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## SHIFTING PERSPECTIVES IN PRODUCTS LIABILITY: FROM QUALITY TO PROCESS STANDARDS\*

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*Products liability law has focused on alternative standards for assessing the quality of product design. In this Article, the authors suggest that this emphasis is misplaced and recommend scrutiny of the process by which product design decisions are made. The authors suggest that manufacturers should be able to present evidence of good process and thereby raise the plaintiff's burden of proving design defects to a level of clear and convincing evidence. Such a process defense, the authors conclude, would better serve the interests of product innovation and consumer safety.*

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## INTRODUCTION

The explosion of design defect litigation during the last two decades has failed to develop products liability into a cohesive and workable body of law. While courts and commentators<sup>1</sup> have struggled to define the contours of product defect, governmental agencies,<sup>2</sup> professional standard-setting groups,<sup>3</sup> and trade organizations<sup>4</sup> have un-

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<sup>1</sup> Most literature on products liability in recent years has focused on establishing standards for design defect. See Birnbaum, *Unmasking the Test for Design Defect: From Negligence [to Warranty] to Strict Liability to Negligence*, 33 Vand. L. Rev. 593 (1980) [hereinafter Birnbaum, *Unmasking the Test for Design Defect*]; Epstein, *Products Liability: The Search for the Middle Ground*, 56 N.C.L. Rev. 643 (1978); Henderson, *Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication*, 73 Colum. L. Rev. 1531 (1973) [hereinafter Henderson, *Judicial Review of Manufacturers' Conscious Design Choices*]; Henderson, *Manufacturers' Liability for Defective Product Design: A Proposed Statutory Reform*, 56 N.C.L. Rev. 625 (1978) [hereinafter Henderson, *A Proposed Statutory Reform*]; Henderson, *Renewed Judicial Controversy Over Defective Product Design: Toward the Preservation of an Emerging Consensus*, 63 Minn. L. Rev. 773 (1979) [hereinafter Henderson, *Renewed Judicial Controversy Over Defective Product Design*]; Hoenig, *Product Designs and Strict Tort Liability: Is There a Better Approach?*, 8 Sw. U.L. Rev. 109 (1976); Keeton, *Products Liability—Design Hazards and the Meaning of Defect*, 10 Cum. L. Rev. 293 (1980) [hereinafter Keeton, *Products Liability—Design Hazards*]; Phillips, *The Standard for Determining Defectiveness in Products Liability*, 46 U. Cin. L. Rev. 101 (1977) [hereinafter Phillips, *The Standard for Determining Defectiveness*]; Schwartz, *Foreword: Understanding Products Liability*, 67 Calif. L. Rev. 435 (1979); Twerski, Weinstein, Donaher & Piehler, *The Use and Abuse of Warnings in Products Liability—Design Defect Litigation Comes of Age*, 61 Cornell L. Rev. 495 (1976) [hereinafter Twerski, Weinstein, Donaher & Piehler, *The Use and Abuse of Warnings*]; Wade, *On Product "Design Defects" and Their Actionability*, 33 Vand. L. Rev. 551 (1980) [hereinafter Wade, *On Product "Design Defects"*].

<sup>2</sup> Many governmental agencies have been granted statutory responsibility for setting or reviewing product safety standards. See, e.g., *Flammable Fabrics Act*, 15 U.S.C. §§ 1191-1204 (1976 & Supp. II 1978) (authorizing the Secretary of Commerce to supervise fabric safety standards); *Hazardous Substances Act*, 15 U.S.C. §§ 1261(f)(1)(D), 1262(e)(1) (1976 & Supp. II 1978) (authorizing the Secretary of HEW to regulate safety standards for toys); *Consumer Product Safety Act*, 15 U.S.C. §§ 2051-2081 (1976 & Supp. III 1979) (establishing the Consumer Product Safety Commission (CPSC)); *Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. §§ 341, 351-360 (1976 & Supp. II 1978) (authorizing the Secretary of Health and Human Services to regulate quality standards for certain foods and drugs); *Occupational Safety and Health Act*, 29 U.S.C. §§ 652, 655 (1976 & Supp. II 1978) (authorizing the Secretary of Labor to promulgate national occupational safety and health standards); *Federal Boat Safety Act*, 46 U.S.C. §§ 1451-1455 (1976) (granting the Secretary of Transportation power to set boating construction safety standards); *Federal Aviation Act*, 49 U.S.C. §§ 1341, 1421-1432 (1976 & Supp. II 1978) (authorizing the Secretary of Transportation to promulgate regulations to promote safety of civil aircraft).

