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# ESSAY

## WILL A NEW RESTATEMENT HELP SETTLE TROUBLED WATERS: REFLECTIONS

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The American Law Institute (ALI) has undertaken the task of drafting the *Restatement (Third) of Torts: Products Liability*. This endeavor is in its early stages. As the Reporters charged with the responsibility of drafting the black letter rules and comments, we have understandable constraints on what can be said about the project until it is released to the public. The work of the ALI involves a complex process of consultation and critique by a broad range of constituencies, review by the ALI Council, and finally, approval by the membership. This Article should not and will not serve as a sneak preview of the ultimate work product. Nonetheless, without delving into detail it is possible to paint in broad strokes the goals that we set for ourselves when we undertook this endeavor and the reasons why we believe that a carefully crafted and sensibly stated restatement of the law of products liability can help settle the troubled waters of tort litigation.

### I. THE LANGUAGE OF THE LAW

In 1963, when William Prosser undertook the drafting of section 402A of the Second Restatement, he stood at the precipice of a new

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era in tort litigation.<sup>1</sup> *Henningsen v. Bloomfield Motors, Inc.*<sup>2</sup> had broken the privity barrier for actions against manufacturers based on implied warranty.<sup>3</sup> For the first time, the entire distributive chain was available as defendants without the necessity of resorting to negligence.<sup>4</sup> Under the new doctrine, if the defendant was the seller of a defective product and the plaintiff could prove causation, a prima facie liability case was fully established.<sup>5</sup> Prosser understood that the Uniform Commercial Code was an inept tool with which to prosecute tort-based cases.<sup>6</sup> It carried too much baggage. Its statute of limitations,<sup>7</sup> notice requirements,<sup>8</sup> and rules regarding disclaimers<sup>9</sup> were strangely out of place in classic tort litigation. A new lexicon was necessary to free the courts not only from the shackles of the Uniform Commercial Code, but also from rigid no-duty con-

1. See William L. Prosser, *The Fall of the Citadel*, 50 MINN. L. REV. 791, 791, 793-94 (1966) [hereinafter Prosser, *The Fall*] (arguing that turning point in products liability revolution occurred in 1960, setting off "the most rapid and altogether spectacular overturn of an established rule in the entire history of the law of torts").

2. 161 A.2d 69 (N.J. 1960).

3. See *Henningsen v. Bloomfield Motors, Inc.*, 161 A.2d 69, 80-81 (N.J. 1960) (acknowledging common law rule permitting action for breach of warranty only by contracting party but declaring that modern systems of product distribution render privity rule invalid as against public policy); see also Prosser, *The Fall*, *supra* note 1, at 791 (stating that *Henningsen* signaled "fall of the citadel of privity"). *Henningsen* was the final blow in an assault that began in 1916, when Judge Cardozo reasoned that manufacturers owed a duty of care to third-party consumers. See *MacPherson v. Buick Motor Co.*, 111 N.E. 1050, 1053 (N.Y. 1916) ("If the nature of a thing is such that it is reasonably certain to place life and limb in danger when negligently made, it is then a thing of danger."); William L. Prosser, *The Assault upon the Citadel*, 69 YALE L.J. 1099, 1100 (1960) [hereinafter Prosser, *The Assault*] (explaining that *MacPherson* eliminated privity rule with respect to "inherently" or "imminently" dangerous chattels).

4. See *Henningsen*, 161 A.2d at 84 (holding that manufacture and marketing of product creates implied warranty that product is suitable for intended use); see also Prosser, *The Fall*, *supra* note 1, at 793 (observing that *Henningsen* imposed liability without considering fault of manufacturer).

5. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. f (1977) ("The rule . . . applies to any manufacturer . . . [and] to any wholesale or retail dealer or distributor."); see also Frank J. Cavico, Jr., *The Strict Tort Liability of Retailers, Wholesalers, and Distributors of Defective Products*, 12 NOVA L. REV. 213, 218 (1987) (noting that majority of states hold retailer liable notwithstanding facts that retailer is not responsible for creating defect and reasonable inspection failed to disclose defect).

