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The Unworkability of Court-Made Enterprise Liability: A Reply to Geistfeld

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FROM A REPORTER'S PERSPECTIVE: A PROPOSED AGENDA

Professor Aaron Twerski *:

Judge Pratt, ladies and gentlemen, before getting into a discussion of the substantive changes that Professor Henderson and I are proposing for the new Restatement, I would like to discuss for a few moments the process which we will be following in developing the Restatement of Torts on Products Liability.¹ We have been working almost exclusively since last September, when we first met with our advisory group, on a preliminary draft of the new Restatement.² Restatement (Second) 402A has only one section.³ It has seventeen comments⁴ and given the time when it

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1. Professors Henderson and Twerski are the co-reporters of the Products Liability section of the Restatement (Third) of Torts. On June 11, 1992, the American Law Institute (A.L.I.) announced the names of their advisors. *See Institute Announces Advisory Committee for Restatement Product Liability Revision*, PROD. LIAB. DAILY (BNA) (June 11, 1992), available in WESTLAW, BNA file. For a list of the practitioners, professors and judges named to the committee see *infra* notes 6-8.

2. On March 18, 1992, the A.L.I. announced its plan to overhaul § 402A of the Restatement (Second) of Torts. The A.L.I. chose to begin its revision of § 402A because it "has proven so influential in the development of modern product liability law" and the current formulation has become "increasingly irrelevant and unresponsive to contemporary needs." *See ALI to Begin Work on Restatement (Third); Professors Propose Revisions to Section 402A*, PROD. LIAB. DAILY (BNA) (Mar. 18, 1992), available in WESTLAW, BNA file. In May, 1992, authorities in the product liability field met to discuss the scope of the new § 402A. It was decided that it "should focus on the 'core areas' unique to product liability" and that five years would be devoted to the revision. *Law Institute Attendees Plan 5-Year Project; Members Agree on Core of Proposed Treatise*, PROD. LIAB. DAILY (BNA) (May 12, 1992), available in WESTLAW, BNA file.

3. RESTATEMENT (SECOND) OF TORTS § 402A (1965) provides in pertinent part:

was drafted in the early 1960's, I think it was all that could be done.

We are now thirty years into the products liability revolution. It is simply not possible to say all that needs to be said about the products liability field in one section. Perhaps we may have added to the confusion by writing our *Cornell Law Review* article, entitled "*A Proposed Revision of Section 402A of the Restatement (Second) of Torts*," in which we did follow the one section format.⁵ You have our word, we will not follow the one section format here.

Hopefully, sometime within the next four to six weeks, we will send out to the advisors, a group of twenty law professors,⁶ practitioners,⁷ and judges,⁸ who are members of the advisory

Special Liability of Seller of Product for Physical Harm to User or Consumer

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer or to his property, if
 - (a) the seller is engaged in the business of selling such a product, and
 - (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it was sold.
- (2) The rule stated in Subsection (1) applies although
 - (a) the seller has exercised all possible care in the preparation and sale of his product, and
 - (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Id.

4. *See id.* cmts. a-q.

5. *See* James A. Henderson, Jr. & Aaron D. Twerski, *A Proposed Revision of Section 402A of the Restatement (Second) of Torts*, 77 *CORNELL L. REV.* 1512 (1992).

6. Kenneth S. Abraham, University of Virginia School of Law; Paul Weiler, Harvard Law School; Oscar S. Gray, University of Maryland School of Law; Robert L. Rabin, Stanford Law School; Gary T. Schwartz, University of California at Los Angeles School of Law; Marshall S. Shapo, Northwestern University School of Law; Roger C. Cramton, Cornell Law School; Michael D. Green, University of Iowa Law School.

7. Sheila L. Birnbaum, Skadden, Arps, Slate, Meagher & Flom (New York); Robert L. Habush, Habush, Habush, Habush & Davis (Milwaukee); Paul D. Rheingold, Rheingold & McGowan, P.C. (New York); Victor E.

group of the American Law Institute (A.L.I.),⁹ the first seven sections on the new proposed Restatement plus comments and reporters notes. It is likely that we will write another fourteen sections during the next two to three years. The first seven sections are the heart of the project since they constitute the *prima facie* case and the affirmative defenses.

