996). The author states:

The traditional situation in which the patient establishes a long-term relationship with a particular physician best suited to his needs is becoming less common. A patient's choice of physician is now often constrained by the patient's third-party payor. Patients enrolled in managed care organizations (MCOs) may be less likely to develop a long-term relationship with a single physician. Because of increasing cost pressures, patients are likely to spend less time with physicians and receive more and more care from health care professionals who are not doctors.

Furthermore, third-party payors use a number of techniques to influence prescription practices. Managed care plans and state Medicaid programs may establish their own formularies of preferred drugs; in some cases, a physician must obtain prior authorization before prescribing a drug not on the formulary. Third-party payors may require substitution of generic or therapeutically equivalent drugs, engage in utilization review of physicians' prescriptions, provide monetary incentives for physicians to use less expensive drugs, or establish protocols to manage diseases that require the use of drugs in a particular order. State Medicaid plans may use techniques such as capping the number of prescriptions that will be reimbursed per month or requiring co-payments for prescriptions.

Increasingly, MCOs, large employers, and other third-party payors (including private insurers and state Medicaid programs) are contracting with pharmacy benefit managers (PBMs) to obtain and provide prescription drug services for the plan. PBMs may serve multiple payors. Studies have estimated that PBMs currently provide services for about 120 million people; according to some estimates, thirty to fifty percent of prescriptions are delivered through managed pharmacy programs.

PBMs negotiate with drug manufacturers to obtain large discounts on particular products; they may also process claims and operate mail-order pharmacies to provide drugs directly to patients with prescriptions. PBMs institute formularies or other techniques to ensure that covered patients are prescribed particular products. If a physician prescribes a drug not preferred by the PBM formulary, the PBM may employ a pharmacist to telephone the physician directly to convince her to change the prescription to the preferred drug. One PBM has estimated that it persuades three out of five doctors to change their prescriptions when they initially prescribe a nonformulary drug.
ignorance. Similarly, if the patient had the ultimate say-so, she might choose the old drug over the new one as a result of promotional activities by the drug manufacturer. But the law should not encourage such choices, whether informed or uninformed. Indeed, the principle set forth in comment 1 to section 2 of the Third Restatement should apply here: “[W]hen a safer design can reasonably be implemented and risks can reasonably be designed out of a product, adoption of the safer design is required over a warning that leaves a significant residuum of . . . risks.”

If a doctor negligently prescribed, or a patient negligently took, a drug, the drug manufacturer could be liable in ordinary negligence if it proximately caused such doctor or patient conduct. But, curiously, a drug manufacturer could not be liable under section 6(c) of the Third Restatement either in negligence or strict liability for defective design, even if a majority of doctors negligently prescribed the drug which had an unreasonably

Alternatively a PBM may pay a fee to an independent pharmacist filling the prescription if the pharmacist convinces the doctor to switch the prescription. Patients whose nonformulary prescriptions manage to survive this process may have to pay more for their prescriptions. In determining which drugs are preferred, cost is extremely important, although PBMs also maintain that they consider factors such as safety and efficacy. Thus, the intervention of PBMs appears to have affected significantly the prescription practices of physicians.

Id.

59. The Reporters note the effect of advertising and consumer choice on the learned intermediary rule, but take no position on the matter:

Those who assert the need for adequate warnings directly to consumers contend that manufacturers that communicate directly with consumers should not escape liability simply because the decision to prescribe the drug was made by the health-care provider. Proponents of the learned intermediary rule argue that, notwithstanding direct communications to the consumer, drugs cannot be dispensed unless a health-care provider makes an individualized decision that a drug is appropriate for a particular patient, and that it is for the health-care provider to decide which risks are relevant to the particular patient. The Institute leaves to developing case law whether exceptions to the learned intermediary rule in these or other situations should be recognized.


dangerous design, as long as any reasonable health care providers would prescribe that drug, for example as a euthanasic, for any class of patients.61

Section 6 pretty clearly contemplates a negligence rather than a strict liability standard regarding knowable risks.62 Commentg to section 6 states that “[d]uties concerning the design and marketing of prescription drugs and medical devices arise only with respect to risks of harm that are reasonably foreseeable at the time of sale.63 However, Tobin v. Astra Pharmaceutical Products, Inc.64 on which Illustration 1 of this section is based, states a manufacturer strict liability design standard for prescription products:

Under Kentucky law, the test for whether a product is in a defective condition and unreasonably dangerous to the user is whether an ordinarily prudent manufacturer, being fully aware of the risks, would have placed the product on the market .... 65

As summarized by the Kentucky Supreme Court, the standard for strict liability is formulated:

The manufacturer is presumed to know the qualities and characteristics, and the actual condition, of his product at the time he sells it, and the question is whether the product creates “such a risk” of an accident “that an ordinarily prudent company engaged in the manufacture” of such a product “would not have put it on the market.”66

Regardless of whether a negligence or strict liability design standard is adopted, the one on whom the standard should be imposed is the manufacturer - not the doctor or the patient. The manufacturer is clearly the one best situated to discover and prevent risks.

61. Id. § 6(c).
62. Id. § 6.
63. Id. at cmt. g.
64. 993 F.2d 528 (6th Cir. 1993).
65. Id. (citing Nichols v. Union Underwear Co., 602 S.W.2d 429, 433 (Ky. 1980)).
66. Id. (citing Montgomery Elevator Co. v. McCullough, 676 S.W.2d 776, 780 (Ky. 1984) (quoting Nichols, 602 S.W.2d at 433)).
Carlin v. Superior Court of Sutter County\textsuperscript{67} illustrates the prevailing rule that it is the role of the drug manufacturer - not the doctor - to determine the design, including warnings, that is appropriate for a prescription drug. That case involved the prescription drug, Halcion.\textsuperscript{68} The court applied a rule of strict liability to the manufacturer in determining what warnings should be given.\textsuperscript{69} Strict liability was defined in terms of a manufacturer’s duty to “warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution.”\textsuperscript{70} Strict liability was distinguished from negligence in that “the reasonableness of the defendant’s failure to warn is immaterial.”\textsuperscript{71} Thus the defendant could not escape liability by evidence that its “own testing showed a result contrary to that of others in the scientific community,” or that “its failure to warn of a known or reasonably scientifically knowable risk conformed to an industry-wide practice.”\textsuperscript{72} If a manufacturer has such a duty to warn, then clearly it would have a comparable duty to design. Comment to section 2 makes the design duty take precedence over the duty to warn.\textsuperscript{73}

Section 2(b) of the Third Restatement created substantial controversy in the American Law Institute by limiting the basis for showing design liability to the establishment of a “reasonable alternative design.”\textsuperscript{74} The Reporters were anxious to avoid design liability based on categorical or generic defect, where a product is found to be “so dangerous that it

\textsuperscript{67} 920 P.2d 1347 (Cal. 1996).
\textsuperscript{68} Id. at 1349.
\textsuperscript{69} Id. at 1351.
\textsuperscript{70} Id.
\textsuperscript{71} Id.
\textsuperscript{72} Id. See also Richard L. Cupp, Jr., Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus a Negligence Approach, 63 GEO. WASH. L. REV. 76, 106 (1994) (noting that the Reporters’ interpretation of Tobin as a basis for the reasonable health care provider standard is “inaccurate”). Teresa Schwartz notes that the reasonable health care provider standard “has no precedent,” and that the appropriate standard is “whether a reasonable manufacturer, presuming full knowledge of the risks and benefits of its products, would have put the product on the market.” Teresa Moran Schwartz, Prescription Products and the Proposed Restatement (Third), 61 TENN. L. REV. 1357, 1381, 1383 (1994). For a general critique of section 8(c), see Jeffrey D. Winchester, Section 8(c) of the Proposed Restatement (Third) of Torts: Is It Really What the Doctor Ordered? 82 CORNELL L. REV. 644 (1997).
\textsuperscript{73} See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. 1 (1998).
\textsuperscript{74} Id. § 2(b).
should not have been marketed at all.” Yet, categorical liability is the standard for design defect established under section 6. A product “is not reasonably safe due to defective design” under that section if the reasonable health care provider, knowing of the foreseeable risks and benefits of a drug, would not prescribe the drug “for any class of patients.” Substitute the term “manufacturer” for “health care provider,” as should be done, and the section establishes a standard of category defect for design liability. Presumably, however, a design defect could also be shown on the basis of other standards discussed below.

Certainly doctors should continue to perform their learned intermediary role in choosing among available prescription drugs. But only the manufacturer is qualified to determine what drugs should be made available, and what their design should be.

POST-REMEDIAL MEASURES

Sections 10 and 11 of the Third Restatement deal with the business supplier’s duty to warn or recall after the time of sale or distribution of a product. Section 10 imposes such a duty if (1) the distributor should know of a substantial risk of harm, (2) the persons at risk “can be identified,” (3) a warning can be effectively communicated to those persons, and (4) the risk of harm is sufficiently great to justify providing the warning. Comment 1 to section 10 states that a duty can arise under this section “whether or not the product is defective at the time of original sale.” A similar duty to

76. Id. § 6.
77. Id.
78. See Richard C. Ausness, Learned Intermediaries and Sophisticated Users: Encouraging the Use of Intermediaries to Transmit Product Safety Information, 46 SYRACUSE L. REV. 1185 (1996).
80. Id. § 10.
81. Id. at cmt. 1. Apparently, a majority of courts restrict the post-sale duty to warn, Patton v. Hutchinson-Wil-Rich Mfg. Co., 861 P.2d 1299 (Kan. 1993), or to retrofit, Romero v. Internet Harvester Co., 979 F.2d 1444 (10th Cir. 1992), to situations where the product was defective when it left the supplier’s hands. This restriction is dubious, in view of the uncertainties of establishing time-of-sale state of art for warning. See Feldman v. Lederle Laboratories, 479 A.2d 374 (N.J. 1984), and for design, see boatland of Houston, Inc. v. Bailey, 609 S.W. 2d 743 (Tex. 1980). See also Lavick v. Wil-Rich, 588 N.W.2d 688 (Iowa
recall can presumably arise under section 11, whether or not the product was
defective at the time of sale.\textsuperscript{82}

If the product was defective at the time of sale, an unsuccessful
post-sale warning or recall may not discharge the distributor’s
time-of-sale duty not to distribute a defective product.\textsuperscript{83} Post-sale duties may exist along
with such date-of-sale duties, and may provide additional remedies based for
example on negligence and the avoidance of a statute of limitations or
repose.\textsuperscript{84}

Section 11 of the \textit{Third Restatement} takes the position that a
distributor has no post-sale duty to recall a product unless a government
directive “specifically requires” such a recall “pursuant to a statute or
administrative regulation,” or unless the distributor undertakes to recall the
product and “fails to act as a reasonable person” in so doing.\textsuperscript{85} The reason
for not imposing a general common law duty to recall is stated in comment
\textit{a} to section 11: “Duties to recall products impose significant burdens on
manufacturers . . . . If every improvement in product safety were to trigger
a common law duty to recall, manufacturers would face incalculable costs
every time they sought to make their product lines better and safer.”\textsuperscript{86} No
such duty should be imposed, even when the product is defective at the time
of distribution, the Reporters say.\textsuperscript{87}

A duty to recall, or retrofit, a product parallels the duty to design a
product safely in the first instance, except that the distributor at post-sale
may have to replace an earlier product free of charge, at cost, or on some
reduced-price basis. If the duty consisted of no more than making known
that a safer product is available at market price, that duty would probably be
included in post-sale duty to warn.

The rationale for imposing a post-sale common law duty to warn,
but not to recall, is questionable in view of the general proposition of

\textsuperscript{82} \textit{See ReStatement (THird) of TOrts: Products Liability} § 11 (1998).
\textsuperscript{83} \textit{Id.} at cmt. d.
\textsuperscript{84} \textit{Id.} at cmt. c. It has been held that a continuing duty to warn tolls a negligence statute
of limitations, Handler v. Remington Arms Co., 130 A.2d 793 (Conn. 1957), but not a
\textsuperscript{85} \textit{ReStatement (THird) of TOrts: Products Liability} § 11 (1998).
\textsuperscript{86} \textit{Id.} at cmt. a.
\textsuperscript{87} \textit{Id.}
comment 1 to section 2 that a warning will not suffice where there is a reasonable design that would eliminate the danger. Comment a to section 11 of the Third Restatement states that a common law duty to recall would "impose significant burdens on manufacturers." If this statement means that a duty to redesign is generally more burdensome than a duty to warn, that statement is true generally and applies not just in the context of post-sale duties. Neither a duty to recall, nor to warn, would be triggered by "every improvement in product safety." A duty should arise only where the risk significantly outweighs the burden. The duty should be to recall rather than just to warn where a warning would leave "a residuum of risk great enough to require adopting a safer design." The common law duty is commensurate with a duty imposed by statute or regulation regarding the relevant factors to be weighed.

Section 11 recognizes that a common law duty to recall may be triggered if the supplier actually "undertakes to recall." Such an undertaking can likely be created by attempting a section 10 post-sale warning. Rescue doctrine in general makes no distinction between verbal warnings, and physical conduct (such as would be involved in redesign): Post-sale duties bear a close resemblance to the general rescue doctrine.

89. Id. § 11, cmt. a.
90. Id.
91. Id. Indeed, the cases impose a post-sale duty to recall, at least where the product was defective when initially sold. Comment a to section 11 of the Third Restatement would negate this common law duty. But see McDaniel v. Bieffee USA, Inc., Prod. Liab. Rep. (CCH) ¶ 15,462 (D. Minn. 1999) (imposing post-sale duty to warn motorcycle helmet users not to wear helmet without properly securing its chin strap, but refusing to impose post-sale duty to recall "because the overwhelming majority of other jurisdictions have rejected such an obligation").
93. See Id. §§ 10, 11.
94. See Restatement (Second) of Torts § 321 (1965). Section 321 provides:

§ 321. Duty to Act When prior Conduct is Found to be Dangerous
(1) If the actor does an act, and subsequently realizes or should realize that it has created an unreasonable risk of causing physical harm to another, he is under a duty to exercise reasonable care to prevent the risk from taking effect.
(2) The rule stated in Subsection (1) applies even though at the time of the act the actor has no reason to believe that it will involve such a risk.
Certainly if the warning proves unsuccessful, the supplier would be ill-advised not to undertake a reasonable recall.

In any event, the attempted restriction of common law duties of recall under section 11 may be to no practical avail. It is widely recognized that actual post-sale improvements in design - whether by the defendant or by others - may be used to show a time-of-sale defect.\footnote{See PHILLIPS, supra note 10, at 278-81. Such evidence may come in as an exception to Rule 407 of the Federal Rules of Evidence or simply as relevant evidence on the issue of defect. It may be questioned why post-sale duties to warn and recall under sections 10 and 11 of the Third Restatement are described as based only on a standard of due care, while evidence of actual post-sale modifications by the defendant or others is admissible to prove both strict liability and negligence. Id. at 228-30, 280-82.} Under a proper state of art analysis, moreover, it will be the rare case in which a post-sale design improvement would not have been reasonably feasible and available at the time of the original sale.\footnote{See, e.g., Brooks v. Beech Aircraft Corp., 902 P.2d 54, 63 (N.M. 1995). The Brooks court stated: In most instances a manufacturer is aware of the risks posed by any given design and of the availability of an alternative design. Further, in those hypothetical instances in which technology known at the time of trial and technology knowable at the time of distribution differ and outside of academic rationale we find little to suggest the existence in practice of unknowable design considerations-it is more fair that the manufacturers and suppliers who have profited from the sale of the product bear the risk of loss. Given the risk-benefit calculation on which the jury is instructed in New Mexico, and the policy considerations that favor strict products liability, we believe that it is logical and consistent to take the same approach to design defects as to manufacturing flaws. If in some future case we are confronted directly with a proffer of evidence on an advancement or change in the state of the art that was neither known nor knowable at the time the product was supplied, we may at that time reconsider application of a state-of-the-art defense to those real circumstances, properly developed under the proffer with applicable briefs and argument. Id.} The distributor would therefore be well-advised to use the best available corrective method - which is recall or retrofit - whenever it is reasonable to do so.
SUCCESSOR CORPORATION LIABILITY

Many courts recognize that where corporation B purchases all the assets of corporation A and continues the operation of A’s product sales business, B may be liable for defective products sold by A before the asset purchase by B. B’s liability in this situation is often referred to in the products context as successor corporation products liability. 97

There are a number of difficulties in finding successor liability. Some courts require that the purchase of A’s assets be in exchange for the stock of B, that there be a substantial continuity of ownership and personnel between A and B after the purchase, or that the purchase not occur as the result of a bankruptcy sale. 98

Even where B does not become liable as a successor corporation for the defective product sales of A, B may nevertheless be liable for those products owing to its ongoing relationship with the former customers of A. This liability thus far has been described in the case law as a duty to warn. 99

Section 13 of the Third Restatement describes the contours of this warning duty:

§ 13. Liability of Successor for Harm Caused by Successor’s Own Post-Sale Failure to Warn
(a) A successor corporation or other business entity that acquires assets of a predecessor corporation or other business entity, whether or not liable under the rule stated in §12, is subject to liability for harm to persons or property caused by the successor’s failure to warn of a risk created by a product sold or distributed by the predecessor if:
(1) the successor undertakes or agrees to provide services for maintenance or repair of the product or enters into a similar relationship with purchasers of the predecessor’s products giving rise to actual or potential economic advantage to the successor, and
(2) a reasonable person in the position of the successor would provide a warning.