6. See Prosser, *The Assault*, *supra* note 3, at 1134 (observing that construing tort claims in contractual terms is circuitous and unnecessary); cf. Prosser, *The Fall*, *supra* note 1, at 801-02 (asserting that although U.C.C. might be amended to provide for direct liability, broad-based standard of § 402A obviates such action by eliminating references to contract altogether).

7. See U.C.C. § 2-725 (1987) (prescribing four-year statute of limitations for breach of sales contract actions).

8. Compare *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 897, 899-900 (Cal. 1962) (holding that although notice is useful in actions for breach of contract, notice is not required in tort claims where injured consumer was not in privity with manufacturer) with U.C.C. § 2-607(3)(a) (1987) (requiring buyer to notify seller of breach within reasonable time period).

9. Compare *Henningsen v. Bloomfield Motors, Inc.*, 161 A.2d 69, 87-95 (N.J. 1960) (discussing contract law pertaining to warranties and determining that where seller has disproportionate bargaining power over buyer, public policy dictates that implied warranty should not be subject to waiver) with U.C.C. § 2-316 (1987) (permitting seller to exclude implied warranties by terms of sales contract).

cepts that stood as a barrier to legitimate liability claims.<sup>10</sup> Creativity would be necessary to confront the new problems that would arise in a privity-free world of litigation.

Prosser adopted the term "strict liability in tort" as the anthem for the revolution.<sup>11</sup> The phrase did, indeed, serve as a liberating force. When faced with obstacles to recovery such as nonliability to bystanders,<sup>12</sup> the "intended use" doctrine,<sup>13</sup> the "patent danger" rule,<sup>14</sup> and difficult evidentiary problems,<sup>15</sup> courts concluded that these doctrines had no place in the new world of "strict tort liability."<sup>16</sup>

There can be little argument that section 402A was a bold initiative. It holds the record as the most frequently cited restatement

10. Cf. Prosser, *The Assault*, *supra* note 3, at 1100 (asserting that most important reversal of nonliability to parties not in privity was *MacPherson's* extension of duty of care to any party "who might be expected to use" product); Prosser, *The Fall*, *supra* note 1, at 802 (explaining that concept of "warranty" was last link between traditional contract liability and strict liability); see also *infra* notes 12-14 (discussing obstacles to recovery, including no liability to bystanders, intended use doctrine, and no duty to design against obvious dangers).

11. See Prosser, *The Assault*, *supra* note 3, at 1134 ("If there is to be strict liability in tort, let there be strict liability in tort, declared outright, without an illusory contract mask.").

12. See, e.g., *Mull v. Colt Co.*, 31 F.R.D. 154, 173-74 (S.D.N.Y. 1962) (refusing to grant strict liability claim of injured bystander in traffic accident); *Kuschy v. Norris*, 206 A.2d 275, 276 (Conn. Super. Ct. 1964) (denying benefit of implied warranty to third party killed in traffic accident); *Rodriguez v. Shell's City, Inc.*, 141 So. 2d 590, 591 (Fla. Dist. Ct. App.) (requiring that injured party be user of defective product rather than bystander to recover on basis of implied warranty), *cert. denied*, 141 So. 2d 279 (Fla. 1962).

13. See, e.g., *Evans v. General Motors Corp.*, 359 F.2d 822, 825 (7th Cir.) (reasoning that "X-body" design of automobile was irrelevant to liability determination because collision is not automobile's intended use), *cert. denied*, 385 U.S. 836 (1966), *overruled by Huff v. White Motor Corp.*, 565 F.2d 104, 109-10 (7th Cir. 1977).

14. See, e.g., *Messina v. Clark Equip. Co.*, 263 F.2d 291, 292 (2d Cir.) (following patent danger rule, which holds that no duty exists for manufacturers to design against obvious dangers), *cert. denied*, 359 U.S. 1013 (1959); *Farmhand, Inc. v. Brandies*, 327 So. 2d 76, 80-82 (Fla. Dist. Ct. App. 1976) (refusing to impose liability for injury resulting from design hazard that would be obvious to ordinary user); *Campo v. Scofield*, 95 N.E.2d 802, 803 (N.Y. 1950) ("[T]he manufacturer of a machine or any other article dangerous because of the way in which it functions, and patently so, owes to those who use it a duty merely to make it free from latent defects and concealed dangers."), *overruled by Micallef v. Miehle Co.*, 348 N.E.2d 571 (N.Y. 1976).