<sup>3</sup> Such professional standard-setting groups include the American National Standards Institute, the American Society for Testing and Materials, and the Underwriters' Laboratory. See *Implementation of the Consumer Product Safety Act: Hearings Before the Subcomm. for Con-*

dertaken the task of setting specific safety standards. These concurrent activities have created tensions between those responsible for setting the standards and those who ultimately must judge their efficacy and worth. An aura of crisis has ensued.<sup>5</sup> Commentators have

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sumers of the Senate Comm. on Commerce, Science, and Transportation, 95th Cong., 1st Sess. (1977) [hereinafter *Implementation of the CPSA*]; Consumer Product Safety Commission Oversight: Hearings on S. 644 and S. 100 Before the Subcomm. for Consumers of the Senate Comm. on Commerce, 94th Cong., 1st Sess. (1975) [hereinafter cited as *Hearings on S. 644 and S. 1000*]. See generally Report on Consumer Representation in Voluntary Standards Setting: Year Two, *Standardization News*, Apr. 1980, at 8-15 (presented by the National Consumers League to the American Society for Testing and Materials).

<sup>4</sup> Trade organizations that have been involved in the process of setting safety standards include the American Gas Association, the Association of Home Appliance Manufacturers, the Outdoor Power Equipment Institute, and the Bicycle Manufacturers Association of America. See generally *Implementation of the CPSA*, *supra* note 3; Hearings on S. 644 and S. 1000, *supra* note 3.

<sup>5</sup> See Model Uniform Product Liability Act, 44 Fed. Reg. 62,714 (1979) [hereinafter UPLA]. Both the Introduction and the Preamble to the UPLA contain discussions of the problems perceived to exist in the current products liability system. Section 101 of the UPLA makes the following specific findings:

(A) Sharply rising product liability insurance premiums have created serious problems in commerce resulting in:

- (1) Increased prices of consumer and industrial products;
- (2) Disincentives for innovation and for the development of high-risk but potentially beneficial products;
- (3) An increase in the number of product sellers attempting to do business without product liability insurance coverage, thus jeopardizing both their continued existence and the availability of compensation to injured persons; and
- (4) Legislative initiatives enacted in a crisis atmosphere that may, as a result, unreasonably curtail the rights of product liability claimants.

(B) One cause of these problems is that product liability law is fraught with uncertainty and sometimes reflects an imbalanced consideration of the interests it affects. The rules vary from jurisdiction to jurisdiction and are subject to rapid and substantial change. These facts militate against predictability of litigation outcome.

(C) Insurers have cited this uncertainty and imbalance as justifications for setting rates and premiums that, in fact, may not reflect actual product risk or liability losses.

(D) Product liability insurance rates are set on the basis of countrywide, rather than individual state, experience. Insurers utilize countrywide experience because a product manufactured in one state can readily cause injury in any one of the other states, the District of Columbia, or the Commonwealth of Puerto Rico. One ramification of this practice is that there is little an individual state can do to solve the problems caused by product liability.

(E) Uncertainty in product liability law and litigation outcome has added to litigation costs and may put an additional strain on the judicial system.

(F) Recently enacted state product liability legislation has widened existing disparities in the law.

attacked courts for expanding the scope of manufacturer liability<sup>6</sup> and providing juries with unchecked discretion in products liability cases.<sup>7</sup> Furthermore, both manufacturers and consumers have criticized governmental agencies for their ineffective attempts at standard-setting.<sup>8</sup> The outcries of manufacturers and insurers have

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Id. at 62,716. See generally Epstein, *supra* note 1; Henderson, *Judicial Review of Manufacturers' Conscious Design Choices*, *supra* note 1, at 1531-34; Henderson, *A Proposed Statutory Reform*, *supra* note 1; Johnson, *Products Liability "Reform": A Hazard to Consumers*, 56 N.C.L. Rev. 677 (1978); Phillips, *An Analysis of the Proposed Reform of Products Liability Statute of Limitations*, 56 N.C.L. Rev. 664 (1978); Twerski, *Rebuilding the Citadel: The Legislative Assault on the Common Law*, Trial, Nov. 1979, at 55-59, 83; U.S. Dep't of Commerce, *Interagency Task Force on Product Liability, Final Report* (1977).