When our preliminary draft is completed, it will be reviewed by the advisors and other A.L.I. members who have joined a Members Consultative Group.¹⁰ We will meet with both groups during the second week of June and will take their comments into account and then prepare a draft which will go to the American Law Institute Council.¹¹ As I understand it, the members of our advisory group do not vote on our draft.¹² Similarly, participants

Schwartz, Crowell & Moring (Washington, D.C.); Michael Traynor, Sierra Club Legal Defense Fund (San Francisco); Bill Wagner, Wagner, Cunningham, Baughan & McLaughlin (Tampa); Conrad K. Harper, Simpson, Thatcher & Bartlett (New York); John W. Martin Jr., Vice President and General Counsel, Ford Motor Co. (Detroit).

8. Hon. Dineen King (U.S. Court of Appeals for the Fifth Circuit); Hon. Hans A. Linde (Oregon Supreme Court); Hon. Vincent L. McKusick (Supreme Judicial Court of Maine); Hon. Robert E. Keeton (U.S. District Court for the District of Massachusetts).

9. The A.L.I. was founded on February 23, 1923 on the recommendation of the Committee on the Establishment of a Permanent Organization for the Improvement of the Law. *RESTATEMENT OF THE LAW OF TORTS* at vii-viii (1934). The objective of the A.L.I. is to "present an orderly statement of the general common law of the United States, including . . . the law developed solely by judicial decision . . . [and] the law that has grown from the application by the courts of statutes that have been generally enacted and have been enforced for many years." *Id.* at viii-ix. This objective is reached to the extent that "the legal profession accepts the Restatement as *prima facie* a correct statement of the general law of the United States." *Id.* at ix.

10. This group is comprised of members of the A.L.I. who have expressed an interest in the revision of § 402A. For a list of members as of April 1, 1993 see *AMERICAN LAW INSTITUTE, 1993 ANN. REP.* at 108-10 (1993) [hereinafter *A.L.I. REP.*].

11. The Council is the executive body of the A.L.I. whose function is to review preliminary drafts and amend these drafts when necessary. See *RESTATEMENT OF THE LAW OF TORTS* at viii (1934).

12. The Director of the A.L.I. may appoint advisors to review the preliminary drafts of a reporter before they are submitted to the Council. *A.L.I. REP.* at 53.

in the Members Consultative Group do not have a vote. The American Law Institute Council, however, will vote on the acceptability of the Council draft, and if it finds favor in their eyes, they will then pass it on to the membership or send it back to us for revisions. At that point, after the American Law Institute Council has reached the conclusion that this draft is worthwhile, it becomes a tentative draft, to be discussed and voted upon at the A.L.I. meetings in May of 1994.¹³ Whether or not we will actually be on the program in May of 1994 is anyone's guess. I do not know the answer to that question. It may be that the American Law Institute Council might take the position that it ought to be reviewed as a total package and they will want all of the other sections before them before any vote is taken. I do not know what the politics of that will be. I can only tell you where we are right now. We are preparing to send out a draft to our advisors around the middle of April of 1993. My understanding is that our preliminary draft is not supposed to become public; it is for the eyes of the advisors and the Members Consultative Group. My own prediction is that Xerox machines will be working overtime, that it will be the world's worst kept secret. That is probably all for the best.

Bar liaison groups from the American Bar Association, trial groups such as the Association of Trial Lawyers of America

13. See A.L.I. REP. at 46. The general procedure and authorization for the publication of restatements is as follows:

1. Material intended for publication shall first be submitted to the Council, and by it to the members.
2. The Council may submit the material to the membership with or without its approval, amendment, or recommendations.
3. The membership may approve, reject, or amend any matter submitted by the Council and may authorize the Council to make such changes as the Council deems proper.
4. The Council shall make or authorize such final editorial or other revisions as it deems appropriate and shall determine the form, time, and manner of publication.
5. No publication using the name of the Institute shall be made without the authorization of the Council.

Id. at 54.