(b) A reasonable person in the position of the successor would provide a warning if:

1. the successor knows or reasonably should know that the product poses a substantial risk of harm to persons or property; and
2. those to whom a warning might be provided can be identified and can reasonably be assumed to be unaware of the risk of harm; and
3. a warning can be effectively communicated to and acted on by those to whom a warning might be provided; and
4. the risk of harm is sufficiently great to justify the burden of providing a warning.\(^{100}\)

Section 13 attempts to restrict this duty to situations where the successor enters into a "maintenance or repair" agreement or a "similar relationship" with purchasers of the predecessor's products.\(^{101}\) The case law is not so restrictive. In *Downtowner, Inc. v. Acrometal Products, Inc.*\(^ {102}\) the court said:

The common thread running through these decisions imposing an independent duty to warn upon a successor corporation is the establishment of a relationship between the successor and its predecessor's customers . . . . Various factors have been considered to establish this nexus, for example: where the successor had inherited the service contracts which included responsibility for servicing the defective product; coverage of the particular product under the service contract; service of the product by the successor; and the successor's knowledge of the location and owner of the machine . . . . This listing cannot be said to be exhaustive. Rather than relying upon specific factors, the courts appear to have employed a risk/benefit analysis.

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100. *Id.*
101. *Id.*
102. 347 N.W.2d 118 (N.D. 1984).
to determine whether it would be just to impose such a duty.\textsuperscript{103}

In \textit{Patton v. TIC United Corp.},\textsuperscript{104} the court said a successor duty to warn could arise if the successor "has a 'more than casual' relationship with the customers of the predecessor."\textsuperscript{105} The duty could arise here because the successor knew that users of the predecessor's product "were being seriously injured" and the successor "benefited economically from its relationship with its predecessor's customers through its authorized . . . dealer network."\textsuperscript{106}

While this duty has to date been described as a duty to warn, there is no reason why it could not be extended to a duty to recall or retrofit. A warning would generally be of slight value unless something could be done by way of a safety device attachment, or a replacement with a newer, more safely designed product. If the customer is reluctant to heed the warning, the prudent successor would be well advised to make the attachment or replacement available on some sort of reduced-price basis. This is particularly true because the successor may end up being liable for the defective products anyway, whether as a legal successor of the predecessor, or because the warning to the customer may be found inadequate either in itself or an unsatisfactory substitute for a safer design.

\textbf{COMPONENT SUPPLIERS}

Section 5 of the \textit{Third Restatement} provides:

\begin{quote}
§ 5. Liability of Commercial Seller or Distributor of Product Components for Harm Caused by Products Into Which Components Are Integrated

One engaged in the business of selling or otherwise distributing product components who sells or distributes a component is subject to liability for harm to persons or property caused by a product into which the component is integrated if:
\end{quote}

\textsuperscript{103} \textit{id.} at 125.
\textsuperscript{104} 77 F.3d 1235 (10th Cir. 1996).
\textsuperscript{105} \textit{id.} at 1240.
\textsuperscript{106} \textit{id.} at 1241.
The component is defective in itself, as defined in this Chapter, and the defect causes the harm; or

(b)(1) the seller or distributor of the component substantially participates in the integration of the component into the design of the product; and

(2) the integration of the component causes the product to be defective, as defined in this Chapter; and

(3) the defect in the product causes the harm.°

The federal government has substantially restricted the liability of "biomaterials suppliers" under the Biomaterials Access Act of 1998.°

"Biomaterials" are component parts or raw materials used in the manufacture or production of an "implant," that is, a medical device placed in, or in contact with, the body, bodily fluids, internal human tissue or suture materials.° A manufacturing supplier of such materials cannot be liable unless the materials are required to be registered with the FDA, or unless the materials "did not constitute the product described in the contract."°

A non-manufacturing supplier of such materials can be held liable if it is impleaded within 90 days after judgment by the manufacturer, as an at-fault cause of a claimant's harm, or if the claimant so impleads such an at-fault supplier because the claimant "is unlikely to be able to collect the full amount of its damages from the remaining defendants."° This Act was likely passed to prevent suits such as those against manufacturers of the Teflon component used in temporomandibular joint implants,° but the scope of the Act covers substantially more than such implants.

Beyond the Act, Section 5 of the Third Restatement is intended to limit the liability of component suppliers.° Section 5(a) would hold the

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109. Id. at §§ 1603(3)(B), (5), & (8).
110. Id. at § 1605(a).
111. Id. at § 1607.
112. See PHILLIPS & PRYOR, supra note 11, at § 3-2(e) (Supp. 1997).
supplier liable if “the component is defective in itself.”

Interestingly, the Third Restatement, comment b, goes a step further to describe as a component “defective in itself” a motorcycle headlight “intended for rugged off-road use,” which fails “when the motorcycle is driven over bumpy roads.” If “foreseeable use” is substituted for “intended” use, the category of components defective in themselves is substantially broadened. The term “foreseeable use” has been widely substituted for “intended use” in products liability generally.

The Third Restatement does not discuss whether there are components that are generically defective in themselves, such as asbestos or tobacco. A jury might find that such products should not be marketed at all, whether as components or otherwise, and might hold the supplier of such products liable for defective design.

Comment b states that the component supplier owes no duty to warn a “sophisticated buyer” how to integrate the component into an assembled product, because such a duty would require the supplier to “monitor the development of products and systems into which their components are to be integrated.” The comment leaves open the possibility of such a duty arising from factors such as the “purchaser’s lack of expertise and ignorance of the risks of integrating the component into the

114. Id. § 5(a).
117. See 1 Amer. Law of Products Liability 3d § 1:54 (1987) (“A manufacturer’s warnings or instructions may evidence the manufacturer’s intended use; however, this does not foreclose any inquiry into the foreseeability of the actual use of the product.”)
119. Comment i to section 402A of the Second Restatement states that “[g]ood tobacco is not unreasonably dangerous merely because the effects of smoking may be harmful.”
purchaser's product, and the component supplier's knowledge of both the relevant risks and the purchaser's ignorance thereof." Indeed, the duty here may be more than one of warning. If the warning is likely to go unheeded, the buyer may owe a duty not to supply the component at all. This duty is indicated by the comment's reference to the "principles of negligent entrustment" as well as by the principles of design risk-benefit analysis previously discussed.

Comment e to section 5 states that the component supplier may be liable if the purchaser "invite[s]" the supplier to participate in the design of the integrated product, or if the supplier plays a "substantial role in deciding which component best serves the requirements of the integrated product." Even then, comment f states, the supplier will be liable only if the component itself is the cause of harm. This restrictive definition of liability for participation is not likely to withstand the general foreseeability rule for determining liability. If the component supplier should reasonably foresee that his component will be unreasonably dangerous when combined with the other components, it should not make any difference which component actually causes the resulting harm. If the harm does not result from a foreseeable danger associated with a combination of the components, but results rather from an inherent, unforeseeable dangerous characteristic associated with one or more of the components, liability should still attach if the presumed seller knowledge standard of strict liability is applied. Such a standard would be applied to a manufacturing flaw, and can well be applied also to a design flaw, to hold both the suppliers - component and assembler - strictly liable.

121. Id.
122. RESTATEMENT (SECOND) OF TORTS § 390 (1965).
123. See supra note 24 and accompanying text.
125. Id. at cmt. f.
126. See supra note 116 and accompanying text.
127. The Reporters contemplate such a situation in comment f to section 5 of the Third Restatement, in their example of a tank failing "due to defective steel in the body of the tank." RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 5 cmt. f (1998). In that situation, a component supplier of a nondefective valve for the tank should not be liable under section 5(b) of the Third Restatement as a participant in integrating the valve into the final product, the comment says. Id.
128. It is widely held that strict products liability attaches if a product manufacturer, assuming he knew the condition of the product, would not place the product on the market. See, e.g., Phillips v. Kimwood Machine Co., 525 P.2d 1033 (Or. 1974).
WARNING VS. DESIGN AND PROBLEMS OF PROOF

Plaintiffs will undoubtedly continue to assert failure to warn claims along with those of inadequate design, because it is widely perceived that warning claims are easier to prove and more easily understood by the jury. Generally the ordinary consumer standard will be sufficient to establish an inadequate warning, and the plaintiff will probably not be required to show exactly what form an adequate warning should have taken.\(^\text{129}\)

But the warning approach is beset with many more hurdles than might initially appear.\(^\text{130}\) One of the biggest of those hurdles is causation. The plaintiffs in Potter v. Chicago Pneumatic Tool Co. "failed to prove that adequate warnings would have prevented their injuries."\(^\text{131}\) They did establish that the design of defendant's pneumatic tools was "unreasonably dangerous based on the ordinary consumer expectation test" because of excessive vibration, which caused plaintiff's "hand arm vibration syndrome."\(^\text{132}\) A warning claim may be especially susceptible to a finding of lack of causation where the plaintiff is alternatively contending that no warning would have been adequate to prevent plaintiff's injury and that therefore a safer design should have been provided.

As noted earlier, one of the main fears of the opponents of the reasonable alternative design requirement in section 2(b) of the Third Restatement was that it would place a heavy burden of proof on the plaintiff to show an actual alternative design by means of expert testimony.\(^\text{133}\) Such fears may be justified if courts take an approach like that of the court in Richards v. Michelin Tire Corp.\(^\text{134}\) The plaintiff there sought to recover against the defendant tire manufacturer for injuries received in a tire-rim mismatch, resulting in a tire explosion.\(^\text{135}\) He tried to establish a design defect by showing that other tire manufacturers used a stronger tire bead that

\(^{131}\) 694 A.2d 1319, 1326 (Conn. 1997).
\(^{132}\) Id. at 1335-36.
\(^{134}\) 21 F.3d 1048 (11th Cir. 1994).
\(^{135}\) Id.
would have prevented the explosion had it been used in defendant's tire.\textsuperscript{136} The court held this evidence was insufficient to establish design defectiveness because plaintiff failed to show "that the alternative design was of greater overall safety."\textsuperscript{137}

The Potter case illustrates a lenient approach to the defective design issue. The plaintiffs there introduced evidence showing that defendants' tools "violated the limits for vibration exposure established by the American National Standards Institute" and that the tools "exceeded the threshold limit promulgated by the American Conference of Governmental and Industrial Hygienists."\textsuperscript{138} They also showed "various methods available to control vibration," including "isolation", "dampening", and "balancing", and a mechanical engineer testified that these methods had been "available to manufacturers for at least thirty-five years."\textsuperscript{139} The court said that the plaintiffs did not have to prove a reasonable alternative design to recover, and that plaintiffs' evidence was sufficient to show defendant's products failed to meet ordinary consumer expectations.\textsuperscript{140} It rejected the reasonable alternative design approach of section 2(b) of the \textit{Third Restatement}, which it found represented a minority position, and it concluded that most courts used ordinary consumer expectations, risk-utility, or some combination thereof to establish design defectiveness.\textsuperscript{141}

The approach taken by the Potter court toward proving design defect resembles that set forth in section 3 of the \textit{Third Restatement}. That section states that a product defect attributable to the distributor may be inferred "without proof of a specific defect" when the harm is of the sort that "ordinarily occurs as the result of [a] product defect" and that was not "solely the result" of non-defect causes.\textsuperscript{142} Such a defect may be proved with or without expert testimony, depending on the complexity of the defect issue.\textsuperscript{143}

Comment \textit{b} to section 3 states that "[t]he most frequent application of this [s]ection is to cases involving manufacturing defects," and only

\begin{footnotesize}
\begin{itemize}
\item 136. \textit{Id.} at 1056.
\item 137. \textit{Id.} at 1057.
\item 138. \textit{Potter}, 694 A.2d at 1326.
\item 139. \textit{Id.}
\item 140. \textit{Id.} at 1331.
\item 141. \textit{Id.}
\item 142. \textbf{RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 3} (1998).
\item 143. See \textit{Soule} v. \textit{General Motors Corp.}, 882 P.2d 298 (Cal. 1994); \textit{Ray} v. \textit{BIC Corp.}, 925 S.W. 2d 527 (Tenn. 1996).
\end{itemize}
\end{footnotesize}
“occasionally” will a design defect be involved. It is hard to see how the Reporters reach this conclusion, since they state in the same comment that the section applies when the plaintiff is unable “to establish specifically the nature and identity of the defect” because, the product “is lost or destroyed in the accident.” The Potter court states that twenty-eight states allow the establishment of a design defect by circumstantial proof similar to that contemplated by section 3.

The comment’s suggestion that section 3 only comes into play when the plaintiff is unable to establish a specific defect - and that the reasonable alternative design requirement of section 2(b) controls when a specific design defect is proven - is unsupported by the language of section 3, by case law, or by logic. The circumstantial evidence approach was used to establish a design defect in Potter. What is critical is not whether the product is destroyed, but whether the accident is of the sort that ordinarily does not happen except in the case of a product defect.

Moreover, as the court in Cronin v. J.B.E. Olson Corp. noted, the distinction between manufacturing and design defects may not be readily discernible. “It is difficult to prove that a product ultimately caused injury because a widget was poorly welded - a defect in manufacture - rather than because it was made of inexpensive metal difficult to weld, chosen by a designer concerned with economy - a defect in design.” In the American Tobacco Co. v. Grinnell the court said that alleged pesticide residues in tobacco, even if they “may be found in many if not all cigarettes,” is a

145. Id.
146. Potter, 694 A.2d at 1332.
148. Potter, 694 A.2d at 1331.
149. See id.
151. Id. at 1163.
manufacturing rather than a design defect because the residues were "not an ingredient American intended to incorporate into its cigarettes." In the case of a manufacturing defect, section 2 of the Third Restatement does not require proof of an alternative design.

Design and manufacturing defects may also overlap. Thus in Bryan v. John Bean Div. Of FMC Corp. the court found that a design defect, in the form of inadequate specifications, led to manufacturing defects in a clevis consisting of a crack, high levels of porosity, impurities and brittleness. Similarly, in Colt Indus. Operat. Corp. v. Frank W. Murphy Mfr., Inc., the court found that a manufacturing defect in the soldering of a sandblaster's shutoff switch was caused by the "manufacturer's design choice of three metals with different expansion, corrosion and resistance characteristics." Overlap between the categories of design and manufacturing defects "is unavoidable," the court said, and the "categories not only overlap, but they may also operate simultaneously or be alleged in the alternative."

If design and manufacturing defects are not readily distinguishable, if they overlap, and operate simultaneously, it is difficult to see why it matters which type of defect is proven for purposes of attaching liability under section 3 of the Third Restatement. A manufacturing defect would certainly fill the bill under section 3, and so should a design defect. If one type of defect does not require proof of an alternative design, neither should the other.