<sup>6</sup> See, e.g., Henderson, *Renewed Judicial Controversy Over Defective Product Design*, *supra* note 1, at 782-94 (criticizing *Barker v. Lull Eng'r Co.*, 20 Cal. 3d 413, 573 P.2d 443, 143 Cal. Rptr. 225 (1978), for shifting the burden of proof to the defendant manufacturer); Twerski, Weinstein, Donaher & Piehler, *The Use and Abuse of Warnings*, *supra* note 1, at 516-17 (criticizing *Moran v. Faberge, Inc.*, 273 Md. 538, 332 A.2d 11 (1975), for failure to consider the societal cost of warning about a very remote risk); id. at 517-20 (criticizing *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968), for inadequate treatment of failure-to-warn cases involving irreducible risks).

<sup>7</sup> See, e.g., Henderson, *Renewed Judicial Controversy Over Defective Product Design*, *supra* note 1, at 799-801 (criticizing *Azzarello v. Black Bros.*, 480 Pa. 547, 391 A.2d 1020 (1978), for improper allocation of functions between judge and jury).

<sup>8</sup> See Consumer Product Safety Commission Oversight: Hearings Before the Subcomm. on Oversight and Investigations and the Subcomm. on Consumer Protection and Finance of the House Comm. on Interstate and Foreign Commerce, 95th Cong., 1st Sess. 3-9 (1977) (statement of Jerome Blomberg) (criticizing CPSC regulations for disruptive effect on the construction industry); id. at 9-61 (statement of Marvin Schneiderman et al.) (criticizing the CPSC for failure to set up specific guidelines and regulations for treatment and testing of hazardous chemicals in consumer products); id. at 61-104 (statement of Edward Garvey et al.) (criticizing the CPSC for failure to study artificial turf used in athletic stadiums); id. at 232-46 (statement of Linda Hudak) (criticizing the CPSC for delay in implementing a set of working priorities and laxness in promulgating mandatory safety standards); Implementation of the CPSA, *supra* note 3, at 2-14 (statement of Robert Harris) (criticizing the CPSC for failure to develop adequate policy guidelines and regulations regarding toxic chemicals, including carcinogens); id. at 24-30 (statement of William T. Cavanaugh) (commenting on general delay and inefficiency of the CPSC standard-setting process and on lack of coordination between the CPSC and another standard-setting organization); id. at 45-46 (statement of Dennis C. Dix) (criticizing absence of factual documentation for power lawnmower product file published by the CPSC); id. at 62-68 (statement of Donald Peyton) (stating that the CPSC's inflexibility and failure to adopt voluntary rather than mandatory standards have impeded the CPSC's ability to promulgate many standards); id. at 68-78 (statement of Aaron Locker) (arguing that the CPSC must use voluntary standard-setting to fulfill its mandate); Hearings on S. 644 and S. 1000, *supra* note 3, at 33-46 (statement of Harry A. Paynter) (calling for greater CPSC resources for setting voluntary standards for gas appliances); id. at 55-62 (statement of Frank Hogdon) (criticizing the CPSC's intention to formulate mandatory standards for gas heaters); id. at 100-06 (statement of Richard H. Gimer) (criticizing the CPSC for failure to perform in-depth analyses, resulting in inability to give adequate attention to existing voluntary standards); id. at 127-33 (statement of Jay Townley) (discussing industry's inability to comply with conflicting state and federal standards); id. at 136-40 (statement by Aaron Locker) (recommending federal preemption of state standards for toy manufacturing).

generated voluminous legislative proposals at the federal<sup>9</sup> and state levels<sup>10</sup> and have led to the enactment of improvident legislation.<sup>11</sup>

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<sup>9</sup> Currently, two major pieces of legislation that seek to alter or clarify liability standards with respect to products liability litigation are before Congress: the National Product Liability Act, H.R. 5626, 96th Cong., 1st Sess., 125 Cong. Rec. H9332 (daily ed. Oct. 17, 1979), and the Uniform Product Liability Act, H.R. 7000, 96th Cong., 2d Sess., 126 Cong. Rec. H2464 (daily ed. Apr. 1, 1980). The UPLA has already been promulgated by the U.S. Department of Commerce as a model act to be adopted voluntarily by the states. See UPLA, *supra* note 5.