(ATLA),¹⁴ and defense oriented organizations such as the Product Liability Advisory Council (PLAC),¹⁵ will also comment on our drafts. The drafts are not written in stone. We are looking for intelligent insights and hope to be responsive to good criticism.¹⁶

Now to the substance. Since we are still polishing the drafts of the black letter and the comments, I think it would be inappropriate to set out in any detail the language of the proposals that we are working with. I think our advisors and the Members Consultative Group deserve the first crack at it. Nonetheless, I think there are some very broad strokes that we can set forth that will be of considerable interest.

Let us go back for a minute in history. When Dean Prosser wrote section 402A back in the early 1960's, products liability law was at its infancy.¹⁷ When Prosser had written his tentative draft of section 402A,¹⁸ *Henningsen v. Bloomfield Motors Inc.*¹⁹ had just been decided and *Greenman v. Yuba Power Products Co., Inc.*²⁰ had not yet been decided. The assault on privity was the issue of the day.²¹ The basic thrust of products liability law,

14. Established in 1946, and consisting of 65,000 members, ATLA is committed to fostering a safer, more just society by protecting victims' rights in various areas, including product safety.

15. PLAC is a non-profit, industry group, consisting of defense attorneys and manufacturers that submit amicus briefs on product liability cases.

16. For criticism and suggestions regarding the first preliminary draft of § 402A see Hildy Bowbeer, *The ALI's Restatement on Products Liability: Some Early Concerns and Suggested Revisions*, PROD. LIAB. DAILY (BNA) (Aug. 2, 1993), available in WESTLAW, BNA file.

17. See William L. Prosser, *The Assault Upon the Citadel (Strict Liability to the Consumer)*, 69 YALE L.J. 1099 (1960); William L. Prosser, *The Fall of the Citadel (Strict Liability to the Consumer)*, 50 MINN. L. REV. 791, 793-94 (1966) (describing the products liability field during the 1960's as "the most rapid and altogether spectacular overturn of an established rule in the entire history of the law of torts").

18. See, e.g., RESTATEMENT (SECOND) OF TORTS § 402A (Tentative Draft No. 7, 1962) (including a section imposing strict liability for products intended for intimate bodily use); RESTATEMENT (SECOND) OF TORTS § 402A (Tentative Draft No. 6, 1961) (advocating the adoption of § 402A).

19. 161 A.2d 69 (N.J. 1960).

20. 377 P.2d 897 (Cal. 1963).

21. See *Spence v. Three Rivers Builders & Masonry Supply, Inc.*, 90 N.W.2d 873, 880 (Mich. 1958) ("[M]anufacturer is not excused . . . [from

at the time, dealt with manufacturing defects.²² There were strong feelings about the inappropriateness of having a negligence regime to decide the issue of liability for such defects. The Restatement thus sought to rid products liability law of two doctrines: (1) privity and (2) reasonableness of quality control as a defense to a case based on a manufacturing defect.²³ Design defect²⁴ and failure-to-warn²⁵ litigation were in their infancy and you will look in vain to the language of section 402A to find

liability] merely because there happened to be a lack of any privity"); *Henningsen*, 161 A.2d 69 (N.J. 1960) (holding that privity is not required because it violates public policy).

22. A manufacturing defect is defined as "an abnormality or a condition that was unintended, and makes the product more dangerous than it would have been as intended." W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 99, at 695 (5th ed. 1984); *see, e.g.*, *Chandler v. Anchor Serum Co.*, 426 P.2d 82 (Kan. 1967) (recovery of loss to herd of livestock due to defective animal serum); *Coca-Cola Bottling Works v. Lyons*, 111 So. 305 (Miss. 1927) (holding manufacturer liable for injuries resulting from broken glass in a bottle of Coca-Cola); *MacPherson v. Buick Motors*, 217 N.Y. 382, 111 N.E. 1050 (1916) (holding manufacturer liable for injuries caused by defective wheel).