15. See, e.g., *Bruce v. Martin Marietta Corp.*, 418 F. Supp. 837, 844-46 (W.D. Okla. 1975) (requiring plaintiff to establish that product was defective when manufactured, that defect rendered product unsafe for intended use, and that defective product was proximate cause of injury), *aff'd*, 544 F.2d 442 (10th Cir. 1976); *Curtiss v. Young Men's Christian Ass'n*, 511 P.2d 991, 996-97 (Wash. 1973) (allocating to plaintiff burden of showing that product was defective at time of manufacture).

16. See *Huff v. White Motor Corp.*, 565 F.2d 104, 109-10 (7th Cir. 1977) (holding that "intended use" of vehicle includes unintended but reasonably foreseeable incidents of use, such as traffic accidents); *Elmore v. American Motors Corp.*, 451 P.2d 84, 88-89 (Cal. 1969) (granting protection to injured bystanders on rationale that bystander has even less control over instrumentality than does purchaser or user); *Prutch v. Ford Motor Co.*, 618 P.2d 657, 659-60 (Colo. 1980) (limiting plaintiff's burden of proof to showing that product was defective at time of purchase); *Micallef v. Miehle Co.*, 348 N.E.2d 571, 576-78 (N.Y. 1976) (rejecting patent danger rule as encouraging manufacturers to design outrageously hazardous products, as long as hazard is obvious).

section,<sup>17</sup> and its widespread acceptance by the courts speaks for itself. That record notwithstanding, Prosser could not and did not foresee in 1963 the broad range of problems that would arise in a fully developed system of products liability. For the most part, section 402A focused on manufacturing defects.<sup>18</sup> In the early 1960s, litigation based on defective product design was in its infancy. A host of no-duty defenses blocked such actions,<sup>19</sup> and section 402A paid little attention to the problem.<sup>20</sup> Even litigation based on failure to warn had not yet come into full bloom.<sup>21</sup> American consumer safety consciousness was relatively undeveloped and consumer expectations were not sufficiently high to fuel an aggressive litigation posture.

As litigation began to move from the idiosyncratic manufacturing defect to generic defects, section 402A was called on to resolve problems that it had not addressed.<sup>22</sup> In one sense the genius of the drafting permitted broad interpretive gloss. The term "defective condition unreasonably dangerous" was marvelously flexible.<sup>23</sup> A

17. See Letter from Marianne M. Walker, A.L.I. Restatement Case Citations Editor, to James A. Henderson and Aaron D. Twerski, Reporters, *Restatement (Third) of Torts: Products Liability* (Oct. 11, 1991) (on file with authors) ("In my nine years with American Law Institute I have found Section 402A to be the most frequently cited section of any Restatement."). As of March 15, 1993, § 402A had been cited in 3156 cases. Search of LEXIS, States library, Mega file (Mar. 15, 1993).

18. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. g (1977) (explaining that rule of strict liability applies "where the product is, at the time it leaves the seller's hands, in a [defective] condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him [or her]").

19. See *supra* notes 12-14 and accompanying text (discussing defenses of nonliability to bystanders, intended use doctrine, and patent danger rule).

20. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. f (1977) ("If the injury results from abnormal handling . . . the seller is not liable."); *id.* cmt. g (noting that "the burden of proof that the product was in a defective condition at the time it left the hands of a particular seller is on the injured plaintiff"); *id.* cmt. i (explaining that product is defective only if "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community").

21. See *id.* cmt. j (requiring reasonable warning on products that may be unreasonably hazardous if misused). In general, even early in the product liability era a manufacturer or supplier had a duty to warn users or consumers that a defect may have existed and to explain procedures or precautions necessary to avoid harm. *Sears, Roebuck & Co. v. American President Lines, Ltd.*, 345 F. Supp. 395, 400 (N.D. Cal. 1971); see also *Gonzalez v. Virginia-Carolina Chem. Co.*, 239 F. Supp. 567, 571 (E.D.S.C. 1965) (reasoning that manufacturer owes duty to test for hazardous propensities and to warn of such danger).