One of the problems the Reporters of the Third Restatement were particularly concerned about was the potential of liability for what are called categorical design defects — when a product is considered defective in design because its danger outweighs its benefit whether or not there is a reasonable alternative design. Manufacturing defects, and defects of the sort described in section 3, resemble categorical defects. So do products with inadequate warnings, and product misrepresentations. But the Reporters were anxious to foreclose such liability in the case of design defects, and

152. 951 S.W.2d 420, 434 (Tex. 1997).
154. 566 F.2d 541 (5th Cir. 1978).
155. Id. at 547-48.
157. Id. at 930.
158. See supra note 37 and accompanying text.
hence the reasonable alternative design requirement of section 2(b).\textsuperscript{159}

The Reporters did, however, recognize the possibility of categorical or generic design defects in comment e to section 2, under the heading of "manifestly unreasonable" designs.\textsuperscript{160} They gave as examples toy guns that shoot "hard rubber pellets with sufficient velocity to cause injury to children," or a trick exploding cigar that may cause injury on explosion. Such products would be inherently unsafe because of the "extremely high degree danger" and "negligible social utility."\textsuperscript{161} Such products are so dangerous that a jury could find they "should not have been marketed at all."\textsuperscript{162}

In comment d to section 2 the Reporters list "alcoholic beverages, firearms, and above-ground swimming pools" as examples of products that should not be found defectively designed except on proof of a reasonable alternative design.\textsuperscript{163} Significantly, they did not include the term "[g]ood tobacco" in this list in the final comments to the Third Restatement, thus leaving the implication that this product may have moved into the "manifestly unreasonable" category of comment e.\textsuperscript{164} Firearms may be moving into this category as well.\textsuperscript{165}

The Reporters seek to restrict the scope of "manifestly unreasonable" products to those products with an "extremely high degree of danger" and "negligible social utility."\textsuperscript{166} The risk-utility test as typically applied in product design cases asks the jury simply to determine whether the product's risk outweighs its utility, without any requirement that the risk be "extreme" or the utility "negligible," and without any necessary proof of a reasonable alternative design.\textsuperscript{167} The Reporters' attempt to cabin the risk-utility test is against the weight of authority, and will likely prove

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\textsuperscript{159} See \textit{Restatement (Third) of Torts: Products Liability} § 2(b) (1998).
\textsuperscript{160} Id. § 2, cmt. e.
\textsuperscript{161} Id.
\textsuperscript{162} Id.
\textsuperscript{163} Id. at cmt. d.
\textsuperscript{164} See supra note 118 and accompanying text.
\textsuperscript{166} \textit{Restatement (Third) of Torts: Products Liability} § 2 cmt. e (1998).
\end{flushleft}
unsuccessful in the development of the common law.

There are other ways that a product can be proven defective in design. The product may fail to meet ordinary consumer expectations because of express or implied representations in the advertising and marketing of the product.\textsuperscript{168} It may fail to meet industry standards.\textsuperscript{169} It may fail to meet statutory or administrative standards.\textsuperscript{170} It may fail to meet the state of the art standards as determined either by time-of-sale or by post-sale design developments.\textsuperscript{171} There may be reasonable substitute products that can establish a standard of reasonable design.\textsuperscript{172} The distributor may be negligent in testing the design of the product, negligent in distributing the product, or negligent in failing to remediate a problem after notice of a product's dangerous condition.\textsuperscript{173} These are some of the ways indicating that the alternative reasonable design requirement of section 2(b) of the Third Restatement is not likely to restrict the common law growth of products liability for defective design, or to affect the continued impingement of design liability on that of warnings.

CONCLUSION

The principle that, as a general proposition, an adequate warning will not serve as a surrogate for a safer design, has far-reaching implications for the law of products liability. It applies not just to the run-of-the-mill products case, but also to the boutique area of prescription drug litigation. It may extend to post-sale duties of product distributors, to successor corporation liability, and to component part suppliers.

A primary goal of the Third Restatement was to tighten the standard for proof of design defect through section 2(b), which requires the plaintiff to prove a reasonable alternative design as an essential condition for recovery based on design defectiveness. It is unlikely that section 2(b) will

\textsuperscript{169} Potter, 694 A.2d 1319.
\textsuperscript{170} See \textit{Restatement (Third) of Torts: Products Liability} \S 4 (1998).
\textsuperscript{171} See supra notes 94, 127 and accompanying text.
become the primary common law standard for proving design defect in this country, however.

A substitute product may serve as well as an alternative design. Courts widely recognize consumer expectations as an independent standard for proving design defect, and section 3 of the Third Restatement reflects this standard. A number of courts apply a risk-benefit analysis, without requiring proof of an alternative design, to determine product design defectiveness. Comment e of section 2 picks up on this risk-benefit analysis as a separate basis for determining design defect. This comment suggests an "extremely high degree of risk" and "negligible social utility" standard for determining such product defects, but the accepted common law approach is simply to determine if the risk outweighs the utility. Marketing techniques, including advertising, have traditionally provided a substantial basis for imposing design liability, as have post-sale design developments which point toward the time of trial as the relevant date for determining design defectiveness. These various methods of proving design defect should substantially reduce the difficulty of proving a design claim as an alternative to a warning claim.

The imposition of liability for failure to warn often seems strained, because of the uncertainty of whether a warning could have been adequately communicated and whether it would have been heeded. A safer design, in lieu of a warning, is preferred by the engineering community because of the recognition that a safer design is generally much more effective than an adequate warning in preventing accidents.
When Warnings Alone Won't Do: 
A Reply to Professor Phillips

by Richard C. Ausness

Introduction

In his paper, Professor Phillips contends that questions about the adequacy of a product's design should be resolved by the use of a risk-utility test and that the existence of an adequate warning should merely be one factor for the jury to take into account. This is essentially the position espoused by the Restatement (Third) of Torts: Products Liability (hereinafter Third Restatement), section 2, comment a. On the other hand, Professor Phillips is very critical of subsections 6(c) and 6(d). These provisions establish liability for the sellers of prescription drugs and medical devices. Section 6(c), which is concerned with design defect claims, protects manufacturers and other sellers from liability as long as a reasonable health-care provider would prescribe their product to some class of patients. Section 6(d), which deals with the duty to warn, permits manufacturers of prescription drugs and medical devices to satisfy their duty to warn, at least in most instances, by communicating the warning to the prescribing physician rather than the patient. In other words, section 6(d) retains the traditional "learned intermediary" rule.

Although I agree with Professor Phillips that a manufacturer should not always avoid liability for defective design by proving that it provided an adequate warning, I have serious doubts about the wisdom of adopting a sweeping rule such as the one set forth in comment l. In my opinion,
I's approach is economically inefficient and undercuts the moral values of individual autonomy and personal responsibility. There is simply no social or economic benefit to be gained by giving large damage awards to product users who fail to follow simple instructions or heed clear warnings.

I also disagree with Professor Phillips' view of section 6 of the Third Restatement. I believe that the Third Restatement's approach in section 6(c), which gives broad protection to manufacturers of prescription drugs and medical devices, is the correct one even though it leaves injured consumers with less protection than they might otherwise have. I also believe that section 6(d)'s retention of the learned intermediary rule is sensible and I find the Reporters' policy justifications for retaining the rule to be persuasive.

THE RELATION BETWEEN DESIGN DEFECT AND FAILURE-TO-WARN CLAIMS

Section 2 of the Third Restatement identifies three categories of product defect: manufacturing defects, design defects and defects arising from inadequate instructions or warnings. According to the Third Restatement, a manufacturing defect occurs when a product fails to conform to its intended design. In contrast, a product is defectively designed when product-related risks could be reduced or avoided by the use of a reasonable alternative design and when the failure to incorporate such a design causes the product to be "not reasonably safe." Finally, a product may be defective when product-related risks could be lowered or prevented by

8. See Phillips, supra note 2, at 10 (concluding that the provisions lack any precedent in case law, are filled with ambiguities, and will probably prove unworkable).
9. See id. § 2.
11. Id. § 2(a) (stating that a product "contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product").
12. Id. § 2(b) (declaring a product is defective in design "when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe").
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This classification scheme is widely accepted by courts and legal commentators. According to Professor Phillips, design defect claims and failure-to-warn claims should be regarded as separate and independent and not mutually exclusive. He bases this conclusion, at least in part, on the text of the Third Restatement. As mentioned earlier, the Third Restatement

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13. Id. § 2(c) (providing that a product may be defective because of inadequate instructions or warnings when "the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe").

14. See, e.g., Lantis v. Astec Indus., Inc., 648 F.2d 1118, 1120 (7th Cir. 1981) (declaring that "a product may be found defective within the meaning of Section 402(A) because of either a manufacturing flaw, a defective design or a failure to warn of dangers in the use of the product"); Gianitis v. American Brands, Inc., 685 F. Supp. 853, 856 (D.N.H. 1988) (observing that plaintiff may bring a claim "for injuries arising out of the defective design of the product, defect in the manufacture of a product, or a defect in the failure to provide adequate warnings in conjunction with the use of the product"); Piper v. Bear Medical Systems, 883 P.2d 407, 410-11 (Ariz. Ct. App. 1993) (stating that "three types of defects can result in an unreasonably dangerous product: manufacturing defects, design defects, and informational defects encompassing instructions and warnings").

15. See, e.g., David G. Owen, The Graying of Products Liability Law: Paths Taken and Untaken in the New Restatement, 61 TENN. L. REV. 1241, 1243 (1994) (declaring that "[t]oday, most courts and commentators accept as axiomatic the fundamental distinctions between three very different forms of product defect: (1) manufacturing flaws, (2) design inadequacies, and (3) insufficient warnings of danger and instructions on safe use"); Jerry J. Phillips, A Synopsis of the Developing Law of Products Liability, 28 DRAKE L. REV. 317, 342 (1978) (stating that "[p]roduct defects are now typically divided into three categories: manufacturing or production defects; design defects; and defects attributable to the absence or insufficiency of warnings or instructions for use of the product"); William C. Powers, Jr., The Persistence of Fault in Products Liability, 61 TEX. L. REV. 777, 782 (1984) (observing that "[d]efects generally are classified in three categories: flaws or manufacturing defects, design defects, and warning or informational defects"); but see Frank J. Vandall, The Restatement (Third) of Torts, Products Liability, Section 2(b): Design Defect, 68 TEMPLE L. REV. 167, 176-79 (1995) (pointing out that courts do not always clearly distinguish between manufacturing or design defects).


17. Id. at 4 (quoting comment I to section 2 stating that "[w]arnings are not ... a substitute for the provision of a reasonably safe design").
recognizes the aforementioned three types of product defect and establishes separate criteria for each category. It would seem to follow, therefore, that if one product can be defective because it has a bad design as defined by section 2(b), while another product can be defective because it has a bad warning as defined by section 2(c), it is possible that a third product may suffer from both a defective design and an inadequate warning. In such a case, there is nothing in the Third Restatement that would require the plaintiff to elect between the design defect claim and the inadequate warning claim. On the contrary, in such a case, the plaintiff could presumably proceed under either or both theories.

Lawsuits based on both defective design and failure-to-warn theories have been brought without challenge for many years. Indeed, Gosewisch v. American Honda Company was the only appellate case I could find where a defendant even raised the issue. The plaintiff in Gosewisch was severely injured while riding a three-wheel All Terrain Cycle (ATC) manufactured by the defendant, Honda Motor Company. He alleged that the vehicle had a number of design flaws which caused it to flip forward unexpectedly. The plaintiff also alleged that Honda was grossly negligent because it failed to warn customers about the unstable characteristics of its ATCs. The trial court refused to allow the plaintiff's failure-to-warn claim to go before the jury because the plaintiff had already alleged that the product was defectively designed. The jury subsequently found in favor of the defendant on the design defect claim and the plaintiff

20. Id. at 378.
21. Id. These design flaws included (1) low tire pressure; (2) failure to install a mechanical suspension system; (3) a high center of gravity; (4) weak front forks; and (5) badly designed front wheel brakes. Id.
22. Id.
23. Id.
The intermediate appellate court affirmed the lower court's decision, but was itself reversed by the Arizona Supreme Court. That court acknowledged that the defective design claim and the failure-to-warn claim were independent of each other and, therefore, could be separately considered by the jury. According to the Gosewisch court, "[a] plaintiff is not required to make an election between pursuing a case on a strict products liability theory of either design defect or failure to warn." ADEQUATE WARNINGS AS A SUBSTITUTE FOR SAFER PRODUCT DESIGN

Professor Phillips concludes that because design defects and inadequate warning defects are distinct categories, a manufacturer should not be able to cut off liability for defective design simply by providing an effective warning about design-related (as opposed to inherent) risks. I must concede that the Third Restatement, as well as many appellate court decisions, agree with Professor Phillips.

24. Id.

25. See Gosewisch v. American Honda Company, 737 P.2d 365, 368 (Ariz. Ct. App. 1985) (declaring that "[b]ecause plaintiffs here did not contend at trial that the ATC was faultlessly manufactured and designed—their sole contention being that the vehicle had design defects—there was no error in failing to give the instruction"). The intermediate appellate court relied on Embry v. General Motors Corp., 565 P.2d 1294 (Ariz. Ct. App. 1977), a case which involved allegedly defective motor mounts. The court in Embry also affirmed a lower court's refusal to give a failure-to-warn instruction, finding that it was redundant because the only danger involved was that created by the defective design. Id. at 1297.

26. Id. at 383.

27. Id. at 379.

28. Id.

29. Professor Phillips has maintained this view for years. See Jerry Phillips, The Standard for Determining Defectiveness in Products Liability, 46 U. Cin. L. Rev. 101, 106 (1977) ("There may be instances where the product is so dangerous that the courts will find the seller's obligation cannot be fulfilled merely by warning."). See also Phillips, supra note 2, at 4-8 (citing Rogers v. Ingersoll-Rand Co., 114 F.3d 841, 843 (D.C. Cir. 1998)).
A. The Issue from a Doctrinal Perspective

As Professor Phillips points out, 30 there is considerable doctrinal support for the proposition that adequate warnings will not necessarily insulate a manufacturer from liability when it is possible to reduce or avoid the harm by redesigning the product. 31 A few courts, however, have taken the opposite view. 32

1. The Third Restatement and Comment 1

Although section 2 of the Third Restatement identifies three distinct types of product defects and implies that litigants are not required to elect among them when they bring suit against manufacturers, it does not tell us whether a manufacturer may respond to a product-related risk by providing an adequate warning as an alternative to eliminating the risk by an improved design. Comment 1 to section 2, however, does expressly address this issue. This provision states that "[i]n general, when a safer design can reasonably be implemented and risks can reasonably be designed out of a product, adoption of the safer design is required over a warning that leaves a

30. Phillips, supra note 2, at 4-8 (citing Uloth v. City Tank Corp. 384 N.E.2d 1188, 1193 (1978) (holding that a product may be defectively designed even if there are warnings to be found adequate, or if the dangers are obvious); Rogers v. Ingersoll-Rand Co., 144 F.3d 841, 843 (D.C. Cir. 1998) (holding that an adequate warning will not automatically discharge the defendant manufacturer's duty to design a safer product)).

31. See Sturm, Ruger & Co., Inc. v. Day, 594 P.2d 38, 44 (Alaska 1979) (declaring that where the most stringent warning will not protect the public, gun manufacturer must eliminate the defect itself); Eads v. R.D. Werner Co., 847 P.2d 1370, 1372 (Nev. 1993) (holding that an adequate warning will not shield a ladder manufacturer from liability if the defect involved could have been corrected through the use of a commercially feasible alternative design); Robinson v. G.G.C., Inc., 808 P.2d 522, 524-25 (Nev. 1993) (concluding that an adequate warning will not prevent the manufacturer of a box-crushing machine from being held liable for defective design if it fails to provide a safety device that is commercially feasible and will not affect product efficiency).

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significant residuum of such risks.”

This, of course, is fully consistent with Professor Phillips’ position.

The Reporters of the *Third Restatement* offer the following rationale to support their position in comment 1: An obvious risk puts the user or consumer on notice that the product is dangerous in some respect. However, the obviousness of the risk does not ordinarily relieve the manufacturer of its duty to provide a safer design because consumers who are unable to avoid obvious risks will suffer avoidable injuries unless manufacturers are encouraged to develop safer designs for their products.

Warnings are similar to obvious risks in the sense that they also provide notice to consumers. Since consumers often ignore warnings, just as they ignore obvious risks, the same accident-cost-avoidance considerations that require manufacturers to eliminate obvious risks through better design also justify requiring manufacturers to eliminate latent risks through better design as opposed to merely warning about them.