23. *See* RESTATEMENT (SECOND) OF TORTS § 402A(2) which provides that strict liability may be imposed on a seller although: "(a) the seller has exercised all possible care in the preparation and sale of his product, and (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller." *Id.*

24. A design defect occurs when the product is manufactured in conformity with the intended design but the design itself poses unreasonable dangers to consumers. James A. Henderson, Jr., *Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication*, 73 COLUM. L. REV. 1531, 1543 (1973); *see* W. Page Keeton, *Manufacturer's Liability: The Meaning of "Defect" in the Manufacture and Design of Products*, 20 SYRACUSE L. REV. 559 (1969).

25. *See* KEETON ET AL., *supra* note 22, § 96, at 685 which states:

A manufacturer or other seller is subject to liability for failing to warn or adequately to warn about a risk or hazard inherent in the way a product is designed that is related to the intended uses as well as the reasonably foreseeable uses that may be made of the products it sells.

Id.; *see, e.g.*, *Wright v. Carter Prods., Inc.*, 244 F.2d 53 (2d Cir. 1957) (action against manufacturer for failure to warn of dangerous side effects of deodorant); *Boyl v. California Chem. Co.*, 221 F. Supp. 669 (D. Or. 1963) (holding manufacturer liable for failing to warn of the long-lasting contamination potential of sodium arsenate used in garden weed killer).

anything like a clear definition dealing with these issues. As the law began to develop, strict products liability became a kind of anthem. It became a kind of code word for change -- much of it very healthy. Courts did not want themselves restrained by limited duty doctrines such as the "open and obvious" danger rule,²⁶ or the "bystander" rule²⁷ and similar kinds of artificial limitations on recovery. Strict liability became a sort of clarion call for change. When courts were faced with traditional arguments seeking to bar recovery, they responded by saying, "Those arguments were sufficient to bar an action based on negligence but not one based on strict liability."

We are now thirty years into the revolution and the idea that we can have one single definition for manufacturing defect, design defect and failure-to-warn seems clearly wrong to us. The fact of the matter is that the courts, treatise writers and scholars all organize the subject around these three categories. In the *Cornell* article and in our preliminary draft, we define defect based on these functional categories.²⁸

26. Also known as the patent danger rule or the latent-patent rule, this doctrine states that a manufacturer of a product is under no duty to protect against open, obvious or patent dangers. Under this doctrine, liability may not be imposed upon a manufacturer for injury resulting from a defective product unless such injury was caused by a latent or hidden danger or defect. See Theresa L. Kruk, Annotation, *Products Liability: Modern Status of Rule that there is No Liability for Patent or Obvious Dangers*, 35 A.L.R. 861, 863 n.2 (4th ed. 1985); see, e.g., *Ford v. Harnischfeger Corp.*, 365 F. Supp. 602 (E.D. Pa. 1973) (finding obvious danger of a forklift crane did not preclude recovery); *Pike v. Frank G. Hough Co.*, 467 P.2d 229, 235 (Cal. 1970) ("[M]odern approach does not preclude liability solely because a danger is obvious."); *Micallef v. Miehle Co., Div.*, 39 N.Y.2d 376, 387, 348 N.E.2d 571, 578, 384 N.Y.S.2d 115, 122 (1976) ("[P]atent-danger doctrine should not, in and of itself, prevent a plaintiff from establishing his case.").

27. See *Passwaters v. General Motors Corp.*, 454 F.2d 1270, 1278 (8th Cir. 1972) (applying Iowa law) (acknowledging that bystanders are covered by strict liability); *Wasik v. Borg*, 423 F.2d 44, 47 (2d Cir. 1970) (applying Vermont law) (manufacturer liable to innocent bystander where automobile was sold in defective condition); *Elmore v. American Motors Corp.*, 451 P.2d 84, 88-89 (Cal. 1969) (extending protection to injured bystanders on rationale that bystander has even less control over instrumentality than purchaser or user).