22. See James A. Henderson & Aaron D. Twerski, *A Proposed Revision of Section 402A of the Restatement (Second) of Torts*, 77 CORNELL L. REV. 1512, 1527 n.9 (1992) (listing 14 types of issues not contemplated by § 402A that courts had to confront in post-402A era).

23. See *Campbell v. General Motors Corp.*, 649 P.2d 224, 233 (Cal. 1982) (permitting finding of defective condition based on plaintiff's use of product, circumstances of injury, and product's objective safety features); *Azzarello v. Black Bros. Co.*, 391 A.2d 1020, 1025 (Pa. 1978) (reasoning that Restatement term "unreasonably dangerous" has "no independent significance and merely represents a label to be used when it is determined that the risk of loss should be placed upon the [negligent] supplier"). These decisions may be blamed in part on the failure of the Restatement to adopt its definition of "defect" in a way that reflects an

court could utilize whichever test for defect it saw fit and find authority for its position in the black letter law.<sup>24</sup> Comments g, h, i, and j to section 402A were wonderfully vague. Like the Oracle at Delphi whose prophecies could not be found wanting, section 402A meant all things to all persons. If in the context of generic defect "strict liability" was something less than strict, so be it. As long as some aspects of the generic defect litigation might not be fully congruent with classic negligence doctrine, there was no harm in adopting the "strict liability" term to describe the new phenomenon.<sup>25</sup>

We believe that the cost to the American judicial system of the babble of language resulting from attempts to establish a single definition that would cover all forms of defect has been unacceptably high. It has spawned needless confusion and fear.<sup>26</sup> The actual holdings of the courts have by and large been eminently sensible. We hope that it will be possible to capture the essence of those decisions in language that will fairly portray a broad-based consensus. The reality is that doctrine has taken a back seat to a pragmatic and functional approach to the issue of defect. A new restatement should reflect that pragmatism. It will go a long way to settling troubled waters. An accurate portrayal of the subtlety and common sense of the common law can assist in soothing and mitigating the "crisis-like" atmosphere that has become so pervasive.

## II. DEFINING THE ISSUES

A new restatement will undoubtedly take positions on some of the controversial issues. But an equally important role will be its defini-

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evolving consensus among state courts. Henderson & Twerski, *supra* note 22, at 1528-29 & n.15.

24. For example, states that advocate risk-utility balancing as the test for defect, *see, e.g.*, Phipps v. General Motors Corp., 363 A.2d 955, 961 (Md. 1976) (stating that design defect in some circumstances depends on balancing utility of design and other factors against magnitude of risk); Morningstar v. Black & Decker Mfg. Co., 253 S.E.2d 666, 682 (W. Va. 1979) (stating that risk-utility analysis in tort product liability sets general contours of relevant expert testimony concerning defectiveness of product), and those that advocate the consumer expectation test, *see, e.g.*, Rahmig v. Mosley Mach. Co., 412 N.W.2d 56, 70 (Neb. 1987) (noting that law of product liability is evolving toward acceptance of risk-utility test), rely on § 402A as the font of authority.

25. *See, e.g.*, Anderson v. Owens-Corning Fiberglas Corp., 810 P.2d 549, 558 (Cal. 1991) (noting that strict liability doctrine has incorporated some well-settled rules from law of negligence and survived judicial challenges asserting such incorporation violates fundamental principles of doctrine); Owens-Illinois, Inc., v. Zenobia, 601 A.2d 633, 640 n.7 (Md. 1992) (stating that despite overlap of negligence principles in strict liability failure to warn case, strict liability differs because contributory negligence is not defense to strict liability claim).