In the Reporters’ Note to section 2, the drafters tacitly acknowledge that the new comment 1 is inconsistent with comment j to the superseded section 402A of the *Restatement (Second) of Torts* (hereinafter the Second Restatement). Comment j declared that “[w]here a warning is given, the seller may reasonably assume that it will be read and heeded; and a product

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34. See Phillips, *supra* note 2, at 8 (indicating that “it seems more responsible to put the loss on the generally better accident avoider, the manufacturer . . .”).
35. *Id.*
36. See *Camacho v. Honda Motor Ltd.*, 741 P.2d 1240, 1246 (Colo. 1987) (declaring that “[u]ncritical rejection of design defect claims in all cases wherein the danger may be open and obvious thus contravenes sound public policy by encouraging design strategies which perpetuate the manufacture of dangerous products”).
37. See *Restatement (Third) Of Torts: Products Liability* § 2 cmt. I (1998). Moreover, some courts have concluded that there may be duty to warn even when the risk is an obvious one. *See Banks v. Iron Hustler Corp.*, 475 A.2d 1243, 1252 (Md. Ct. Spec. App. 1984) (holding that there is no valid reason for automatic preclusion of liability based solely upon obviousness of danger in an action based on failure to warn); *Campos v. Firestone Tire & Rubber Co.*, 485 A.2d 305, 309-10 (N.J. 1984) (stating that “in our state the obviousness of a danger, as distinguished from a plaintiff’s subjective knowledge of the danger, is merely one element to be factored into the analysis to determine whether a duty to warn exists”).
bearing such a warning, which is safe for use if it is followed, is not in
defective condition, nor is it unreasonably dangerous. The drafters of
comment I have rejected the approach of the old commentJ for two reasons:
first, it is inconsistent with the judicial abandonment of the patent danger
rule; and, second, a growing body of social science research suggests that
warnings are not always very efficient accident-cost-avoidance
mechanisms.

The Reporters cite Uloth v. City Tank Corp. to support their
conclusion that an adequate warning cannot redeem a defective design. The
plaintiff in Uloth, a sanitation worker, was injured when a garbage truck
packer blade severed his foot. The plaintiff brought suit against the
manufacturer of the truck, claiming that the truck's compactor mechanism
had been defectively designed. The plaintiff also showed that several
safety devices were available that would have prevented the accident
without affecting the efficiency of the product. In response, the defendant
argued that the court should disallow the plaintiff's design defect claim if an
adequate warning had been given. The trial court rejected this argument
and the jury eventually found in favor of the plaintiff.

The lower court's judgment for the plaintiff was affirmed on

the patent danger rule in a design defect case involving failure to provide crash bars on
motorcycle); Koske v. Townsend Engineering Co., 551 N.E.2d 437, 442 (Ind. 1990)
(rejecting the patent danger rule in a products liability case where the manufacturer of a
meat-slicing machine failed to provide shielding); Owens v. Allis-Chalmers Corp., 326
N.W.2d 372, 377 (Mich. 1982) (rejecting the patent danger rule in a design defect case
involving failure to provide driver restraint devices on forklift).
41. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § (1998) (Reporters' Note
101) (citing Howard Latin, "Good" Warnings, Bad Products, and Cognitive Limitations,
41 UCLA L. REV. 1193 (1994)).
42. 384 N.E.2d 1188 (Mass. 1978).
43 See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1998) (Reporters' Note
101).
44. Uloth, 384 N.E.2d at 1190-91.
45. Id. at 1191.
46. Id.
47. Id. at 1191-92.
48. Id. at 1190.
appeal. The appellate court refused to adopt a rule which permitted a manufacturer to discharge its duty to consumers by simply issuing a warning about product-related dangers. Instead, the court declared that the adequacy of any warning given (or the obviousness of the danger if a warning was not given) was a factor that could be considered in determining whether the product was defectively designed.

The *Uloth* court based its decision on the assumption that manufacturers had more control over product-related risks than consumers. For example, the court observed that workers often had no choice but to work with dangerous products and almost no ability to reduce these product-related risks. In addition, warnings did little to eliminate accidents that were caused by inadvertence, instinctual reactions or forgetfulness. Manufacturers, on the other hand, could anticipate these accident scenarios and often had the ability, through design changes, to reduce or eliminate product-related risks at relatively small cost. For this reason, in the court’s view, it made sense to place the burden of reducing product-related risks on manufacturers instead of allowing this burden to be shifted to users and consumers.

2. **Recent Decisions Adopting the Third Restatement’s Position**

Recently, a number of courts have expressly relied on comment to conclude that adequate warnings are no substitute for safer designs. Two of these cases, discussed by Professor Phillips, are *Rogers v. Ingersoll-Rand Co.* and *Uniroyal Goodrich Tire Co. v. Martinez.*

In *Rogers,* the plaintiff, a member of a road construction crew, was seriously injured when a large machine backed into her while she was directing traffic at a busy work site. The machine in question, known as

49. *Id.* at 1195.
50. *Id.* at 1192.
51. *Id.*
52. *Id.*
53. *Id.*
54. *Id.*
55. *Id.*
56. 144 F.3d 841 (D.C. Cir. 1998).
57. 977 S.W.2d 328 (Tex. 1998).
58. *Rogers,* 144 F.3d at 842.
a MT-6520 milling machine, was being used to strip away layers of asphalt from a road.\textsuperscript{59} The driver of the MT-6520 did not see the plaintiff because she was standing in a blind spot, and the plaintiff did not hear the machine approaching because its alarm system did not function properly.\textsuperscript{60} The plaintiff sued the manufacturer of the MT-6520, alleging that the machine was defectively designed because it did not have rear-view mirrors, kill switches or a reliable alarm system.\textsuperscript{61} At the end of the trial, the defendant proposed a jury instruction that would have effectively precluded liability as long as the manufacturer provided an adequate warning.\textsuperscript{62} The trial court, however, refused to give the requested instruction and the jury returned a $16.7 million verdict for the plaintiff.\textsuperscript{63}

On appeal, the District of Columbia Court of Appeals affirmed the lower court’s ruling.\textsuperscript{64} It concluded that courts in the District of Columbia had adopted a risk-utility test for use in design defect cases.\textsuperscript{65} Under this approach, the \textit{Rogers} court declared, a defendant could show that a warning reduced a product’s dangers (and, therefore, reduced the risk side of the risk-utility equation), but that a warning would not necessarily be determinative on the issue of defectiveness when an alternative safer design was available.\textsuperscript{66} In the court’s words, “[i]t is thus not correct that a manufacturer may, under the law of the District of Columbia, merely slap a warning onto its dangerous product, and absolve itself of any obligation to do more.”\textsuperscript{67}

Indeed, as the court observed, a warning would have done very little to reduce the danger that the MT-6520 would accidently back into an

\textsuperscript{59.} \textit{Id.}
\textsuperscript{60.} \textit{Id.}
\textsuperscript{61.} \textit{Id.} at 843.
\textsuperscript{62.} \textit{Id.} The MT-6520’s maintenance manual stated that other workers should stay at least ten feet away from the machine while it was operating. It also admonished the operator to verify that the alarm worked and to check for people in the area. Finally, a sign on the machine itself warned people to stay ten feet away. \textit{Id.}
\textsuperscript{63.} \textit{Id.} at 842-43. Ten million and two-hundred thousand dollars were awarded for compensatory damages along with another $6.5 million in punitive damages. \textit{Id.} at 842. The district court opinion is reported at 971 F. Supp. 4 (D.D.C. 1997).
\textsuperscript{64.} See \textit{Rogers}, 144 F.3d at 842.
\textsuperscript{65.} \textit{Id.} at 843 (citing \textit{Warner Fruehauf Trailer Co., Inc. v. Boston}, 654 A.2d 1272, 1276 (D.C. 1995)).
\textsuperscript{66.} \textit{Id.} at 844-45.
\textsuperscript{67.} \textit{Id.} at 844.
WHEN WARNINGS ALONE WON'T DO

unsuspecting worker. 68 In such a case, therefore, the manufacturer was legally obligated to incorporate additional safety features, where feasible, to guard against foreseeable harm. 69 The Rogers court bolstered its decision by citing comment l of the Third Restatement, implicitly adopting the reasoning of that comment and the Uloth case. 70

The Third Restatement's approach was also endorsed by the Texas Supreme Court in Uniroyal Goodrich Tire Co. v. Martinez. 71 In that case, an automobile mechanic was injured when a 16-inch tire exploded as he was attempting to mount it on a 16.5-inch rim. 72 The plaintiff contended that the tire was defectively designed because it used a 0.037-inch multi-strand weftless bead on the tire instead of safer 0.050-inch single strand programmed bead. 73 The jury found in the plaintiff's favor and awarded him $5.5 million in compensatory damages and $11.5 million in punitive damages. 74 This judgment was affirmed by an intermediate appellate court, 75 and ultimately by the Texas Supreme Court. 76

Attached to the tire in question was a prominent label which warned against mounting the tire on a 16.5-inch rim, failing to use a tire mounting machine, inflating the tire without using an extension hose, or reaching over the tire during inflation. 77 The plaintiff, who had inflated more than a thousand tires during his career, ignored all of these warnings. 78 The tire manufacturer urged the court to adopt the rule enunciated in comment f to section 402A of the Second Restatement, which provided that an adequate warning would prevent design defect liability. 79 The court, however, rejected comment j in favor of the position set forth in comment l of the

68. Id. at 845.
69. Id.
70. Id.
71. 977 S.W.2d 328 (Tex. 1998).
72. Id. at 331-32.
73. Id. at 333-34.
74. Id. at 334. The compensatory award was later reduced to $4.1 million and the punitive award was reduced to $4.1 million as well, resulting in a final award of $10.3 million, including interest. Id.
75. 928 S.W.2d 64 (Tex. Ct. App. 1995).
76. Martinez, 977 S.W.2d at 331.
77. Id. at 332.
78. Id. at 343 (Hecht, J., dissenting).
79. Martinez, 977 S.W.2d at 335-36.
Third Restatement\textsuperscript{80} and held that “warnings and safer alternative designs are factors, among others, for the jury to consider in determining whether the product as designed is reasonably safe.”\textsuperscript{81} Applying the Third Restatement’s approach, the court in Martinez concluded that the jury could have reasonably found that the tire was defectively designed.\textsuperscript{82}

3. The Minority View

Although the rule set forth in the Third Restatement no doubt represents the prevailing view, there is some case law to the contrary. Simpson v. Standard Container Co.\textsuperscript{83} and Taylor v. Yale & Towne Manufacturing Co.\textsuperscript{84} are illustrative. The Simpson case involved a four-year-old child who was injured by burning gasoline.\textsuperscript{85} The plaintiff and a companion took the cap off a gasoline container and spilled it on the floor.\textsuperscript{86} The fumes from the spilled gasoline somehow ignited, injuring the plaintiff.\textsuperscript{87} The plaintiff sued the manufacturer of the gasoline container, arguing that the container should have been equipped with a child-proof cap.\textsuperscript{88} The trial court dismissed the case and the plaintiff appealed.\textsuperscript{89} The Maryland Court of Special Appeals upheld the lower court’s ruling.\textsuperscript{90}

The appellate court based its conclusion in part on the fact that the product was not being used for its intended purpose.\textsuperscript{91} In the court’s view, the storing of the gasoline container where unsupervised four-year-old children could play with it was unforeseeable misuse.\textsuperscript{92} In addition, the court relied on section 402A, comment/j to conclude that the container was not unreasonably dangerous since clear warnings were affixed to it which

\begin{itemize}
\item \textsuperscript{80} Id. at 336.
\item \textsuperscript{81} Id.
\item \textsuperscript{82} Id.
\item \textsuperscript{83} 527 A.2d 1337 (Md. Ct. Spec. App. 1987).
\item \textsuperscript{84} 520 N.E.2d 1375 (Ohio Ct. App. 1987).
\item \textsuperscript{85} Simpson, 527 A.2d at 1339.
\item \textsuperscript{86} Id.
\item \textsuperscript{87} Id. at 1339
\item \textsuperscript{88} Id.
\item \textsuperscript{89} Id. at 1338.
\item \textsuperscript{90} Id. at 1341.
\item \textsuperscript{91} Id. at 1340-41.
\item \textsuperscript{92} Id. at 1341.
\end{itemize}
directed consumers to “Keep Out of Reach of Children” and “Do Not Store in Vehicle or Living Space.” Apparently, the Simpson court felt that it was appropriate to put the burden on the parents to keep the gasoline container away from small children.

An Ohio intermediate appellate court reached a similar result in Taylor v. Yale & Towne Manufacturing Co. In that case, a worker was injured by an explosion at a cement plant. The explosion occurred when sparks from a truck manufactured by the defendant ignited fumes that were emanating from the “mix center” at the plant. The injured worker brought suit against the truck manufacturer, alleging failure to warn and defective design; however, the trial court granted a motion for directed verdict in favor of the defendant. This decision was affirmed by the Ohio Court of Appeals.

According to the Taylor court, the only evidence the plaintiff presented in support of his design defect claim was that the defendant failed to warn about the Yale truck’s tendency to spark. The court, however, observed that the plaintiff and other workers at the plant were well aware of this characteristic and, consequently, rejected the plaintiff’s design defect claim. Relying on section 402A, comment j, the Taylor court also disallowed the plaintiff’s failure-to-warn claim, declaring that the manufacturer had no duty to warn about an obvious hazard.

B. The Issue from a Policy Perspective

Various policies can be invoked to support the approach taken by comment I. For example, the comment I approach appears to promote economic efficiency by imposing liability on the cheapest cost avoider.

93. Id.
95. Id. at 1376.
96. Id.
97. Id.
98. Id. at 1378.
99. Id. at 1377-78.
100. Id. at 1377.
101. Id.
102. Id. at 1378.
103. According to Guido Calabresi, the cheapest cost avoider is the party who “an arbitrary
In addition, one can argue that the rule set forth in comment 1 is consistent with tort law’s distributive goals because it shifts accident costs to the best loss-spreader. In my view, however, the efficiency and loss-spreading effects of comment 1’s approach are overrated. Furthermore, the comment 1 approach arguably produces outcomes that are inconsistent with moral values.

1. Accident Costs

It is generally assumed that accident costs will be optimized if product sellers are held liable for product-related injuries. Producers, because of their control over the design and production processes, are deemed to be in a better position than consumers to discover and correct dangerous characteristics in their products. Subjecting producers to liability provides an incentive for them to improve the safety of their products when it is cost-effective to do so. However, producers are not always the cheapest cost avoiders. Sometimes, consumers are able to bear some product-related risks more cheaply than producers, and in such cases, it may be better to shift these risks to them. Thus, it makes sense to require manufacturers to make design improvements when the risk involved is inherent and unavoidable or when consumers cannot reasonably be expected

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to exercise sufficient vigilance to avoid injury. At the same time, it seems appropriate to allow warnings to suffice in cases where consumers can easily avoid injury by heeding warnings or following directions. To require manufacturers to redesign their products in such cases will cause resources to be wasted on over-designed products.

But if this is the case, then neither the old comment 1 approach nor the new comment 1 approach will necessarily optimize accident costs. Comment 3 assumes that consumers will always be the cheapest accident cost avoiders, while comment 1 stands for the proposition that producers are inherently better at preventing accidents than consumers. Since neither of these assumptions is universally correct, I believe that it is better to allow manufacturers to provide warnings, even when it was possible to eliminate the risk by redesigning the product, when the additional cost of the alternative design is greater than the increased accident costs that occur when only a warning is provided. To illustrate this point, assume that a warning would be essentially costless and would reduce existing accident costs by $200, while a safer alternative design would cost the manufacturer an additional $500, but would reduce accident costs by $600. The original design plus warning option would result in a net reduction in social costs of $200. A safer alternative design would also result in a net reduction of social costs, but only of $100 ($600-$500) even though it would produce fewer accident costs. In this case, therefore, the first alternative would be more cost efficient than the second alternative, although both alternatives would be more efficient than doing nothing at all. Consequently, the most efficient liability rule is one which would encourage the first alternative rather than the second.