28. See *Henderson & Twerski*, *supra* note 5, at 1519-22 (comments g-j).

Now to the sixty-four dollar question, "What happens to strict liability and negligence?" Should we adopt a doctrinal approach drawing sharp distinctions between negligence and strict liability? In our *Cornell* article, we suggested that we ought to stay away from doctrinal distinctions.²⁹ We thought it was a good idea then. We think it is a good idea now. The fact of the matter is that manufacturing defect cases are essentially true strict liability cases in that the conduct of the defendant is irrelevant.³⁰ In design and failure-to-warn cases, since we are dealing primarily with whether the product was reasonably designed or whether there was a reasonable warning given, it becomes negligence-like in its approach.³¹ But it is not functionally equivalent with the traditional negligence doctrine.³²

29. See Henderson & Twerski, *supra* note 5, at 1532. ("[I]t is unlikely that the distinction between this test [strict liability] and the negligence test is sufficiently significant to warrant the creation of a separate track for liability. In any event, we do not believe that the issue is of sufficient moment to saddle our revision with it.").

30. See *Phipps v. General Motors Corp.*, 363 A.2d 955, 958 (Md. 1976) ("The relevant inquiry in a strict liability action focuses not on the conduct of the manufacturer but rather on the product itself."); *Phillips v. Kimwood Mach. Co.*, 525 P.2d 1033, 1036 (Or. 1974) ("To impose [strict] liability there has to be something about the article which makes it dangerously defective without regard to whether the manufacturer was or was not at fault for such condition."); see generally KEETON ET AL., *supra* note 22, at 695-97.

31. See, e.g., *Balido v. Improved Mach. Inc.*, 105 Cal. Rptr. 890, 895 (Cal. Ct. App. 1972) ("A manufacturer's failure to achieve its full potential in design . . . is a liability whose essence parallels the lack of due care that is the essence of its liability for negligence."); *Fiberboard Corp. v. Fenton*, 845 P.2d 1168, 1174 (Colo. 1993) (noting that courts should not "shy away from using appropriate 'negligence terms' that are necessary to properly define defect and unreasonably dangerous in the context of either design defect or failure to warn claims"); *Jarrel v. Monsanto Co.*, 528 N.E.2d 1158, 1168 n.7 (Ind. Ct. App. 1988) ("[I]n cases involving deficient or absent warnings as the sole 'defect' or 'defective condition' we have nothing more and nothing less than a negligence action . . ."); *Prentis v. Yale Mfg. Co.*, 365 N.W.2d 176, 183-84 (Mich. 1984) (stating "[t]he underlying negligence calculus is inescapable" in determining the liability in a design defect case); *Feldman v. Lederle Lab.*, 479 A.2d 374, 386 (N.J. 1984) (stating that negligence and strict liability may be deemed to be "functional equivalents" in failure to warn cases); see also Gary T. Schwartz, *Foreword: Understanding Products Liability*, 67 CAL. L. REV. 435, 462-63 (1979) (observing that although

John Vargo used a very good phrase on the phone with me one day. We were talking about negligence and John asked whether we were talking about "old negligence" or "new negligence." I thought that was a very valuable insight; it stuck with me. Traditional negligence comes with a lot of baggage that we may not wish to import into products liability law. There is good reason to stop and think about whether or not we wish to spend our efforts in fighting the doctrinal battles. Our position is that we should look at what the elements of the cause of action are, describe them and then leave the courts free to adopt the terminological labels which they are most comfortable with. There is going to be a need to take sides on the issue of what it takes to make a design defect.

We have argued in our *Cornell* article that the fundamental definition for design defect must be "risk-utility" based.³³ There is only one serious competitor to "risk-utility" and that is the "consumer expectation" test.³⁴ I think properly understood, the "consumer expectation" test simply does not work as an adequate test in a design defect setting. There are a small subclass of

characterized as a form of strict liability, failure to warn defects are really a form of negligence).

32. See Henderson & Twerski, *supra* note 5, at 1532.

33. See Henderson & Twerski, *supra* note 5, at 1532-33. A product is defectively designed under a "risk-utility" analysis if its inherent danger outweighs its utility. KEETON ET AL., *supra* note 22, at 699.