Several other bills bearing on the products liability crisis have been introduced: H.R. 1061, 96th Cong., 1st Sess., 125 Cong. Rec. H187 (daily ed. Jan. 18, 1979) (bill to improve the safety of products manufactured and sold in interstate commerce and to reduce the number of deaths and injuries caused by such products); H.R. 1675, 96th Cong., 1st Sess., 125 Cong. Rec. H402 (daily ed. Jan. 31, 1979) (bill to establish federal products liability standards); H.R. 1676, 96th Cong., 1st Sess., 125 Cong. Rec. H402 (daily ed. Jan. 31, 1979) (bill to provide uniform standards for state products liability laws); H.R. 2964, 96th Cong., 1st Sess., 125 Cong. Rec. H1357 (daily ed. Mar. 14, 1979) (bill to establish a federal Insurance Commission to regulate the insurance industry, to establish federal products liability standards, and to amend the Internal Revenue Code to exempt trusts established for the payment of products liability claims from income tax); the Product Liability Risk Retention Act of 1980, H.R. 6152, 96th Cong., 1st Sess., 125 Cong. Rec. H12,101 (daily ed. Dec. 14, 1979) (bill to facilitate establishment by sellers of product liability risk retention groups and to purchase product liability insurance on a group basis) (This bill was passed by the House on March 10, 1980, 126 Cong. Rec. H1671. The Senate held hearings on April 22, 1980, on the bill but has not yet voted on it. See Senate Comm. on Commerce, Science, and Transportation, S. Rep. No. 984, 96th Cong., 2d Sess. (urging passage of the bill)); H.R. 7040, 96th Cong., 2d Sess., 126 Cong. Rec. H2544 (daily ed. Apr. 15, 1980) (bill to amend Title 18 of the U.S.C. to impose penalties for nondisclosure by businesses of serious concealed dangers in products and business practices).

<sup>10</sup> Many states have passed statutes of limitation on products liability actions. E.g., Ariz. Rev. Stat. Ann. § 12-551 (Supp. 1957-1979); Conn. Gen. Stat. Ann. § 52-577a(a) (West Supp. 1980); Ga. Code Ann. §§ 105-106 (4408) (Insert 1978 in Cum. Supp. 1977); Ill. Ann. Stat. ch. 83, § 22.2(b) (Smith-Hurd Supp. 1966-1979); Ind. Code Ann. § 34-4-20A-5 (Burns Cum. Supp. 1979); N.H. Rev. Stat. Ann. § 507-D:2 (Supp. 1979); N.D. Cent. Code § 28-01.1-02 (Supp. 1979); Or. Rev. Stat. § 30.905 (1979); R.I. Gen. Laws § 9-1-13 (Cum. Supp. 1979); S.D. Comp. Laws Ann. § 15-2-12.1 (Supp. 1979); Tenn. Code Ann. § 23-3703 (Cum. Supp. 1979); Utah Code Ann. § 78-15-3 (1977).

Some states recognize a defense or create a rebuttable presumption of no defect if the alleged defect results from a design that conformed to the state of the art at the time the product was first designed or sold. E.g., Colo. Rev. Stat. § 13-21-403(1)(a) (Cum. Supp. 1979); Ind. Code Ann. § 34-4-20A-4(b)(4) (Burns Cum. Supp. 1979); Ky. Rev. Stat. § 411.310(2) (Cum. Supp. 1980); N.H. Rev. Stat. Ann. § 507-D:4 (Supp. 1979).