26. *See* Charles E. Cantu, *Reflections on Section 402A of the Restatement (Second) of Torts: A Mirror Crack'd*, 25 GONZ. L. REV. 205, 218 (1989-1990) (suggesting that diversity of approaches taken by courts in product liability litigation results from confusion over possible definitions of "defect" under § 402A).

tion of the problems that have plagued difficult areas of the law.<sup>27</sup> A

27. For example, we have identified a number of issues for which § 402A did not provide an adequate solution. It is our hope to address many of those issues in the Restatement (Third). We believe that the following issues deserve treatment:

(1) Liability for lessors, commercial builders, franchisors, etc. *See, e.g.*, *Harris v. Aluminum Co. of Am.*, 550 F. Supp. 1024, 1026-28 (W.D. Va. 1982) (extending implied warranty principle to franchisor that promoted, but did not manufacture or sell product); *Cintrone v. Hertz Truck Leasing & Rental Serv.*, 212 A.2d 769, 775 (N.J. 1965) (finding liability for breach of implied warranty where product was leased, not sold); *Schipper v. Levitt & Sons, Inc.*, 207 A.2d 314, 323 (N.J. 1965) (imposing liability on builder for injury resulting from defect in construction of house).

(2) The problems of damage assessment arising from enhanced injury cases. *See, e.g.*, *Huddell v. Levin*, 537 F.2d 726, 737-38 (3d Cir. 1976) (placing burden on plaintiff to establish extent of enhancement of injury in crashworthiness case). *Contra* *Lahocki v. Contee Sand & Gravel Co., Inc.*, 398 A.2d 490, 501 (Md. Ct. Spec. App. 1979) (noting that plaintiff need only prove enhancement of injury to shift apportionment of damages burden to defendant).

(3) Liability in cases involving sale of used products. *See, e.g.*, *Crandell v. Harkin & Jones Appliance Co.*, 334 N.W.2d 31, 34 (S.D. 1983) (holding strictly liable used products merchant who rebuilt or reconditioned goods).

(4) The difficulty in drawing a line between sales and services. *See, e.g.*, *Murphy v. E.R. Squibb & Sons, Inc.*, 710 P.2d 247, 249-52 (Cal. 1985) (holding pharmacist who merely filled prescription for apparently safe drug immune from strict liability); *Magrine v. Krasnica*, 227 A.2d 539, 547 (N.J. Super. Ct. Law Div. 1967) (refusing to apply strict liability to dentist where patient was injured by defective hypodermic needle), *aff'd sub nom. Magrine v. Spector*, 241 A.2d 637 (N.J. Super. Ct. App. Div. 1968), *aff'd*, 250 A.2d 129 (N.J. 1969).

(5) The difficulties of working out the relationship between comparative fault and strict tort liability. *See, e.g.*, *Murray v. Fairbanks Morse, Beloit Power Sys., Inc.*, 610 F.2d 149, 154-63 (3d Cir. 1979) (discussing effect of plaintiff's fault on recovery in strict tort liability and concluding that, in jurisdiction governed by appropriate comparative negligence statute, recovery in strict liability should be reduced "in proportion to the plaintiff's causal contribution to his [or her] own injury").

(6) The problems related to recognizing a cause of action for mental distress arising from products-related injuries. *See, e.g.*, *Kennedy v. McKesson Co.*, 448 N.E.2d 1332, 1334-36 (N.Y. 1983) (reasoning that where dentist's mental condition prevented him from working after defendant's product caused death of patient, plaintiff could recover for loss of business but not for emotional distress); *Payton v. Abbott Labs*, 437 N.E.2d 171, 174-81 (Mass. 1982) (reasoning that to recover from DES manufacturer for negligent infliction of emotional distress, plaintiff must show causation in form of physical injury rather than mere statistical probability of future injury).

(7) The difficulties in deciding which forms of product-related economic loss were to be covered by products liability law and which were to be governed by the Uniform Commercial Code. *See, e.g.*, *East River S.S. Corp. v. Transamerica Delaval Inc.*, 476 U.S. 858, 866-76 (1986) (holding that where only loss claimed is economic, plaintiff's ability to recover benefit of bargain through contract claim overrides any benefit that would accrue from action in strict liability).

(8) Whether there is a duty to warn of scientifically unknowable or unforeseeable risks. *See, e.g.*, *Anderson v. Owens-Corning Fiberglas Corp.*, 810 P.2d 549, 552-59 (Cal. 1991) (discussing state-of-the-art defense and concluding that manufacturer's actual or constructive knowledge of defect is prerequisite to strict liability for failure to warn); *Beshada v. Johns-Manville Prods. Corp.*, 447 A.2d 539, 546-49 (N.J. 1982) (reasoning that state-of-the-art defense is grounded in negligence theory, but where action is in strict liability and manufacturer's culpability is not in issue, state of the art is irrelevant).