Of course, one could argue that the comment 3 approach does not always require the manufacturer to redesign a dangerous product. In the

example discussed above, a manufacturer would theoretically escape liability if it could show that a warning was more cost-effective than a safer alternative design. Unfortunately, few juries really understand, or sympathize with, the notion that a manufacturer could deliberately choose to subject consumers to a known risk when this risk could be eliminated by an alternative safer design. What is needed, therefore, if economic efficiency is an important goal, is a rule that effectively protects producers from jury scrutiny when they make product safety decisions based on an objective assessment of costs and benefits.

2. Distributive Effects

Commentators often argue that the secondary costs of accidents can be reduced if losses are spread among a large group of people instead of being allowed to fall entirely on a small group of individuals. Since product sellers are thought to be better loss-spreaders than individual consumers, it advances the goal of loss-spreading if accident costs are shifted from consumers to producers. Since the approach embodied in comment l is more expansive than the approach embodied in the old comment j, one can argue perhaps that comment l’s approach is superior because it results in more liability, and hence more loss spreading, than the

108. See Guido Calabresi, Some Thoughts on Risk Distribution and the Law of Torts, 70 YALE L.J. 499, 517 (1961) (maintaining that “taking a large sum of money from one person is more likely to result in economic dislocation . . . than taking a series of small sums from many people . . .”). Secondary accident cost avoidance, therefore, is concerned with reducing the adverse economic effects that result when people suffer serious personal injuries. See Stanley Ingber, Rethinking Intangible Injuries: A Focus on Remedy, 73 CAL. L. REV. 772, 794 (1985) (declaring that “secondary cost avoidance involves allocating injury costs so as to decrease the economic dislocation caused by injuries”).

109. See James A. Henderson, Jr., Coping with the Time Dimension in Products Liability, 69 CAL. L. REV. 919, 934 (1981) (stating that “manufacturers are believed to be better able to obtain insurance than are consumers, and are assumed to be able to pass on most, if not all, of the insurance costs by raising the prices of products”).

110. See Escola v. Coca Cola Bottling Co., 150 P.2d 436, 441 (Cal. 1944) (Traynor, J., concurring) (declaring that “the cost of an injury and the loss of time or health may be an overwhelming misfortune to the person injured, and a needless one, for the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business”).
rule in comment j.111 I am skeptical of this argument, not because it is illogical, but because I have doubts about the use of loss spreading as a rationale for the existing tort liability regime.

First, as mentioned above, the conventional case for loss spreading assumes that product sellers can spread losses more cheaply and effectively than consumers.112 However, this assumption has not been proven and it is quite possible that individual consumers can insure against loss more cheaply than producers.113 Second, the vast majority of consumers already have health, life, disability insurance or workers compensation protection14 and, therefore, any additional loss-spreading by means of tort liability is redundant.115 Finally, the high cost of litigation makes a tort system much more expensive to operate than private first-party insurance schemes.116

111. I am not suggesting that Professor Phillips would make such an argument.
112. See Sheila L. Birnbaum, Unmasking the Test for Design Defect: From Negligence [to Warranty] to Strict Liability to Negligence, 33 VAND. L. REV. 593, 596 (1980) (contending that “[t]he manufacturer can spread the risk through insurance and price adjustments, whereas the injured individual might suffer a crushing financial blow underwriting the loss himself”).
113. See James E. Brittain, Product Honesty Is the Best Policy: A Comparison of Doctors' and Manufacturers' Duty to Disclose Drug Risks and the Importance of Consumer Expectations in Determining Product Defect, 79 NW. U. L. REV. 342, 410 (1984) (declaring that “[t]he blithe assumption underlying loss-spreading arguments that manufacturers are in a better position than consumers to both bear and spread losses has never been empirically verified”).
114. See Stephen D. Sugarman, Doing Away With Tort Law, 73 CAL. L. REV. 558, 647-48 (1985) (pointing out that approximately 85% of the American population is protected against accidents, either through private insurance or through government health care and welfare programs).
115. See Stephen D. Sugarman, Serious Tort Law Reform, 24 SAN DIEGO L. REV. 795, 798 (1987) (observing that “[o]nce tort law finally does deliver money to victims, a considerable sum goes to duplicate compensation that they otherwise have or will receive from other sources, such as health insurance, sick leave, Social Security, and the like”).
116. Private insurance systems spend about 15 percent of their premium income on administrative expenses. See Robert E. Litan, The Liability Explosion and American Trade Performance: Myths and Realities, in TORT LAW AND THE PUBLIC INTEREST 127, at 135 (Peter H. Schuck ed., 1991) (stating that transaction costs “consume 30 percent of the costs of the workers' compensation system, 15 percent of health insurance, and just 1 percent of the social security system”). In contrast, the tort system’s overhead rate is closer to 50 percent. See Robert L. Rabin, Some Reflections on the Process of Tort Reform, 25 SAN DIEGO L. REV. 13, 35 (1988) (“Reduced to a single figure, injury victims were receiving slightly less than half of every dollar expended by the system on accident claims”).
3. Moral Issues

Some legal commentators stress that product sellers have a strong moral responsibility to protect consumers against harm from defective products.\textsuperscript{117} They are right, of course, but I would suggest that consumers and other parties have moral responsibilities as well. For example, I believe as a matter of personal autonomy, that one should be allowed to consume products, such as whiskey, butter or tobacco, that are inherently dangerous or unhealthy;\textsuperscript{118} but at the same time, an individual who engages in such risky behavior can not expect product sellers to compensate them when they are injured while engaging in risky behavior. Unfortunately, many consumers seem to feel that they are entitled to compensation regardless of how much they may have contributed to their own injury.\textsuperscript{119}

As a matter of personal autonomy and responsibility, when consumers have the ability to prevent injury by heeding warnings or following simple directions but deliberately fail to do so, I do not believe that they should recover from product manufacturers for their own carelessness.\textsuperscript{120} The unfairness of this practice is exacerbated by the large damage awards that these people often receive. For example, in Martinez, the plaintiff, an individual who ignored clear warnings and refused to use safety equipment obtained a judgment of more than $10 million.\textsuperscript{121} Even if the plaintiff actually received only $6 million after paying attorneys' fees

\textsuperscript{117} See Mary J. Davis, Design Defect Liability: In Search of a Standard of Responsibility, 39 WAYNE L. REV. 1217, 1271-319 (1993) (proposing a standard for product design that reflects the special relationship of trust that exists between manufacturers and their customers).

\textsuperscript{118} See Robin L. West, Taking Preferences Seriously, 64 TUL. L. REV. 659, 673 (1990) ("He chooses what he prefers, he prefers what he wants, he wants what he desires, and he desires what is in his interest. Therefore, his interest is best promoted by leaving him with whatever his choices have yielded.").

\textsuperscript{119} See Robert M. Ackerman, Tort Law and Communitarianism: Where Rights Meet Responsibilities, 30 WAKE FOREST L. REV. 649, 674 (1995) (observing that "[t]here is no shortage of people who could have protected themselves through simple, inexpensive measures but preferred to expose themselves to injury and then sue others who arguably might have protected them through more complex, expensive measures").

\textsuperscript{120} I would not characterize inadvertent or reflexive actions as either deliberate or careless.

\textsuperscript{121} See Uniroyal Goodrich Tire Co. v. Martinez, 977 S.W.2d 328 (Tex. 1998).
and litigation expenses, this would have produced a comfortable income of at least $300,000 a year without having to dip into his multi-million dollar nest egg. Overcompensation on that scale is bad enough under any circumstances, but it is particularly outrageous when the recipient is largely responsible for his injuries. Of course, it is not the manufacturer who ultimately pays when it is forced to design “foolproof” products; rather, this financial burden falls primarily upon responsible consumers who are required to pay for safety features they neither want nor need.

Of course, as Professor Phillips points out, courts can instruct juries to apply comparative fault principles and reduce damage awards when injured consumers are careless or negligent. Thus, at least in theory, comparative fault forces careless victims to bear some of the losses they inflict on themselves. That is the way comparative fault is supposed to work; in reality, comparative fault works somewhat differently. Although I have no empirical evidence to support my conclusions, I strongly suspect that when juries are sympathetic to the plaintiff, they either refuse to apply comparative fault principles at all or they increase the size of their award (after all no one can objectively measure pain and suffering) prior to applying the comparative fault formula, thereby ending up with the verdict they would have reached anyway.

Another problem with the approach taken by comment l is that it allows third parties to escape responsibility for their wrongdoing. Parents, fellow employees and employers are some of the worst offenders. In Simpson v. Standard Container, for example, primary responsibility for the child’s injury ought to have been placed on the parents who ignored explicit warnings and allowed two small children to play with a container filled with gasoline. Arguably, this act of stupidity pales in comparison with the failure of the manufacturer to equip the container with a child-proof cap. Likewise, in Rogers v. Ingersoll Rand Co., the employee who

122. See Phillips, supra note 2, at 7-8 (citing Uniroyal Goodrich Tire Co. v. Martinez, 928 S.W.2d 64, 68 (Tex. Ct. App. 1995).
123. For example, the jury in Uniroyal Goodrich Tire Co. v. Martinez refused to attribute any responsibility to the victim even though he failed to determine the correct size of the tire and declined to use a tire-changing machine. 977 S.W.2d at 340. The jury’s decision was upheld by two appellate courts. Id.
125. See also Larue v. National Union Electric Corp., 571 F.2d 51 (1st Cir. 1978) (parents
backed up a heavy machine in an area crowded with people without bothering to see if anyone was in the path of the vehicle was the one who was primarily responsible for the plaintiff's injuries, not the machine's manufacturer. Of course, the guilty employee paid nothing, while the product manufacturer was stuck with a $17 million dollar judgment. In the Martinez case, while the victim contributed to the accident by ignoring the tire manufacturer's warnings, his employer also was at fault for failing to provide an operable tire-changing machine, an action that would have prevented the accident as effectively as anything the tire manufacturer could have done.

In sum, the liability rule reflected in comment unfairly shifts the entire accident-cost-avoidance burden to product sellers while exonerating more culpable parties, such as victims, parents, employers and fellow workers. Such results are morally suspect to say the least.

C. An Alternative Approach

Professor Phillips rightly criticizes the approach reflected in comment because it allows a manufacturer to satisfy its duty to the consumer by providing a warning even in cases where the warning will not be effective. On the other hand, the approach adopted by comment does not place sufficient responsibility on consumers; even they can and should take the initiative to look out for their own safety. This suggests that a new approach might be superior to either of these alternatives.

Unfortunately, it is difficult to develop an approach that will avoid


126. 144 F.3d 841 (D.C. Cir. 1998).
128. See Rogers, 144 F.3d 841.
the Scylla and Charybdis of comments $j$ and $l$. One possibility would be to return to the approach taken by comment $j$, that a safer design is not required when a warning will do,\textsuperscript{130} but articulate this as a strong presumption rather than as a categorical rule. A presumptive approach, such as this, would provide a safe harbor for producers, but still allow a court to impose liability in particularly egregious cases. Courts could also give more weight to compliance with statutory or administrative safety standards.\textsuperscript{131} Thus, manufacturers who complied with statutory design standards could argue that their products were presumptively reasonably safe, thereby reducing the opportunity for juries to second guess their design decisions.\textsuperscript{132}

**DESTRUCTIVE WARNINGS, DESTRUCTIVE DESIGNS, AND PRESCRIPTION DRUGS**

Section 6(c) of the *Third Restatement* sets forth the requirements victims must meet in order to recover against sellers of prescription drugs or medical devices under a design defect claim, while section 6(d) establishes the criteria for failure-to-warn claims.\textsuperscript{133} Professor Phillips believes that these provisions do not provide enough protection for consumers.\textsuperscript{134} On the other hand, I would conclude that the FDA’s strict licensing process and the availability of trained personnel to serve as learned intermediaries provide adequate protection for consumers. Consequently, I would conclude that tort law should not play a significant role in the

\textsuperscript{130} See *Restatement (Third) of Torts: Products Liability* § 2 cmt. l (1998).
\textsuperscript{132} See Richard C. Ausness, *The Case for a “Strong” Regulatory Compliance Defense*, 55 Md. L. Rev. 1210, 1253-57 (1996) (proposing that sellers whose warnings and designs comply with applicable government product safety standards be protected against liability unless plaintiffs can establish by clear and convincing evidence that the applicable safety standards are grossly inadequate).
\textsuperscript{133} See *Restatement (Third) of Torts: Products Liability* §§ 6(c)-(d)(1998).
\textsuperscript{134} See Phillips, *supra* note 2, at 10-16.
production and marketing of prescription drugs or medical devices.

A. Requirements for Design Defect and Failure-to-Warn Claims

Section 6(c) declares that a prescription drug or medical device will be regarded as defectively designed if the foreseeable risks posed by the product "[a]re sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients." As Professor Phillips observes, this provision effectively limits the design defect liability of drug manufacturers to situations where the product has virtually no therapeutic value. If this minimal threshold requirement is met, injured parties can recover only if the manufacturer fails to warn their prescribing physicians about foreseeable risks of harm.

According to Professor Phillips, the drafters of this provision mistakenly assume that if a manufacturer is forced to redesign a drug which is useful for one class of patients in order to make it safer for another class of users, the redesigned drug will then be less useful to the original class of users. In his view, it makes sense to encourage the manufacturer to redesign a dangerous drug because the redesigned drug might be safer for the second class of users without necessarily losing its utility for the first class of users. In the alternative, the manufacturer might develop separate designs for each class of user and thereby minimize the harmful effects of the first design.

Section 6(d) states that the supplier of a prescription drug or medical device will be subject to liability if reasonable instructions or warnings are not provided to prescribing physicians or other health care providers. This provision also declares that drug manufacturers may be held liable for failure to warn patients (as opposed to the prescribing physicians and health care providers) when they know that these learned

135. See Restatement (Third) of Torts: Product Liability § 6(c)(1998).
136. See Phillips, supra note 2, at 13.
137. Id. at 11-13.
138. Id.
139. See Restatement (Third) of Torts: Product Liability § 6(c)(1998).
intermediaries will be unable to reduce product-related risks by following instructions or warnings. Professor Phillips questions the merits of this provision on two grounds: first, the Reporters are wrong to assume that learned intermediaries will always act reasonably; second, the direct marketing of prescription drugs by pharmaceutical companies undermines the learned intermediary doctrine's rationale.

B. The Issue from a Doctrinal Perspective

Section 6(c) departs from section 402A, comment k's "unavoidably unsafe" analysis. Comment k provided that when products were incapable of being made safe for their intended use, but were sufficiently beneficial, their continued production and use was fully justified, notwithstanding the high degree of risk associated with their use, and they would be classified as "unavoidably unsafe." Sellers of such unavoidably unsafe products would not be subject to strict liability in tort as long as the products were properly prepared and marketed, and as long as a proper warning was given. Although comment k was not expressly limited to any particular kind of product, courts traditionally applied it only to pharmaceutical products.

Although section 6(c) does not use the term "unavoidably unsafe" like its predecessor, section 402A, comment k, its treatment of prescription drugs and medical devices is similar to section 402A's basic approach. For example, section 6(c) appears to cover the same sorts of pharmaceuticals as its predecessor, namely chemical drugs, biologics such as antibiotics, blood and vaccines, as well as medical devices. Furthermore, like comment k, section 6(c) requires drug manufacturers to warn about inherent product-related risks if they wish to avoid tort liability. However, section 6(c)'

140. Id.
141. See Phillips, supra note 2, at 13-16.
142. Id.
143. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965).
144. Id.
145. See Richard C. Ausness, Unavoidably Unsafe Products and Strict Products Liability: What Liability Rule Should be Applied to the Sellers of Pharmaceutical Products?, 78 KY. L.J. 705, 713-15 (1989-90) (observing that almost all comment k cases have involved pharmaceuticals, but discussing a few that have involved other products).
formula for determining the product’s social utility is somewhat different than comment k’s. In theory, under comment k, courts engaged in a perfunctory form of risk-utility analysis in order to determine whether a product’s therapeutic benefits outweighed its inherent risks. In contrast, section 6(c) uses the prescribing practices of "reasonable health care providers" as a proxy for determining a prescription drug’s therapeutic utility. The assumption seems to be that courts should not independently evaluate the risks and benefits of prescription drugs, but should instead defer to the judgment of health care professionals. This is reminiscent of the deference shown to the medical profession in malpractice cases by courts which employ the "accepted practice" rule.