34. Under the "consumer expectation" test, a product is defectively dangerous if it is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." RESTATEMENT (SECOND) OF TORTS § 402A cmt. i (1965). For an application of this test see *Toliver v. General Motors Corp.*, 482 So. 2d 213, 218-19 (Miss. 1986) (en banc) (holding that the product's design fell below the standard of design contemplated by the user and thus became unreasonably dangerous to the user); *Young v. Tide Craft, Inc.*, 242 S.E.2d 671 (S.C. 1978) (holding that a manufacturer's failure to install a safety device to a boat's motor did not constitute a defect unreasonably dangerous to the consumer); *Menard v. Newhall*, 373 A.2d 505 (Vt. 1977) (holding that a BB gun is not dangerous beyond that which could be contemplated by an ordinary consumer). *But see* *Sperry-New Holland v. Prestage*, 617 So. 2d 248, 253 (Miss. 1993) (holding that Missouri now follows the "risk-utility" test).

design defect cases that can go off on a form of consumer expectation. For example, when a product fails in its intended use, very much like the car failed in the famous *Henningsen* case,³⁵ identifying the form of defect is a matter of monumental insignificance. If that is true, we ought to be able to cabinet that class of cases separately and functionally identify them. However, most design defect cases are what my colleague, Professor Henderson has called “conscious design choice” cases.³⁶ These are cases where the manufacturer has a design choice in front of it and has to decide which design to choose. Assuming we face these conscious design choice cases in courts, and we do every day, these cases ought to be decided on “risk-utility” grounds. The authority, as we see it throughout the country, both judicially and academically, is overwhelmingly in support.³⁷ Even the courts that attempt to decide design defect cases on the basis of some form of “consumer expectation” fall back on “risk-utility” theory.³⁸ Consumer expectations are de-

35. See *Henningsen v. Bloomfield Motors, Inc.*, 161 A.2d 69 (N.J. 1960).

36. See generally Henderson, *supra* note 24.

37. See *Camacho v. Honda Motor Co.*, 741 P.2d 1240, 1246-49 (Colo. 1987) (en banc) (applying a “risk-utility” analysis where manufacturer of motorcycle failed to equip motorcycle with leg protection devices); *Phipps v. General Motors Corp.*, 363 A.2d 955, 961 (Md. 1976) (acknowledging that design defect requires the balancing of utility of design against the magnitude of risk); *Prentis v. Yale Mfg. Co.*, 365 N.W.2d 176 (Mich. 1984) (adopting a pure “risk-utility” test for products liability action predicated upon defective designs); *Bilotta v. Kelley Co.*, 346 N.W.2d 616, 622 (Minn. 1984) (applying a “risk-utility” analysis in evaluating manufacturer’s conscious choice of design where employee was injured when a forklift truck fell on him); *Thibault v. Sears, Roebuck & Co.*, 395 A.2d 843, 846 (N.H. 1978) (applying “risk-utility” analysis where consumer was injured by power lawnmower in a manner contrary to manufacturer’s instructions); see also Sheila L. Birnbaum, *Unmasking the Test for Design Defect: From Negligence [to Warranty] to Strict Liability to Negligence*, 33 VAND. L. REV. 593 (1980) (discussing “risk-utility” analysis); W. Page Keeton, *The Meaning of Defect in Products Liability Law—A Review of Basic Principles*, 45 MO. L. REV. 579 (1980) (advocating abandonment of the “consumer expectation” test and adopting the “risk-utility” test).

38. See *Aller v. Rodgers Mach. Mfg., Co.*, 268 N.W.2d 830, 835 (Iowa 1978) (determining whether the product was dangerous to an unreasonable extent required a balancing of the product’s risk and liability); *Baughn v.*

efined as “reasonable” consumer expectations. When you ask what do consumers reasonably expect, the answer is that they can expect reasonably designed products. This gets us back to “risk-utility” analysis. It seems to us that we ought not have to go this circuitous route to arrive at “risk-utility” analysis. There are a host of subsidiary questions that we will have to deal with in the comments and in later sections, but the fundamental defect test really ought to be “risk-utility.”