Several states recognize a defense or create a rebuttable presumption of no defect when someone other than the defendant alters or modifies the product in a manner not reasonably foreseeable by the defendant and the alteration or modification is the proximate cause of the claimant's injury. E.g., Ariz. Rev. Stat. Ann. § 12-683(2) (Supp. 1957-1979); Ga. Code Ann. § 105-106 (4408) (Insert 1978 in Cum. Supp. 1977); Ind. Code Ann. § 34-4-20A-4(b)(3) (Burns Cum. Supp. 1979); Ky. Rev. Stat. § 411.320(1), (2) (Cum. Supp. 1980); N.C. Gen. Stat. § 99B-3 (1979); N.D. Cent. Code § 28-01.1-04 (Supp. 1979); Or. Rev. Stat. § 30.915 (1979); R.I. Gen. Laws § 9-1-32 (Cum. Supp. 1979); Tenn. Code Ann. § 23-3703 (Cum. Supp. 1979); Utah Code Ann. § 78-15-5 (1977).

Several states recognize a defense or create a rebuttable presumption of no defect when the design of the product or its method of manufacturing conforms to federal or state standards.

The harsh criticisms by industry and insurers have struck a responsive chord in some quarters of the legal community. One commentator, for example, has questioned whether courts are capable of deciding complex design defect cases.<sup>12</sup> He argues that product design involves sensitive trade-offs which are often polycentric in nature; every design decision can impinge on or foster ancillary changes in other features of the product.<sup>13</sup> The cumulative effect of these polycentric trade-offs, he suggests, may be that courts are incapable of approving or condemning the design of a product.<sup>14</sup> An alternative to judicial review might be for state and federal administrative agencies to undertake the decisionmaking role because they would not suffer from the structural infirmities that plague courts.<sup>15</sup> This alternative, however, is neither practicable nor desirable. The simple truth is that although there are tens of thousands of products on the market, government has been able to regulate only in narrowly defined categories.<sup>16</sup> Furthermore, the imposition of overly stringent

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E.g., Colo. Rev. Stat. § 13-21-403(b) (Cum. Supp. 1979); N.D. Cent. Code § 28-01.1-05(3) (Supp. 1979); Tenn. Code Ann. § 23-3704 (Cum. Supp. 1979); Utah Code Ann. § 78-15-6(3) (1977).

Finally, several states recognize a defense for unforeseeable misuse of the product. E.g., Ariz. Rev. Stat. Ann. § 12-683(3) (Supp. 1957-1979); Ind. Code Ann. § 34-4-20A-4(b)(1), (2) (Burns Cum. Supp. 1979); N.C. Gen. Stat. § 99B-4 (1979).

<sup>11</sup> Some of the statutes are particularly onerous. See, e.g., Ariz. Rev. Stat. Ann. § 12-683(1) (Supp. 1957-1979) (recognizing a defense if defect results from fabrication that conformed to the state of the art at the time the product was first sold by defendant); Ind. Code Ann. § 34-4-20A-4(b)(4) (Burns Cum. Supp. 1978) (recognizing state of the art defense if product was prepared in conformity with the generally recognized state of the art at the time the product was designed); N.H. Rev. Stat. Ann. § 507-D:3 (Supp. 1979) (recognizing defense of product alteration even if product alteration is a concurrent cause). See generally Twerski, *Rebuilding the Citadel: The Legislative Assault on the Common Law*, Trial, Nov. 1979, at 55.

<sup>12</sup> This thesis has been presented forcefully by Professor James Henderson in a series of articles. See Henderson, *Judicial Review of Manufacturers' Conscious Design Choices*, supra note 1; Henderson, *Expanding the Negligence Concept: Retreat from the Rule of Law*, 51 Ind. L.J. 467 (1976) [hereinafter Henderson, *Expanding the Negligence Concept*]; Henderson, *Renewed Judicial Controversy Over Defective Product Design*, supra note 1.

<sup>13</sup> Henderson, *Expanding the Negligence Concept*, supra note 12, at 475-76; Henderson, *Judicial Review of Manufacturers' Conscious Design Choices*, supra note 1, at 1534-42.

<sup>14</sup> Henderson, *Judicial Review of Manufacturers' Conscious Design Choices*, supra note 1, at 1539-42; Henderson, *Expanding the Negligence Concept*, supra note 12, at 488-91.