Section 6(d) declares that pharmaceutical manufacturers can satisfy their duty to warn in most instances by communicating their warnings to "prescribing and other health care professionals" and do not have to directly warn the ultimate users or consumers of their products. This approach follows the traditional "learned intermediary" rule, which provides that the manufacturer of a prescription drug has no duty to inform a patient about drug-related risks as long as it provides an adequate warning to the patient’s prescribing physician. The rule also applies to medical devices.

146. Id. at 716.
148. See Joseph H. King, Jr., In Search of a Standard of Care for the Medical Profession: the "Accepted Practice" Formula, 28 VAND. L. REV. 1213, 1234-36 (1975) (discussing the accepted practice rule).
149. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) (1998).
150. See Thomas v. Hoffman-LaRoche, Inc., 949 F.2d 806, 811 (5th Cir.), cert. denied, 504 U.S. 956 (1992) (failure to communicate directly with patient does not make a product defective as long as manufacturer provides an adequate warning to learned intermediary); Anderson v. McNeilab, Inc., 831 F.2d 92, 93 (5th Cir. 1987) (seller of prescription drug satisfies its duty to warn by informing prescribing physician about product’s inherent dangers); Tracy v. Merrell Dow Pharmaceuticals, Inc., 569 N.E.2d 875, 878 (Ohio 1991) (manufacturer discharges its duty to warn by adequately communicating with prescribing physician). See also Richard C. Ausness, Learned Intermediaries and Sophisticated Users: Encouraging the Use of Intermediaries to Transmit Product Safety Information, 46 SYRACUSE L. REV. 1185, 1195-200 (1996) (discussing the learned intermediary rule).
Warnings can be communicated to physicians by means of package inserts, advertisements in medical journals or the *Physician's Desk Reference*, letters to physicians or by office visits from company representatives (formerly known as "detail men").

The learned intermediary rule assumes that the prescribing physician will act as an intermediary between the manufacturer and the patient. Consequently, once the manufacturer warns the physician, the burden shifts to the physician to pass this information on to his or her patients. Although the learned intermediary doctrine has been criticized by some commentators, it continues to be recognized in almost all jurisdictions. Thus, the *Third Restatement*’s retention of the learned intermediary rule is entirely consistent with the prevailing case law.

C. The Issue from a Policy Perspective

In my opinion, section 6's treatment of prescription drugs and medical devices appears to optimize accident costs and it also establishes a liability regime which permits manufacturers to market essential products at reasonable cost to consumers.

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*Issues, 32 GA. L. REV. 141, 156 (1997) (declaring that some courts have extended the learned intermediary doctrine to implantable medical devices).*


154. See Brooks v. Medtronic, Inc., 750 F.2d 1227, 1232 (4th Cir. 1984) (declaring that once the manufacturer warns the physician, "the choice of treatment and the duty to disclose properly fall on the doctor").

155. See, e.g., Margaret Gilhooley, *Learned Intermediaries, Prescription Drugs and Patient Information*, 30 ST. LOUIS U. PUB. L. REV. 633, 657-58 (1986) (contending that "[t]he change in the informed consent doctrine makes appropriate a corresponding change in the role that the physician should perform as 'learned intermediary'"); Susan A. Casey, Comment, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 WM. MITCHELL L. REV. 931, 958 (1993) (arguing that "the learned intermediary doctrine is based on medical paternalism that is inconsistent with the concept of informed consent").

156. See Barbara P. Flannagan, Comment, *Products Liability: The Continued Viability of the Learned Intermediary Rule as It Applies to Product Warnings for Prescription Drugs*, 20 U. RICH. L. REV. 405, 411 (1986) (acknowledging that the learned intermediary doctrine is universally recognized in the United States).
I. Accident Costs

Arguably, section 6(c) optimizes accident costs by ensuring that the benefits of a prescription drug will outweigh its benefits. However, instead of allowing juries to evaluate a drug’s risks and benefits in the context of litigation, which is the way section 2 deals with design defect claims, section 6(c) employs surrogates to perform this function. The first of these surrogates is the FDA, which engages in a sophisticated risk-benefit analysis as part of its drug-licensing process. The Reporters expressly rely on the FDA to act as a regulatory watchdog and keep unreasonably dangerous drugs off the market. The medical profession also acts as a surrogate. Section 6 immunizes only drugs which have been recognized as effective and beneficial by prescribing physicians. Thus, physicians as a group determine the drug’s overall utility by deciding whether to prescribe it or not.

Section 6(d) also promotes economic efficiency by allowing physicians to make individualized determinations of costs and benefits for each of their patients. While manufacturers could warn patients directly by means of package inserts, it would be difficult to communicate such complex and technical information in a way that would be comprehensible to ordinary consumers. In contrast, physicians are ideal sources of information for consumers. Not only can prescribing physicians understand technical data, but they can translate this information into language that lay persons can understand. In addition, physicians can screen information provided by the manufacturer so that patients receive only such information

158. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 (1998) (Reporters’ Note 146) (stating that “government regulatory agencies adequately review new prescription drugs and devices, keeping unreasonably dangerous products off the market”).
as is directly relevant to their medical condition. Thus, by utilizing physicians to communicate information about product-related risks to their patients, the learned intermediary rule takes advantage of the existing physician-patient relationship and thus ensures that such information will be communicated to the ultimate recipient cheaply and effectively.

2. Distributive Effects

The liability rules adopted by section 6 of the Third Restatement are less favorable to injured consumers than the approaches suggested by Professor Phillips. In effect, individual product users will be prevented from shifting product-related losses to drug manufacturers and, instead, will have to bear these losses themselves. At first blush, this result seems contrary to the loss-spreading goals of products liability. However, some countervailing arguments can be made in response to this claim. First, most of those who suffer drug-related injuries will have health insurance (since by hypothesis they are receiving medical treatment) and may also have disability or life insurance. Consequently, a large proportion of their out-of-pocket expenses will be spread by means of first-party insurance. In such cases, the primary loss that would be left unspread would be pain and suffering, a type of loss that most victims are less concerned with recouping, at least as compared with pecuniary losses. Second, and more

161. See Richard C. Ausness, Learned Intermediaries and Sophisticated Users: Encouraging the Use of Intermediaries to Transmit Product Safety Information, 46 Syr. L. Rev. 1185, 1229 (1996) (arguing that physicians can transmit information to patients more effectively than drug manufacturers).
162. See Jeffrey O’Connell, A Proposal to Abolish Defendant’s Payment for Pain and Suffering in Return for Payment of Claimants’ Attorneys’ Fees, 1981 U. Ill. L. Rev. 333, 364 (declaring that “[e]ven among the seriously injured, payment for pain and suffering, while more important than to the general public, was still ranked much less important than protection against the claims of others and payment for medical expenses, property damage, and wage loss”). This conclusion is reinforced by data that suggests that most people would be unwilling to purchase private insurance to compensate them for nonpecuniary injuries. See Patricia M. Danzon, Tort Reform and the Role of Government in Private Insurance Markets, 13 J. Legal Stud. 517, 520 (1984); Alan Schwartz, Proposals for Products Liability Reform: A Theoretical Synthesis, 97 Yale L.J. 353, 362-67 (1988) (describing the insurance theory of compensation); Ellen S. Pryor, The Tort Law Debate, Efficiency, and the Kingdom of the Ill: A Critique of the Insurance Theory of Compensation, 79 Va. L. Rev.
importantly, prescription drugs are vital necessities for many people. At the same time, the drug industry has historically been prone to over deterrence. Thus, in many instances, drug producers have taken apparently useful products off the market, or raised drug prices dramatically, in response to concerns about tort liability. Arguably, the Third Restatement’s approach, though ungenerous to injured consumers, is necessary to protect a greater public interest.

CONCLUSION

Sections 2 and 6 of the Third Restatement deal with a number of difficult and interesting matters. Although Professor Phillips and I do not see eye to eye on very much, we agree on this much: The Third Restatement is not consistent in its treatment of the duty-to-warn/duty-to-design issue. Under Section 2 a warning will not do when the product seller can eliminate or reduce the danger by redesigning the product; however, under section 6, a manufacturer need only warn about a product-related risk and is under no duty to redesign the product in order to make it safer. The Reporters justify this apparent discrepancy on the basis that different liability rules are needed for prescription drugs. Professor Phillips and I would prefer to see the same set of liability rules applied to all products. We differ, however, over what the appropriate liability rule should be. In general, Professor Phillips would prefer that producers be required to take active steps to make their products more safe; on the other hand, I would prefer to shift more responsibility for product safety to users and consumers and, thus, would give more protection to producers as long as they provide adequate warnings and instructions.


164. See Phillips, supra note 2, at 26-31.

165. Id. at 32-33.
DIALOGUE WITH THE DESIGNERS:
COMPARATIVE INFLUENCES ON PRODUCT DESIGN NORMS
IMPOSED BY REGULATORS AND BY
THE THIRD RESTATEMENT OF PRODUCTS LIABILITY

by James T. O'Reilly

Products sometimes injure or kill users, despite the efforts of product design engineers. A significant role exists for lawyers to translate complex messages of regulatory controls and liability risks, and to communicate the public expectations of safer product design to those who design and manufacture consumer products. This article suggests that the Restatement (Third) of Torts: Products Liability (hereinafter Third Restatement) makes such a dialogue urgently necessary. The common law tort system and the governmental safety regulation system serve as parallel and protective deterrents, encouraging the safer design of products. A dialogue is needed among tort lawyers, regulators and product designers that would integrate these separate influences. Key to such a dialogue is teaching designers how the Third Restatement of Products Liability will interact with regulated products' future designs.

INTRODUCTION
THE AUDIENCE FOR SAFER DESIGN KNOWLEDGE

Times are changing in American product safety law. Products seem to be safer today, in design and label wording, than they were in decades past. Safety developments include more durable designs for consumer products, more safety devices for electrical products, and better warnings for medical products. Recent qualitative improvements in product safety deserve to be expanded and encouraged. The role of lawyers in accident reduction will involve effective communication to the designers of tomorrow’s consumer products.

The audience for new safety-related design knowledge has expanded: the rapid expansion of availability of imported goods sold to U.S. consumers, as a result of the NAFTA and GATT treaties, necessitates

1. Visiting Professor of Law, University of Cincinnati College of Law; B.A., Boston College; J.D., University of Virginia.
even more educational activity among the non-U.S. manufacturers who seek to sell in U.S. markets. Globalizing the awareness of safer design requires greater international sensitivity to consumer safety trends. Lawyers need to become safety advocates outside the courtroom, and lawyers should be heard inside the design studio as products are created or modified.

The task of explaining to designers about the legal aspects of design safety requires a complex and multi-level presentation. When U.S. lawyers explain our liability system to non-U.S. manufacturers, the audience frequently asks how a prudent firm can reconcile its compliance with the common law norms, as manifest in the Third Restatement, with its need to comply with the statutory and regulatory norms of government regulators like the Food and Drug Administration, Consumer Product Safety Commission, and other safety-oriented bureaucracies. Beyond these parallel trends of safety regulation and tort law evolution, the overlay of dozens of state products liability reform statutes challenges a lawyer to make sense out of a multi-factorial matrix of litigation risk analysis, when talking with the engineering-trained product designer.

This article encourages counsel to educate manufacturers and importers about the integration of the safety-protective systems, and to make product designers more aware of interplay between the common law and regulatory methods of product “defect” determination.

DESIGN DEFECTS

The design of consumer products is an incremental art of evolutionary steps, premised on engineering and experimentation. Products that are designed for safer operation than conventional competitor brands may have safety devices as physical barriers to injury; less toxic ingredient formulations; smaller numbers of flammable units in a container; or otherwise reflect the designer’s awareness of risk-avoidance techniques. Many designers understand the approaches and

3. For purposes of this article, we will examine only the safety-related regulations of the Food & Drug Administration, Consumer Product Safety Commission and National Highway Traffic Safety Administration. The generic missions of these agencies are addressed in detail in their internet sites, <http://www.fda.gov>, <http://www.cpsc.gov>, and <http://www.dot.gov>.
select prudently. But times have changed. Today, some manufacturers, particularly those operating in remote exporter nations with a greater local tolerance for individual risk from product defects, are cost-driven and time-sensitive in their choice of the product design for their exported products. The counsel for a manufacturer or importer should attempt education for each level of product designer.

A. Comparative Safety

Existing marketed products had historically formed the base line from which a designer begins to put together a newly-designed product. Building a better mousetrap requires understanding the ways of mice and men, as measured by other marketed mousetraps. The legal issue of comparative safety of designs necessitates a sound basis for comparison. What is the safety of our competitor's design? How safe are designs by other vendors of this commodity? Would a safer design lessen attractiveness, dampen utility or add cost?

For many years, the common law evolution of negligence doctrine had allowed the industry practice and "custom of the trade" to be a consideration in determining the reasonableness of a design. If no "reasonable seller" marketed a safer model, the defendant's design was not negligent.

But times have changed with the new breed of regulatory approaches. By the 1970s, regulatory agency demands for safer automobiles and lessened industrial pollution produced the era of so-called


5. Classic negligence theory presupposes an existing norm of reasonableness against which the defendant's product is measured; the quest for liability turns upon the comparison of the norm with the marketed design of the defendant's product. See Restatement (Second) of Torts: Products Liability § 283 cmt. c (1965).


8. Sometimes this considers the local area of similar sellers as the base upon which the duty is evaluated. See Doss v. Apache Powder Co., 430 F.2d 1317, 1322 (5th Cir. 1970).
"technology forcing" regulations. These were explicit departures from the longstanding acceptance of industry practice and custom. Environmental laws imposed a "maximum achievable" or "best available" norm that compelled the whole market of products to shift their performance away from the industry-wide custom. The new performance threshold was intentionally fixed at a level that current equipment, products or vehicles had not met, as of the time of the rule's proposal. Standards-setting became an affirmative exercise, driven by technology rather than market economics; designs were not simply the confirmation of what the competing sellers chose as their internalized norm. Regulators spoke; designers listened.

B. Effects of the Third Restatement

The 1998 Third Restatement went much further down the road away from acceptance of an industry status quo of product design. Now the test to be considered is whether a plaintiff's expert witness can offer any "reasonable alternative design" that would not have caused this same accident or injury. A product using the reasonable alternative design need not be on the market currently. The plaintiff establishes such a design, demonstrates its feasibility as an alternative, and thereby shows the design defect of the challenged product. Omission of that reasonable alternative design could render the defendant's product "not reasonably safe."

Like the evolutions that occur in product design, the common law

9. Technology-forcing rules do not rest with currently utilized practices, but set a standard that forces the development of means by which to achieve them. See CELIA CAMPBELL-MOHN ET AL., SUSTAINABLE ENVIRONMENTAL LAW § 4.2(b)(3) (1993), for an analysis of the technology-forcing concept.
11. See, e.g., id. § 7479.
14. See id. at cmt. d.
15. See id.
16. See id. § 2(b).
of torts moves incrementally. The dominant tort law test, strict liability for designs and the use of a risk-utility balancing test, will gradually be supplanted as state appellate courts accept the reasoning of the Third Restatement. Within several years, many U.S. courts will be asking the plaintiff "whether a reasonable alternative design would, at reasonable cost, have reduced the foreseeable risks of harm posed by the product." Absent a statutory command to utilize some other norms, state and federal courts are likely to apply this Third Restatement's new test in product design defect cases. Choices of design made by competitors in industry will no longer be a horizon for the prudent designer, where safety is concerned.

The historical importance of the debate over this change has been explored by others. The historic interplay between tort and regulation has been studied as well. When lawyers and designers interact, the federal regulatory system's "technology-forcing" approach will be an additional conceptual element that may ease understanding of the transition to the new liability structure.

C. How Regulators Impact on Designs

The reasonable designer always wishes to avoid a "defect." Regulatory agencies have power to act against many manufacturers of consumer goods if they find "defects" in products. Attorneys who deal with both regulators and liability juries have a role in explaining to designers the aspects of the product that would present a "defect," and would thus be subject to negative consequences for the designer and the designer's employer. If a government standard is not met, the product is defective in a regulatory sense -- even if it is not defective in a tort sense.