Let me mention one other major issue where a tough decision has got to be made. It is one of the areas in which everyone admits section 402A has been a monumental failure. Section 402A comment k,³⁹ that deals with so-called “unavoidably unsafe products” (prescription drugs), is a masterpiece of confusion and double-speak.⁴⁰ I have regularly offered an “A” in my course to

Honda Motor Co., Ltd., 727 P.2d 655, 660 (Wash. 1986) (en banc) (“In determining a consumer’s expectations regarding a product’s safety, factors such as the relative cost of the product, the gravity of the potential harm from the claimed defect and the cost and feasibility of eliminating or minimizing the risk are to be considered.”); Seattle-First Nat’l Bank v. Tabert, 542 P.2d 774, 779 (Wash. 1975) (en banc) (treating “consumer expectation” test as an element in a “risk-utility” analysis).

39. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). Comment k reads in pertinent part:

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 Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous.

Id.

40. See Joseph A. Page, *Generic Product Risks: The Case Against Comment k and for Strict Tort Liability*, 58 N.Y.U. L. REV. 853 (1983); Aaron D. Twerski, *National Product Liability Legislation: In Search for the Best of All Possible Worlds*, 18 IDAHO L. REV. 411 (1982). There is a significant amount of discrepancy among the courts regarding the nature and scope of comment k. Some courts interpret comment k as reducing strict liability to a negligence standard. See *Plummer v. Lederle Lab.*, 819 F.2d 349, 356 (2d Cir.) (“Drug manufacturers are obligated by law to provide doctors and/or consumers with the adequate knowledge of the hazards of the drugs they manufacture. If they do so, they are held not to a strict liability standard . . . but to a negligence standard.”), *cert. denied*, 484 U.S. 898

any student who could explain it to me, and so far I have given A's, but none because the student was able to explain section 402A comment k. I think this comment seeks to address the problem of drug design, but I cannot be sure. If it is talking about drug design, it is very difficult to understand because it compares a drug design case with a non-drug design case. However, since there is no authority in the Restatement on how to cover non-drug design cases, I do not know how to distinguish out drug design cases.

There is a possibility that section 402A comment k speaks only to the warning issue. If it speaks to the warning issue, I am not certain whether or not there is liability under the Restatement for unforeseeable risks arising from drugs. The language can be interpreted both ways. On the other hand, the judicial authority in the drug field is clear -- there is no liability for unforeseeable reactions or for unforeseeable risks arising from drugs.⁴¹ The authority is crystal clear throughout the country. I do not know of a single exception to that statement.

Now, the real tough issue on which we will have to make a decision is whether the A.L.I. should recognize a cause of action for defective drug design. One possible solution is to say that drug design litigation ought not to exist at all.⁴² The other is it

(1987); *Ferrigno v. Eli Lilly & Co.*, 420 A.2d 1305, 1318 (N.J. Super. Ct. Law Div. 1980) (“[I]t is clear that although the comment k rules appear under the title ‘Topic 5. Strict Liability’ in the Restatement, they are not strict liability rules at all. They are merely rules of negligence embodying the long-standing concepts of a lack of due care and foreseeability of the risk.”). *But see Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652 (1st Cir. 1981) (precluding comment k immunity where plaintiff suffered injury following ingestion of oral contraceptive); *Toner v. Lederle Lab.*, 732 P.2d 297, 308 (Idaho 1987) (“We do not believe comment k was intended to provide nor should it provide all ethical drugs with blanket immunity from strict liability design defect claims.”).

41. *See Ferrigno*, 420 A.2d 1305; *Incollingo v. Ewing*, 282 A.2d 206 (Pa. 1971); *see also Woodill v. Parke Davis & Co.*, 402 N.E.2d 194, 199-200 (Ill. 1980) (recognizing that a contrary rule would deter the introduction of new and useful products).

42. Those opposed to drug design litigation argue that a decision by the Food and Drug Administration (FDA) to license a drug and make it available through prescription is sufficient to render it “unavoidably unsafe” as a matter

ought to exist under some very special rules.⁴³ Let me tell you what I think the controversy is all about. It is clear that drug design cases are a different animal. If we were to take the position that a drug is defectively designed, when that drug can service a specific group of patients who need the drug, I think we would be making a terrible mistake. Nobody wants to say that a drug is defectively designed if it is a drug of choice for a discreet group of patients. What needs to be done in that instance is to warn, and to warn very sharply and very accurately, about the dangers of the drug, limiting the drug to its appropriate use.