<sup>15</sup> A governmental decisionmaker who decides to impose a safety standard must balance all the risk-utility factors and reach a managerial decision in favor of the preferable design. Professor Henderson does not contend that polycentric decisions cannot be made rationally, but that the courts are ill-equipped to do so because they can resolve questions only in a linear sequence. See Henderson, *Expanding the Negligence Concept*, supra note 12, at 471-73; Henderson, *Judicial Review of Manufacturers' Conscious Design Choices*, supra note 1, at 1538-39, 1576; Henderson, *A Proposed Statutory Reform*, supra note 1, at 626.

<sup>16</sup> See note 8 supra.

and inflexible design parameters by governmental agencies might severely inhibit product innovation.<sup>17</sup> Additionally, as consumer advocates fear, governmental regulation could become the lowest common denominator to which manufacturers flee to escape liability or, at the very least, governmental harassment.<sup>18</sup> Solutions to the problems of

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<sup>17</sup> See, e.g., Consumer Product Safety Commission Oversight: Hearings Before the Subcomm. on Oversight and Investigations and the Subcomm. on Consumer Protection and Finance of the House Comm. on Interstate and Foreign Commerce, 95th Cong., 1st Sess. 3-9 (1977) (statement of Jerome Blomberg) (criticizing federal regulations for lack of flexibility and disruptive effect on the construction industry); Implementation of the Consumer Product Safety Act: Hearings Before the Subcomm. for Consumers of the Senate Commerce, Science, and Transportation Comm., 95th Cong., 1st Sess. 62-68 (1977) (statement of Donald Peyton) (emphasizing need for flexibility and voluntary standards to provide incentive to improve standards); id. at 68-86 (statement of Aaron Locker) (arguing that government cannot provide sufficient resources to mandate adequate standards without incorporating voluntary standards); Hearings on S. 644 and S. 1000, *supra* note 3, at 33-35 (statement of Harry A. Paynter) (contending that governmental standards would be inflexible and would hinder innovation while voluntary standards would not); id. at 108-09 (statement of Richard Gimer) (criticizing the CPSC for its failure to give adequate attention to existing voluntary standards which, unlike government mandates, maximize product safety by marshalling the managerial and technological talent in American industry).

<sup>18</sup> The most recent attempt to resolve the problem of compliance with regulatory standards can be found in UPLA § 103(A) which provides:

(A) When the injury-causing aspect of the product was, at the time of manufacture, in compliance with legislative regulatory standards or administrative regulatory safety standards relating to design or performance, the product shall be deemed not defective . . . unless the claimant proves by a preponderance of the evidence that a reasonably prudent seller could and would have taken additional precautions.

UPLA, *supra* note 5, § 103A, at 62,730. This provision does not appear to accomplish anything more than the traditional common law approach. It does not shift the burden of proof because the plaintiff bears the burden of proving defect. Every product at the outset is deemed "not defective" unless the claimant proves the unreasonableness of the design.

Some of the recently enacted state statutes go beyond the UPLA by creating either an absolute defense or a rebuttable presumption of nondefectiveness if the manufacturer has complied with statutory or administrative standards. See, e.g., Colo. Rev. Stat. § 13-21-403(1)(b) (Cum. Supp. 1979) (rebuttable presumption); N.H. Rev. Stat. Ann. § 507-D:4 (Cum. Supp. 1979) (affirmative defense); Tenn. Code Ann. § 23-3704 (Cum. Supp. 1979) (rebuttable presumption); Utah Code Ann. § 78-15-6(3) (1977).

In an attempt to be evenhanded, the drafters of the UPLA addressed the question of noncompliance with a statutory standard:

When the injury-causing aspect of the product was not, at the time of manufacture, in compliance with legislative regulatory standards or administrative regulatory safety standards relating to design or performance, the product shall be deemed defective . . . unless the product seller proves by a preponderance of the evidence that its failure to comply was a reasonably prudent course of conduct under the circumstances.

UPLA, *supra* note 5, § 103(B), at 62,730 (emphasis added). This section appears to create a reasonableness defense to negligence per se. It is possible that the drafters meant to excuse a violation of the statute only when compliance would have created greater dangers than noncompliance. See Restatement (Second) of Torts § 288(A)(e) (1977). The language of § 103(B), however, would permit a finding of nonnegligence merely because the conduct of the defendant was reasonable under the circumstances. The doctrine of excused violation, see W. Prosser, Handbook of the Law of Torts § 36, at 199-200 (4th ed. 1971), was never meant to undermine the basic judgment reflected in the statute as to the standard of care.



design defect litigation, therefore, should be sought in the legal standards applied by courts.