The "defect" definition used by the particular government agency responsible for public safety in that product category should be explained

17. Id. § 2 cmt. d.
to the designer, before counsel tries to explain modern liability litigation norms. A designer should know that a product can be forced off the market faster and with greater personal consequences for the seller, if the challenge comes from a regulatory agency like the National Highway Traffic Safety Agency (NHTSA)\(^2\) which regulates vehicle design safety. But not all NHTSA "defects" will be a source of plaintiffs' tort recovery, especially those with strong evidence of concurrent error by the driver.\(^2\)

**D. Catching Designers' Attention**

Product designers pay attention to the highly visible negative effects of regulatory prosecutions and punishments. These cases have a deterrent effect in proportion to their public attention in the news media. Just as punishment of manufacturers for use of fraudulent ingredients\(^2\) keeps other formulators honest, so designers are deterred by well-publicized instances of enforcement penalties.\(^2\) For example, prudent U.S. designers of paints, crayons and graphic supplies have been made aware that the government expects a wide margin of safety for chemicals that are found in children's' art supplies.\(^2\) The federal auto recall announcements engender a close attention to detail among other auto makers.\(^2\) Airlines know that the FAA has a very severe regulatory punishment awaiting uses of defective or counterfeit aircraft replacement parts.\(^2\)

Another option for regulators, arm-twisting to induce better behavior, works with the most responsible companies but is ignored by

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\(^2\) The statute's consideration of "specified use or reasonably foreseeable abuse" implies Congress is aware of human error. See U.S. v. General Motors Corp., 518 F.2d 420, 447 (D.C. Cir. 1975) (manufacturer has available affirmative defense of unforeseeable owner abuse).


\(^2\) For example, the personal criminal liability of individual corporate officers in the food industry increased executives' awareness of compliance duties. See, e.g., United States v. Park, 421 U.S. 658 (1975).


many smaller firms. The U.S. Consumer Product Safety Commission awards honors to companies that make their products safe. Designing a safe child-resistant cap has some publicity value when an award is presented. If the design is more costly, that day’s positive publicity for the manufacturer will probably not induce a price-sensitive competitor to follow the safety ideal. The price is higher, so the change is omitted from the competitor’s packaging. Unfortunately, the governmental effort toward positive encouragement of safer design tends to be overlooked or unheard by the marginal weaker performers in a particular market and by non-U.S. companies who respond only to a purchase specification tied to price.

A gap of knowledge exists that exacerbates the issue of unsafe consumer products. By whatever means, the concept of “defect” from the regulator’s definition becomes an implicit curb on the U.S. designer’s palette of design elements. The foreign designer’s choices are less likely to reflect such a restraining influence. Outreach beyond U.S. markets is particularly necessary with the rise of imports, but outreach is expensive. Most federal agencies have, for budget reasons, been unable to visit many foreign product designers, so the agencies rely on intermittent import screening of products selected for sampling at the Customs ports of entry. Whenever possible, trade associations and the major retailers who import goods are encouraged to educate the non-U.S. designers. But education and other forms of subtle persuasion may be of little effectiveness in reaching many of the foreign designers who are exporting goods to U.S. consumers. It is true that a post-design and post-manufacture scrutiny by courts or government inspectors will occur after injuries have occurred -- but these rarely constrain the design decisions of the offshore product manufacturer.

30. CPSC’s press activities in praise of compliant companies can be reviewed on the internet at <http://www.cpsc.gov>.
31. Child-resistant caps are required on products such as pharmaceuticals, 15 U.S.C. § 1472 (1994), and stringent test protocols have been established to assure compliance, 16 C.F.R. § 1700.20 (1998).
E. Influencing Designers to Avoid Liability

A lawyer who wishes to educate clients’ designers about safety expectations should understand the limited value of regulatory compliance as a defense. The prudent counsel educates the designer about the Third Restatement as well, beginning with the interaction of tort and regulatory schemes, observing the demise of industry custom as a defense to liability, and explaining the reasonable alternative design issues.

The Third Restatement expects designers will meet the federal norms as a minimum and then exceed them. This effort optimally achieves a design level of safety that reduces the economic risks to the company of mass torts, a class action, or a punitive damages lawsuit. Federal standards compliance is not enough, as the Third Restatement and the majority of courts have agreed. Prudent design cannot stop with satisfying only the regulatory agency norms. For example, flammable fabrics test standards developed in the 1950s and eye irritant test methods of the 1940s are obsolete yet still firmly fixed in the language of federal regulations. Inertia about technical changes to product standards is an endemic part of the fabric of regulatory life, even where the standard is out of date and out of touch, since the career federal employee in a safety related assignment feels few institutional or personal incentives to rock the boat and create new rulemaking controversies. Juries are being made aware of this reality by plaintiffs’ counsel. Prudent risk-averse product designers must do more to promote safe use than the federal rules literally require.

The Third Restatement and the great majority of civil tort law agree that compliance with a regulatory agency standard is a minimum requirement, and compliance will not shield one against jury verdicts holding that a defendant should have done more. Regulatory compliance is a "piece of the evidentiary puzzle" on the issue of defectiveness and not a dispositive fact. "Compliance . . . does not immunize" the tort

37. See Sours v. General Motors Corp., 717 F.2d 1511, 1517 (6th Cir. 1983).
defendant from civil liability. 39

Under the Third Restatement, if the product has failed to comply with an "applicable product safety statute or administrative regulation," then the product is defective with respect to the risks sought to be reduced by the statute or regulation.40 Note the conditions: the plaintiff proves the law or rule applies to the specific factual situation, and then the finding of product defectiveness is made only as to the risks that the law or rule had sought to prevent.

The status quo of industry acceptance of a particular design no longer protects the product from strict liability. Today's designers cannot rely on an "everybody gets away with it" attitude, if they ever did. The Third Restatement persuasively rejected this industry-custom defense in section 2 comment d.41 The significance of eschewing common design practice as a defense should be understood: negligence law's "reasonable manufacturer" norm is unavailable in a tort case that follows a Third Restatement analysis of defectiveness. Plaintiff's design challenge can introduce improvements in safety technology into a reluctant marketplace, whether or not a competitor has utilized that technology. This tort standard's effect parallels the "technology forcing" federal regulations described earlier. Each has the power to move behaviors, as the technology forcing rules have done in the environmental emissions area.42

F. Mixed Signals to Designers

Lawyers' advice about design risks may be drowned in a cacophony of sounds. In practice, the designer gets many simultaneous signals: Lower Cost! More Color! Ease of Operation! Flexible Sourcing! Don't be radical compared to competitors' offerings on the same retail shelf, in appearance or in price! A purchasing agent's mentality creeps into many design choices: using common components or readily available designs, product pricing can be held low enough to make a product successful. If a design deviates from norms either to appear distinctive on

41. See Henderson & Twerski supra note 18, at 687.
42. For example, automobile emissions have been reduced since the introduction of pollution control devices that would not have become commercially available, but for the technology-forcing pressures of the Clean Air Act.
the retail shelf, or to add a costly safeguard that boosts prices, then the
design may be a "failure."

Even when legal messages are heard, the signal sent to designers
by regulatory agencies is stronger than the subtle message imparted by
products liability. "Make these pills inaccessible to children" and "make
the package sealed so that any tampering would be visible" are clear.
Compared to the blare of messages reaching the designer's worktable, the
Third Restatement's message of "defect" is a mere whisper: "Remember
that if you are sued and if the plaintiff shows a reasonable alternative
design existed, then the company could lose millions over and above its
insurance coverage." But the subtlety, the contingent nature of the
message, diminishes its force when compared to the clear signal of
regulatory commands.

G. When Lawyers and Designers Meet

This paper urges a meeting of the minds. In a meeting of product
designers with their legal counsel, the lawyer should encourage creativity,
sensitivity to user needs, and safety consciousness. Then counsel should
explain the "defect" requirements in the particular federal oversight
agency. Next the counsel should explain how the products liability trends
favor claimants who offer the safer "reasonable alternative design,"
whether or not such a design is accessible to consumers today. After the
chagrined groans of the designers fade, the lawyer then should explain that
the wide regional or national distribution of the product makes it necessary
to consider state laws such as those which impose a risk-utility test\footnote{See, e.g., \textit{Ohio Rev. Code Ann.} § 2307.75(B) (1998).} and a
few that still look to the expectation of the "ordinary" consumer.\footnote{See, e.g., \textit{Ind. Code} § 34-20-4-1(1) (1983).}

A prudent lawyer will prepare for the meeting with designers by
studying the risk features of this product, the claims and litigation
experience, and the industry profile of competing products. Such
preparation aids the designers' receptivity to safety education.

"Can't We Warn Against This?" Proud and aesthetically sensitive
design professionals do not enjoy being told how to design or redesign
their products, so the credibility and background research by the lawyer
will weigh heavily in the quality of their reception to this meeting. It is
inevitable that lawyers will be asked, "So can't we just warn against this
[instead of redesigning]?” Common law sometimes allowed the warning to cure the design defect, but the Third Restatement “rejects this primitive notion decisively.” Recent case law also rejects it.

The Third Restatement favors design changes as a better means of risk-avoidance, and does not accept the defendant’s use of warnings as a defense where the risk is avoidable through a feasible redesign. A pure economic assessment might favor the least costly option, label changes, but optimal social policy outcomes would be produced by design changes, the result that avoids injuries to the wise and the illiterate users alike.

H. The Decline of Regulatory Measures of Avoidance

The methods by which federal agencies promote product safety have been affected by congressional budget appropriations. Today, because of budget shortfalls, federal agencies choose defect avoidance by standards much less frequently than defect remediation by ad hoc recalls. Regulatory agencies could use options including design standardization authority, defect-enforcement authority, or informal jawboning to achieve safer product designs.

Of the three options, a strategy of risk avoidance by standards creation has been the least frequent. Standards-creation efforts are tightly constrained by the statutory process steps that lobbyists impose on agencies in the bargaining that leads to statutes. More process requirements equal more length of the standards-creation path. Pragmatically, standards-creation projects are restrained by the high cost of developing a new standard in an era of tight budgets. The alleged “capture” of an agency’s technical staff by industry views, because of the staff members’ need for expertise from industry experts, will produce a federal standard that may be deemed the “least bad outcome.” When technology is forced to respond to a product safety crisis, such as drug tampering that led to the rapid adoption of mandatory tamper-evident

45. Henderson & Twerski, supra note 18, at 689.
46. See, e.g., Uniroyal Goodrich Tire Co. v. Martinez, 977 S.W.2d 328, 337 (Tex. 1998).
48. See id.
container closures for common household drugs like aspirin,

designers feel overly constrained. The designers are squeezed by regulators during a crisis to accept the unsatisfactory, in order to hastily serve one constituency's design parameter. So the safety-related federal standards option is less likely to be selected as an answer to product defectiveness.

EFFECTS OF REGULATORY VIOLATIONS
UNDER THE THIRD RESTATEMENT

If a product violates a federal design or warning requirement, the manufacturer faces significant legal problems. Tort law norms add to those problems. The Third Restatement accepts the trend of prior common law to recognize violation of governmental product safety requirements as a basis for liability. But it does not easily accommodate a plaintiff's desire to turn a regulatory noncompliance issue into a winning "defect" claim. In an analysis of such a claim that applies the 1998 Third Restatement, the court would examine the law or rule; determine whether it applies (taking into consideration the exclusions and qualifiers that the law or rule provides); explore the historical record of the statutory findings, statutory purpose clause, or rulemaking preamble explaining the purposes of the regulation; and compare the law's or rule's purposes of preventing risk, with the scenario of actual harm this plaintiff has suffered. This is not a simple, easy win for the plaintiff.

For example, a plaintiff sues the maker of a potentially explosive concrete sealer for "defective warnings" because its warning to "assure adequate ventilation" was too small relative to regulations on adequate placement of the warning. The Federal Hazardous Substances Act and its regulations would apply if the product were sold to consumers, or the Hazard Communication Standard under the Occupational Safety & Health Act would apply if it was only sold to industrial users. Plaintiff examines the exclusions and exceptions from the particular rule, e.g. a clause excusing warnings where the danger is obvious to any user. Then

plaintiff's counsel will dig into the history of the rules to determine if the rule was intended to deal with fire prevention, skin contact or inhalation risks. With this history, the plaintiff will determine whether the accident that harmed the plaintiff was within the intent of the regulation. A mandate for a warning to use adequate ventilation and avoid breathing fumes is not aimed at flammability risks. The rule's Federal Register preamble that explains the agency's intent might contain no reference to fire prevention at all. If so, the omission of the required ventilation warning is not within the Third Restatement provision and the plaintiff must prove each element of "defect" without help from the presumptions allowed by the Third Restatement.

If the statutory product safety law or rule addressed design issues that would have avoided the injury in this case -- not merely that some regulatory rule applied to this product design, for other purposes -- then the applicable requirement will be applied to this design, the presumption would become available, and the product would be found defective. A power cord safety standard that prevents shocks to users is not relevant to a claim of defect in a trip and fall case, if a person alleged the cord should have been colored orange so as to be more visible in darkness. Not all regulations about product safety can be deemed "applicable" and hence relevant to the plaintiff's case.

The plaintiff has the burden to meet the criteria to invoke the presumption of defectiveness, from violation of rules, as a shortcut to proof of "defect" status. The defense will do its best to dissuade the court from admitting evidence of a regulatory problem. The defense will argue inapplicability, variation between protective intent of the rule and the facts of the case, and will try parsing the vague words of the regulation. A plaintiff with an especially good relationship with regulators will obtain an advisory opinion supporting plaintiff's views, or seek a Warning Letter or Notice of Violation against the product. These are becoming commonplace tactics in the manipulation of regulatory means to aid tort liability ends.

56. The history and purpose of a rule would include the preamble to the proposed regulation, see 5 U.S.C. § 553(b)(3) (1994), and the preamble to the final regulation, see 5 U.S.C. § 553(c) (1994).
A. Limited Tort Benefits of Conformity to Regulation

Designers might expect that satisfying a law or rule is a good defense to tort liability, but it is not so. The Third Restatement provides that compliance with laws and rules is "properly considered" in making decisions about defectiveness but "does not preclude as a matter of law a finding of product defect".\(^5\) This policy, derived from extensive case law developments,\(^59\) is especially applied when the court determines the standards to be "minimum standards."\(^60\) The defense will offer argument in favor of non-defectiveness claims, asserting that the product complied with a federal or state requirement, and that this should be deemed per se compliance with the state of the art in designs, warnings, etc.

The plaintiff's experts will often contest, on factual grounds, the defense assertion that the product was in full compliance, as well as challenging the claim that compliance equates with non-defectiveness in tort cases. The case law and Third Restatement\(^61\) will be used by plaintiffs to rebut the assertion that compliance alone satisfies the tort duty of strict liability for design or warning defects. Courts disfavor the dismissal of plaintiffs' claims in these circumstances, especially where the regulation was old and was arguably obsolete in terms of protective value, as is the case for federal fabric flammability norms.\(^62\)

The Third Restatement, like the case law that overwhelmingly supports its position,\(^63\) denies defendants the power to equate tort duties of defect avoidance with regulatory duties. The tactical consequence will be that plaintiffs are likely to defeat a defendant's summary judgment motion, in which the defense claims there cannot be a defect as a matter of law

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\(^5\) Id. § 4(b).
\(^59\) See, e.g., O'Gilvie v. International Playtex Inc., 821 F.2d 1438 (10th Cir. 1987) (compliance with FDA regulation not a defense); Sours v. General Motors Corp., 717 F.2d 1511 (6th Cir. 1983) (compliance properly left for jurors as factor of reasonable design); Carlin v. Superior Court, 920 P.2d 1347 (Cal. 1996); Brooks v. Beech Aircraft Corp., 902 P.2d 54 (N.M. 1995).
\(^62\) See, e.g., Gryc v. Dayton-Hudson Corp., 297 N.W.2d 727 (Minn. 1980).
\(^63\) See, e.g., Ferebee v. Chevron Chemical Co., 736 F.2d 1529 (D.C. Cir. 1984) (the product's mandated EPA labeling for pesticide risks was not deemed to be the maximum warning that the jury could consider, so plaintiff prevailed).
since the product complied with the rule. The case then would go to the jury.

The strategic importance of this policy for the defense is that it must stay attuned to both regulatory commands and the trends of products liability. The prudent defendant who faces potential liability exposure from a rulemaking decision is more likely to be active in the separate rulemaking proceeding, challenging and litigating over terms of the final rule, so as to avoid its negative consequences in future tort cases.