The question arises in today's world in which drug companies put out huge numbers of drugs, whether or not there is a legitimate place for drug design cases, because a drug can come on the market that has no social utility for even a discreet group of patients. Now I could make the argument that if that were the case, failure-to-warn would operate because the manufacturer clearly would have a duty to warn that the drug simply does not function or does not have a particularly good use. Let me give you an example. Consider the Ortho-Novum birth control pill⁴⁴ manufac-

of law, thus making the court's role unnecessary. See *McDaniel v. McNeil Lab., Inc.*, 241 N.W.2d 822 (Neb. 1976) (FDA approval of safety not subject to challenge without proof of fraud or nondisclosure); John P. Reilly, *The Erosion of Comment k*, 14 U. DAYTON L. REV. 255 (1989) (suggesting that a manufacturer's compliance with the FDA regulatory process should entitle the manufacturer to a rebuttable presumption indicating that at the time a prescription drug is manufactured, the apparent benefit of the product outweighs its apparent risks); Victor E. Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment k*, 42 WASH. & LEE L. REV. 1139, 1142-43 (1985) (stating the underlying policy behind comment k applies to drugs in which there has been reasonable care on the part of the manufacturer, and presumably on the part of the FDA).

43. See *Davis v. Wyeth Lab., Inc.*, 399 F.2d 121, 129 (9th Cir. 1968) (stating that it must be determined whether the drug's benefits justify its use); *Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541, 545 (Ind. Ct. App. 1979) (balancing public interest in availability of a drug against attendant risks).

44. Ortho-Novum is an oral contraceptive manufactured by the Ortho Pharmaceutical Corporation. For a comparable illustration of this example see *Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652 (1st Cir. 1981) (holding manufacturer liable for injuries resulting from the ingestion of a birth control

tured at a 100 milligram dose, when a 50 milligram dose will provide adequate protection and present far less risk to the patient. Is that a design defect case or a failure-to-warn case? At first blush, it is a failure-to-warn case because the manufacturer clearly should be warning the user, do not use 100 milligrams when 50 will do, 100 milligrams gives you more risk. On the other hand, there may be a role for design defect. Why the devil would you manufacture and sell the 100 milligram dose? It serves no useful function. Now the argument on the other side is that opening drugs to design litigation will create a new category of litigation when none presently exists. The fact of the matter is that in the last couple of years, there has been a fair amount of discussion by the courts recognizing the possibility of drug design litigation. We have heard both opinions and we will have to work it out. It should be clear, however, that the issue is not whether strict liability or negligence applies to design defect cases. Nobody in a drug design case has ever imposed strict liability. No one has imputed knowledge to a drug manufacturer which it could not have reasonably obtained through reasonable testing and development. There is no such thing as true strict liability in design litigation. So to say you are creating a section 402A comment k exemption for strict liability when it does not exist in design litigation seems to me a strange way to talk about the problem.

Let me conclude now with a few final observations. I think that this project is very doable. I believe we can effectively and honestly restate the law of products liability. I hope the new Restatement will clarify concepts that have been unnecessarily confused, but I think that part of the problem is the fact that we will indeed need to clarify the law.

I have a joke that I tell my students about a religious Jewish man who decided that he was going to sort of give up the faith and wanted to eat ham. He went into a delicatessen and marched over to the display counter, pointed to the ham and said: "Give

pill containing 100 milligrams of estrogen where an equally effective but far less dangerous contraceptive containing only 50 milligrams of estrogen was available).

me a piece of that,” and the clerk behind the counter said, “Do you mean the ham, sir?” He said, “Who asked you to name it?”

We are likely to be criticized for identifying the “ham.” Why should someone be against clarification? The answer is that it allows for strategic behavior on the part of the lawyers. When you are dealing with terms that make sense only to the Oracle at Delphi, there is room for huge amounts of maneuvering. Lawyers are jealous of that maneuvering space and sometimes correctly so. We have not written and will not write a manifesto for “law reform.” Although we have our own personal view about what the law of products liability should be, we have not imposed them on the Restatement. But we will impose some clarity, and there are costs to clarity. Thirty years into the product revolution, we think that the time has come to do that. Thank you.