(9) The complex interaction between design defect and failure to warn. *See, e.g.*, *Uloth v. City Tank Corp.*, 384 N.E.2d 1188, 1192 (Mass. 1978) (refusing to permit manufacturer to discharge responsibility for designing safe product by merely providing warning about unsafe product's hazardous nature).

(10) Whether strict liability will attach even if manufacturer met state of the art standards extant at the time of manufacture. *See, e.g.*, *Boatland of Houston, Inc. v. Bailey*, 609 S.W.2d 743, 746 (Tex. 1980) (stating that defective design must be judged relative to state of the art

restatement is, however, not primary authority. Courts are free to disagree with restatement positions and do so with considerable frequency. Whatever positions it takes, however, a restatement can, by its formulation of black letter law and explanatory comments, provide the courts with crisp and unclouded formulations of legal problems.

One area where such problem clarification is sorely needed will serve to demonstrate how a new restatement can provide the courts with a clear policy choice. One of the most oft-cited comments to section 402A deals with "unavoidably unsafe" products.<sup>28</sup> Comment k sets forth the following guidelines for dealing with this special genre of products:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new and experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he [or she] has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.<sup>29</sup>

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at time of manufacture, but that plaintiff may rebut defense by showing availability of economically feasible and safer alternative design).

28. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1977) (addressing unavoidably unsafe products); Henderson & Twerski, *supra* note 22, at 1536 n.38 (observing that "[a]lmost all jurisdictions pay some allegiance to comment k").

29. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1977).



This most important comment<sup>30</sup> has befuddled courts and scholars alike. Does it address the issues of drug warnings or drug design? If it speaks to the issue of defective drug design, how do drug cases differ from nondrug design claims? To answer that question, one searches in vain in the restatement comments for a clear liability standard for nondrug design cases. Comments g and i do appear to adopt a consumer expectation test for liability, but it is very unclear as to whether that definition of defect was intended to cover design defect claims.<sup>31</sup> How then, can comment k create an exception to strict liability for drug design when the restatement has not explained the ordinary standard for design liability?

It is again unclear whether comment k speaks to warnings. The discussion in the comment that exempts new and experimental drugs from strict liability seems to be saying that there is no liability for failure to warn against *unknown and unforeseeable* risks. Does that mean that in nondrug cases strict liability imposes a duty to warn of unknown and unforeseeable risks? Comment j, which discusses warnings, seems to belie that thesis.<sup>32</sup> Comment k appears to be internally inconsistent because it concludes that an exemption from strict liability applies only when *known* risks are warned against.<sup>33</sup> Whether liability attaches for unknown and unforeseeable risks is unclear.

It is high time that this confusion come to an end. First, a new restatement must address the question of whether liability should attach for failure to warn about unforeseeable risks both for drug- and nondrug-related products. Second, a new restatement must directly confront the standard of liability for nondrug design cases. Third, having set the parameters for liability in the nondrug arena, a new restatement must tackle the difficult question of whether drug design review is an appropriate subject for the courts.

The overwhelming majority of cases brought against prescription drug manufacturers have been brought on failure-to-warn

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30. For an extensive discussion of the authorities who have written about this comment, see Henderson & Twerski, *supra* note 22, at 1536-45.

31. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. g (1977) (stating that defect exists where product is "in a condition not contemplated by the ultimate consumer"); *id.* cmt. i ("The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer.").

32. See *id.* cmt. j (asserting duty to warn if seller "has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge" of danger inherent in product).