B. Negligence Per Se

Prior to the Third Restatement, courts had held that noncompliance with a relevant governmental requirement was "negligence per se." This theory in negligence cases was applied to Food and Drug Administration regulatory requirements and to those of other regulatory entities. The courts differed in a key criterion: a product's statutory violation may either be considered as some evidence of negligence, or as conclusive evidence.

Sometimes courts compromised and allowed admission of a standard to determine "unreasonably dangerous" condition of the product, but required that the jury be told that the regulatory standard is not binding on the defendant's tort liability.

Many products liability claims for sophisticated products deal with negligent warnings, i.e., the inadequacy of the label to warn the user of the foreseeable problem that had actually occurred. If one count of the plaintiff's complaint states a claim in negligence, then the negligence per se claim can be used against products that omitted a needed warning, or had a deficiency in product warnings. Of course, either a statute or

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65. See Ross Lab. v. Thies, 725 P.2d 1076 (Alaska 1986); see also Orthopedic Equipment Co. v. Eutsler, 276 F.2d 455 (4th Cir. 1960).
67. See Lowe v. General Motors Corp., 624 F.2d 1373 (5th Cir. 1980).
adoption of the *Third Restatement* might merge the negligence and strict liability causes of action.

In some states, adoption of tort reform legislation has already considered and dealt with this compliance issue. The defendant enjoys an exclusion from design liability for FDA-approved drugs under some state laws, for example. The legislative "safe harbor" provisions supersede the lesser protection that would come from judicial acceptance of the *Third Restatement*’s compliance provisions. In such a state, the designer has a clearer benchmark for product design and labeling.

MEDICAL PRODUCTS UNDER THE *THIRD RESTATEMENT*

The medical products category of liability is perhaps the ideal illustration of the need for counsel to offer its client’s designers a comparison of their regulatory and their tort duties. However, flaws in the drafting of the *Third Restatement* appear in this category more than in others, especially two flaws: The *Third Restatement* errs in its line-drawing exercise when it requires medical devices to be of prescription status, and it exceeds reasonable bounds when it sweeps all prescription drugs under a very pro-defendant standard of design.

The medical device category is well known to students of federal preemption law because of the Supreme Court’s decision in *Medtronic, Inc. v. Lohr.* As the Court concluded, a medical device that has undergone long and careful scrutiny by the Food & Drug Administration cannot be subjected to a state tort law verdict that contradicts a specific label or specific design criterion “required” by the federal regulators. But a device that entered the market via a simple notification method, in which FDA’s review is brief, remains fully subject to tort verdicts and to state regulations.

A. Flaws in the Third Restatement

A significant flaw of the *Third Restatement*’s coverage of this

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72. See id.
73. See id. at 494.
category lies in its treatment of "prescription medical devices." The defense will have a difficult time qualifying for this category of special consideration. The great majority of medical devices used in non-consumer settings have never undergone the final rulemaking process by which FDA establishes "prescription" status of a device. A few have done so, and a few are declared prescription-only devices when a pre-market approval application is granted. But the choice of the device maker to promote its sale only to surgeons, dentists, etc. does not make a medical device a "prescription" device, and the drafters apparently overlooked this matter of device categorization. For example, neither a toothbrush, a heating pad nor a hospital magnetic resonance imagery (MRI) machine are categorized as restricted, and therefore are not shielded by the Third Restatement as prescription devices. If a device were subject to a final regulation declaring it "prescription only" or if FDA ordered a label to that effect, the narrow exception would apply and its design would be shielded from assault.

An arguably larger flaw is the pro-defendant bent of the category of design of prescription drugs, which goes far beyond the common law of the Restatement (Second) of Torts: Products Liability. The new rule would be: It only takes one prescriber and one patient to save a multi-billion dollar drug from design defect liability. If a reasonable prescriber, for example the defense's expert physician, can think of any patient/disease combination for which this drug would be useful, the drug escapes design defect liability. For example, giving radioactive cobalt in high doses might arrest the growth of an aggressive lung tumor in patients for whom no other remedy has succeeded. That hypothetical scenario justifies selling drug tablets with high-dose radioactive cobalt, even with the awareness of "off-label" use that plastic surgeons would use this pill to tag body fat for liposuction. The plastic surgeon's malpractice liability aside, the drug seller wins a dismissal of the plastic surgery patient's product liability case. The case is dismissed under Third Restatement norms even if it has sold hundreds of thousands more tablets than could be justified by the commercial market for end-stage lung cancer remedies. Patterns of off-label use and marketing are debated elsewhere, but the

74. See Restatement (Third) of Torts: Products Liability § 6(a) (1998).
75. See id. § 6(c).
76. See id. § 6 cmt. f.
77. See generally James O'Reilly, Products Warnings, Defects, & Hazards (2d
Third Restatement approach unfairly defeats many patients' design claims.

One of the joys of teaching is explaining the law to young students who give an unvarnished common sense response. When the prescription drug "any use" defense is explained, my law students could not believe that tort law would be so accommodating of prescription drug makers. Indeed, the combination of the Third Restatement defense and state tort reform laws protecting FDA-approved products will drive away plaintiffs who previously would have fought defective designs in pharmaceutical cases. Whether the social policy of drug development exceeds the corrective justice remedial policy is a topic that future Restatement analysts will parse for years to come.

RECALLS AND WARNINGS

Sometimes the designer errs but only belatedly discovers the error. The existence of a post-sale duty to communicate warnings to past purchasers of a product has been hotly controversial. The common law did not impose tort liability for post-sale failure to recall a product. The Third Restatement requires that adequate communications be sent to consumers where certain post-sale risks become known to the manufacturer.

The regulatory schemes for dealing with risks once the products are in consumer hands vary widely. For medical devices, the government can either issue a safety alert on its own, or demand a notification to purchasers, or induce a voluntary form of consumer notification. For motor vehicles, a recall notification in rigidly prescribed formats must be used. For aviation defects, the government can issue an Airworthiness Directive compelling licensed airlines and mechanics to check for a particular defect on a particular type of aircraft.

Since the 1960s, Congress has given several federal agencies

ed. 1999).

78. See Henderson & Twerski, supra note 18, at 692.
80. Examples of each are found at http://www.fda.gov.
82. These airworthiness directives are the vehicle by which the Federal Aviation Administration requires safety checks to be performed. Airlines cannot operate aircraft without complying with any applicable FAA directives. See 14 C.F.R. 39.3 (1999).
selective powers to force product recalls.\textsuperscript{83} One can speculate that
government regulation was filling a gap, doing what the common law did
not require at that time as a matter of tort responsibility. Now the \textit{Third
Restatement} has caught up with the regulators, by adding a tort basis for
the inducement to recall.\textsuperscript{84}

Government had used its recall authority as leverage for private
firms' "voluntary" recalls: if the manufacturer will voluntarily recall, the
regulator will not unleash its draconian set of penalties, seizures,
injunctions, etc.\textsuperscript{85}

Recalls are a frequent bargaining tool for overworked regulators.
The "defect" norm that regulators would impose on future products is
sometimes discernable from the precedents in which regulators respond to
recall situations with other products. After the \textit{Third Restatement}, more
classes of products will be subjected to a tort-driven (as contrasted to a
regulation-driven) desire to communicate to purchasers.

\textbf{A. Designers and Recalls}

In practical terms, designers do not become involved with post-
sale communications, which are a marketing task. Those familiar with
product recalls presume that the imagery and appealing messages that led
to purchase choices can be employed anew, to get users to surrender the
defective product in return for a replacement, or to use a self-help method
of securing the product against failure in use. The "reverse-sale"
phenomenon occurs during the recall of the product; a prudent
manufacturer takes the same care and makes the same effort to reach the
same consumer a second time to induce a safer response to a potential
product hazard.

The designer also does not become involved in recall decisions,
except to explain the design when government inspectors ask why and
how the defect arose. The marketing executive's decision to recall can
have vastly more impact upon a company than any tort judgment, since
recall removes sale opportunities for a consumer-desired product, and

\textsuperscript{84} See \textit{Restatement (Third) of Torts: Products Liability} § 4(a) (1998).
\textsuperscript{85} See 2 \textit{JAMES O'REILLY, FOOD & DRUG ADMINISTRATION} § 21.03 (Supp. 1998). So
the vast majority of Food & Drug Administration recalls are "voluntary," with the
coercive pressure implicitly exercised but not overt.
recalls may induce buyers to shift to an alternate brand of the same product. Longer-term damage to reputation is quite possible. In a rare case, a court granted a form of remittitur contingent on a recall, but the courts generally do not take recall decisions into consideration since these tend to be deemed subsequent remedial measures that are usually inadmissible. The post-sale discovery of a defect in a product design or manufacture may lead to a recall. The Third Restatement chose to establish an extremely narrow circumstance for the duty to recall, one that exists in very infrequent circumstances. All other recalls are considered by a reasonableness and negligence analysis, so that the manufacturer who undertakes the recall must use reasonable care.

PREEMPTION

The defendant who does not want to deal with the issues of defect, risk and negligent conduct may assert the affirmative defense that any potential state court civil tort verdict, finding a defect in this design or warning, would be "preempted" by existence of a federal standard or law. Such a federal norm, under constitutional Supremacy of the federal Constitution and laws, preempts a state finding of defectiveness that either expressly or implicitly conflicts with the federal decision.

The Third Restatement acknowledges existence of preemption norms but avoids making preemption doctrine part of the Third Restatement. This article addresses preemption briefly because preemption explicitly elevates the product design issue to a higher standard than the common law norms one would apply in an ordinary common law case applying the Third Restatement.

87. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 11(a)(1) (1998). The duty only applies where a mandatory federal order "specifically" compels the conduct of a recall and the manufacturer violates that final order. See id.
88. See id. §11(b).
A. When Preemption Applies

When should federal rules preclude state tort liability? In general, federal preemption of state tort actions is only narrowly available; and it is tied to the specific determination by a federal agency that a design or warning must have certain features.\(^91\)

Preemption may be express or implied. Express preemption means that Congress fixed a standard and state tort juries cannot go beyond it; a plaintiff's alternative design for an auto that would violate a mandatory federal vehicle safety standard is preempted.\(^92\) Implied preemption defenders assert that the federal agency has occupied the field of label choices, and a separate state tort determination that the norm was not sufficient, would cause adverse effects and conflicts with federal uniformity.\(^93\)

In the case of products that receive routine or categorical regulatory approval, a federal agency's general clearance or review of a product for the market is not sufficient to preempt or preclude state tort findings.\(^94\) The Supreme Court's view of regulatory agency approvals and their effect on constitutional supremacy of federal principles (the "preemption doctrine") has been articulated in several cases in the 1990s, principally in the fields of cigarettes and medical devices with the *Cipollone v. Liggett Group, Inc.*\(^95\) and *Medtronic* cases, respectively.

The court's analysis responding to a preemption claim will look at the statute for express preemption: did Congress squarely address this risk and impose only one criterion for "defect," which this product satisfied? Or was the statutory power set as a "minimum", as it was for automotive products?\(^96\) If the law spoke of preemption of state "regulation", the court

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\(^93\) If a federal rule or statute occupied the field of label choices, the consequence of a jury's finding of inadequate warning would be to challenge the federal command, and preemption concepts are applied to preclude such verdicts. A useful discussion of "field" and "statutory" preemption is seen in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992).

\(^94\) See, e.g., *Medtronic*, 518 U.S. at 470 (1996) (determination of FDA that medical device was substantially equivalent to existing device so that device can enter market without undergoing pre-market approval was not a "requirement" which preempted state law).

\(^95\) 505 U.S. 504 (1992).

is unlikely to expand it to read "regulation or tort verdict." Precluding state activity is disfavored in our constitutional system. If there is express preemption for some matters, there is less likelihood that a court would find any implied preemption for other matters.

B. Types of Preemption

In express preemption cases, courts see the literal text of the congressional decision to allocate labeling decisions to the federal agency. The wording of the particular statute is very important to the success of preemption claims. Where Congress expressly preempted certain activities by statute, states may not adopt different requirements, and under some statutes, common law tort verdicts would impose such a requirement.

Implied preemption is asserted when a statute occupies the field so heavily that there is no jurisdictional room remaining for the state to act. Interstate commerce power of the Congress allows federal statutes to be supreme in their regulation of product labels. A state verdict of defectiveness in tort law may infringe on a federal warning label system in a way that clashes with the uniformity desired by federal law, so the federal scheme implicitly preempts the state verdict. Usually, a court

97. See, e.g., Gryc v. Dayton-Hudson Corp., 297 N.W.2d 727 (Minn. 1980), cert. denied, 449 U.S. 921 (1980) (state law private civil remedies and punitive damages were not preempted even though state regulation was expressly preempted by statute).
98. See, e.g., San Diego Building Trades Council v. Garmon, 359 U.S. 236 (1959). "[I]n the absence of compelling congressional action we could not infer that Congress had deprived the states the power to act." Id. at 244.
100. See, e.g., Medtronic, Inc. v Lohr, 518 U.S. 470 (1996) (text of preemption statute did not support contention that all common-law claims were preempted against manufacturer of medical devices).
102. Plaintiffs and occasionally states have defeated preemption where the state requirement can be satisfied in a way that does not infringe the federal rules. See, e.g., Committee of Dental Amalgam Mfrs. & Distributors v. Stratton, 92 F.3d 807 (9th Cir. 1996) (state law requiring labeling of products containing dental amalgam found to be statute of general applicability and therefore did not conflict with federal requirements); Chemical Specialties Mfrs. Assn. v. Allenby, 958 F.2d 941 (9th Cir. 1992), cert. denied, 506 U.S. 825 (1992) (point-of-sale warning signs required under state law did not constitute additional labeling requirements so as to conflict with federal labeling laws.)
will not accept arguments for an implied preemption once there is a showing of express preemption in the same statute, with the reasoning that Congress had selected some but not all provisions to be preemptive. Sometimes the federal statute blocks state "regulations," and tort suits are not precluded.

C. Preemption and the Third Restatement

The Third Restatement takes the position that preemption is a constitutional issue beyond the scope of conventional tort theories; "the issue of defectiveness under state law is never reached" in these cases because federal power precludes state tort actions. So reasonable alternative designs that a plaintiff might have asserted are not legally relevant, because the content of the design has been particularized in a regulation or a specific product approval decision with which the states, and by extension state tort law juries, are not entitled to interfere. Each state's courts will work out the interaction of design alternatives with preemption claims.

FUTURE TRENDS

Existence of a "defect" and awareness of that defect are critical aspects of the successful plaintiff's pretrial preparations. Increasingly, the federal safety agencies appear to be the silent partners of the plaintiff's counsel. A synergy between under-funded regulator and sophisticated litigator has developed, using information access tools. The most skilled plaintiffs' groups will often utilize regulatory information about product design and user experiences when evaluating which tort cases to pursue.

Today, the best source of early warning concerning the potential defectiveness of products is on the federal agency internet websites or in the agency's Freedom of Information Act disclosures. Plaintiffs' counsel

106. Id. § 2(b).
107. See Medtronic, 518 U.S. at 470.
who are most savvy and sophisticated know this regulatory phenomenon works well for them. The leaders of the Association of Trial Lawyers of America (ATLA) have been masterful in creating parallel structures of plaintiffs' data assembly that mirror the regulators' study of product hazards.

The evolution of product safety regulation away from the traditional approach of fixed design standards, and toward new duties for manufacturers' "defect" self-recognition and self-reporting, has reached a remarkable stage. Inevitably, the more data and self-reporting of problems that government agencies demand of companies, the more robust will be the cases brought by the most sophisticated members of the plaintiff's bar. Defendants are already aware of these effects. It is a historic coincidence that the rise of regulatory agency support to the plaintiffs' tort enforcement of product safety came just at the time that Third Restatement trends add several burdens upon the tort plaintiff.109

Ultimately, we as consumers all benefit when consumer product design teams listen to lawyers, and when lawyers listen to both designers' capabilities and the safety needs of the consumer.

The agency Freedom of Information rules are summarized in 1 JAMES O'REILLY, FEDERAL INFORMATION DISCLOSURE §§ 14.16, 14.19 (Supp. 1998).

109. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §2(b) (1998). Such burdens include the formulation and proof of a reasonable alternative design for a product. Id.