33. See Joseph A. Page, *Generic Product Risks: The Case Against Comment k and for Strict Tort Liability*, 58 N.Y.U. L. REV. 853, 868-69 (1983) (highlighting internal inconsistencies in comment k, such as known-risk exception apparently covered by comment i, and experimental-drugs-with-unknown-risk exception that would be irrelevant because participants in drug trials give informed consent).

grounds.<sup>34</sup> Design defect claims against prescription drug manufacturers have been rare.<sup>35</sup> If a drug brings a particular therapeutic benefit to some patients that cannot be provided by another drug, it should not be declared defective in design.<sup>36</sup> The drug manufacturer clearly has a duty to warn and alert physicians to the dangerous propensities of the drug so that it not be used when a safer alternative is available.<sup>37</sup> But to declare the design defective would unfairly deny some patients the benefits of a drug that is an effective part of their treatment.<sup>38</sup> No sensible advocate would promote such a policy. Drug design cases have surfaced, however, asserting the claim that the challenged design provides no therapeutic advantage over existing drugs and subjects users to needless additional risk.<sup>39</sup>

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34. *See, e.g.*, *Gaston v. Hunter*, 588 P.2d 326, 340 (Ariz. Ct. App. 1978) (holding that in case of experimental drug, manufacturer must advise that product is experimental and must warn of all known or probable risks); *Brown v. Superior Court*, 751 P.2d 470, 480 (Cal. 1988) (interpreting comment j as conditioning manufacturer's liability on actual or constructive knowledge of hazard at time of sale); *Woodill v. Parke Davis & Co.*, 374 N.E.2d 683, 686 (Ill. App. Ct. 1978) (concluding that manufacturer or seller has duty to warn only "when it knows or should have known" of hazard, and that interpreting comment j otherwise would be "incongruous"), *aff'd*, 402 N.E.2d 194 (Ill. 1980); *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541, 548 (Ind. Ct. App. 1979) (holding that duty to warn under comment k does not attach unless actual or constructive knowledge can be imputed to manufacturer).

35. *See Henderson & Twerski, supra* note 22, at 1542-43 (asserting that courts have based liability on failure to warn "[a]lmost without exception"). *But see, e.g.*, *Heath v. Ortho Pharmaceutical Corp.*, 722 P.2d 410, 413 (Colo. 1986) (permitting claim of design defect in pharmaceutical case); *Lindquist v. Ayerst Lab., Inc.*, 607 P.2d 1339, 1349 (Kan. 1980) (allowing recovery for design defect where manufacturer failed to properly test drug).

36. *See, e.g.*, *Hill v. Searle Lab.*, 884 F.2d 1064, 1068-69 (8th Cir. 1989) (stating that decision to apply comment k exception must be case-by-case determination based on societal need for product and availability of safer alternatives); *Feldman v. Lederle Lab.*, 479 A.2d 374, 383 (N.J. 1984) (rejecting blanket comment k exception for prescription drugs in favor of inquiry into feasibility of safe alternatives); *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 781 (R.I. 1988) (basing determination of comment k exception on risk/utility analysis, including availability of alternatives). *But see* *McDaniel v. McNeil Lab., Inc.*, 241 N.W.2d 822, 828 (Neb. 1976) (asserting that absent showing of manufacturer's bad faith in obtaining approval, FDA approval of drug constitutes comment k immunity); *Grundberg v. Upjohn Co.*, 813 P.2d 89, 96 (Utah 1991) (reasoning that FDA approval process establishes elements of comment k immunity).

37. The general rule for prescription drugs requires that a warning be given only to the physician, as a learned intermediary. *See, e.g.*, *Anderson v. McNeilab, Inc.*, 831 F.2d 92, 93 (5th Cir. 1987) (reasoning that manufacturer of prescription drug discharges duty to warn by informing doctors of potential harmful side effects of drug); *Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89, 95 (D. Md. 1989) (applying learned intermediary rule to instance involving manufacturer's duty to warn consumer); *Polley v. Ciba-Geigy Corp.*, 658 F. Supp. 420, 421-22 (D. Alaska 1987) (reasoning that learned intermediary rule applies where physician can best judge patients' likely reaction to potentially harmful drug).

38. *Cf.* RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1977) (observing that although certain products may possess dangerous propensities, they are otherwise so beneficial as to be judged dangerous but not defective, as matter of policy).

39. *See, e.g.*, *Toner v. Lederle Lab.*, 732 P.2d 297, 310-11 (Idaho 1987) (suggesting that comment k analysis is similar to negligence analysis in that both look to potential benefit, realized benefit, and availability of alternatives); *Feldman v. Lederle Lab.*, 479 A.2d 374, 382-83 (N.J. 1984) (refusing to grant blanket immunity under comment k where safer alternative products are available).

These cases demand a decision as to whether design defect claims should be allowed.

Those who advocate design review for drugs argue that such claims are valid and deserve to be litigated under the rubric of classic design defect principles.<sup>40</sup> Those opposed believe that design review of drugs involves the courts in second-guessing the Food and Drug Administration.<sup>41</sup> Opponents argue further that when a drug presents a gratuitous risk, a manufacturer can be held liable for failing to warn about the needless risk that the drug presents.<sup>42</sup> A new restatement should confront this issue and set clear guidelines. We are hopeful that courts will adopt the position ultimately taken by the ALI. Whether they agree or disagree, however, the issue will have been clarified and the courts will have a clear policy choice to make.

### III. THE COST OF CLARIFICATION

Clarifying the law has obvious benefits. To the extent that a restatement rings true and is adopted by the courts, not only does the law become more comprehensible, but precious time that is now spent litigating and relitigating issues around which there is broad consensus is saved. In the absence of a clearly stated consensus rule, parties cannot judge the merits of their cases reliably and tend to engage in strategic behavior, maximizing perceived weaknesses in the opposition's position to resolve cases by settlement on terms most favorable to their own positions. The existence of a consensus is not always clearly discernible. Linguistic differences between different judicial opinions may give the impression of dissension when in reality such dissension is only facially significant.

Although all may agree in the abstract that clarity is a desidera-

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40. See, e.g., Frank M. McClellan, *Strict Liability for Drug Induced Injuries: An Excursion Through the Maze of Products Liability, Negligence and Absolute Liability*, 25 WAYNE L. REV. 1, 32, 34 (1978) (arguing that permitting design defect claims would protect consumers' interests and that in practice, defects in design, manufacture, and warning tend to merge).

41. See, e.g., John P. Reilly, *The Erosion of Comment k*, 14 U. DAYTON L. REV. 255, 256 (1989) (arguing that FDA approval establishes rebuttable presumption that product's benefits outweigh its risks); Victor E. Schwartz, *Unavoidably Unsafe Products: The Meaning and Policy Behind Comment k*, 42 WASH. & LEE L. REV. 1139, 1142-43 (1985) (contending that good-faith compliance with FDA approval procedures ensures that manufacturer will exercise care necessary to establish product's safety for prescribed use); Sidway H. Willig, *The Comment k Character: A Conceptual Barrier to Strict Liability*, 29 MERCER L. REV. 545, 562 (1978) (asserting that although noncompliance with regulatory measures may create separate cause of action for fraud, compliance with drug approval process creates presumption of comment k immunity).

42. See Schwartz, *supra* note 41, at 1142-43 (asserting that manufacturer who fails to inform FDA of all potential risks attendant to use of drug should face compound liability); Willig, *supra* note 41, at 562 (suggesting that failure to disclose fully all risks in regulatory proceeding should permit additional action for fraudulent misrepresentation).

tum, there may be considerable sympathy and nostalgia for the studied ambiguity of section 402A.<sup>43</sup> The confusion may be viewed as a positive good allowing for a more leisurely development of the law, even if it is relatively clear what the ultimate rule is destined to be. We believe that most of the law that has developed around products liability makes good common sense. Rules and doctrines that are sensible should not be frightening or daunting, and sharp controversy need not send shock waves to those on either side of a conflict. In the long run, confusion is far more disturbing to those who must conform their behavior to a set of norms than is a standard of conduct that sets firm but understandable rules. The dark of the night sends shivers down the spines of those who must find their way without a compass. Admittedly, the heat of the sun may cause some discomfort. But there is a vast difference between fear and discomfort.

If the *Restatement (Third) of Torts: Products Liability* can remove the fear of the night and replace it with sunlight, it will contribute to a greater consensus and to a world of more rational debate. Both objectives will serve to mute the inflammatory rhetoric that has characterized discussions over the fairness of tort litigation.

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43. See *supra* notes 22-25 and accompanying text (discussing inherent flexibility in interpretation of § 402A).