In the past decade, the emphasis in both design defect litigation<sup>19</sup> and standard-setting<sup>20</sup> has been on evaluating the quality of

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<sup>19</sup> Although the approaches to identifying "unreasonably dangerous" designs have proliferated in recent years, the approaches generally fall into four classes. The first, usually associated with Dean Wade, focuses on whether the manufacturer would be judged negligent if he had known of the product's unreasonably dangerous condition at the time it was marketed (the "retrospective negligence" approach). See Wade, *On the Nature of Strict Tort Liability for Products*, 44 *Miss. L.J.* 825, 834-35 (1973) [hereinafter Wade, *On Strict Liability*]. The second, associated with Dean Keeton, compares the risk and utility of the product at the time of trial (the "risk-utility" approach). See Keeton, *Manufacturers' Liability: The Meaning of "Defect" in the Manufacture and Design of Products*, 20 *Syracuse L. Rev.* 559, 569-71 (1969) [hereinafter Keeton, *Manufacturers' Liability*]. The third, following the Restatement, focuses on consumer expectations about the product (the "consumer expectation" approach). See Restatement (Second) of Torts § 402A, Comment i (1977). The fourth combines the risk-utility and consumer expectation tests. See cases cited *infra* in this note. Because Wade would focus on the risk and utility of the product as well, the disagreement between Wade and Keeton is over the time factor. Keeton would hold a manufacturer liable when the risks in his product—based upon information available at the time of trial—exceed its utility, even if those risks were unknowable at the time of manufacture or sale. Wade would not. See Keeton, *Products Liability—Design Hazards*, *supra* note 1, at 307-08; Keeton, *Products Liability—Inadequacy of Information*, 48 *Tex. L. Rev.* 398, 408-09 (1970); Wade, *On Strict Liability*, *supra*, at 834-35. On the distinction between unforeseeable risk and unforeseeable technology in this context, see Schwartz, *supra* note 1, at 482-83; Twerski & Weinstein, *A Critique of the Uniform Product Liability Law—A Rush to Judgment*, 28 *Drake L. Rev.* 221, 227-28 (1979) [hereinafter Twerski & Weinstein, *A Critique of the UPL*] (suggesting that manufacturer could be held liable for unforeseeable risks but not for unforeseeable technology). Some commentators oppose strict liability in design defect and failure-to-warn cases altogether. See note 29 *infra*.

Although most courts agree that some form of risk-utility balancing is appropriate in design defect cases, see note 22 *infra*, controversy reigns over the propriety of an independent consumer expectation standard. See Montgomery & Owen, *Reflections on the Theory and Administration of Strict Tort Liability for Defective Products*, 27 *S.C.L. Rev.* 803, 843-44 (1976); Twerski, *From Defect to Cause to Comparative Fault—Rethinking Some Product Liability Concepts*, 60 *Marq. L. Rev.* 297, 312-16 (1977) (championing such a standard). But see UPLA § 104B and Analysis, 44 *Fed. Reg.* 62,724 (1979) (opposing an independent consumer expectation standard as overly subjective); Birnbaum, *Unmasking the Test for Design Defect*, *supra* note 1, at 611-16 (criticizing the incorporation of "haphazard subjectivity" into straightforward risk-utility approach); Schwartz, *supra* note 1, at 472-81 (questioning the ability of a consumer expectation standard to apply to complex technological questions).

A number of courts have embraced a combined standard. See *Caterpillar Tractor Co. v. Beck*, 593 P.2d 871, 885 (Alaska 1979); *Barker v. Lull Eng'r Co.*, 20 *Cal. 3d* 413, 432, 573 P.2d 443, 455-56, 143 *Cal. Rptr.* 225, 237-38 (1978); *Suter v. San Angelo Foundry & Mach. Co.*, 81 *N.J.* 150, 170-71, 406 A.2d 140, 150 (1979). Although it would not seem that the expectations of consumers, reasonable or otherwise, necessarily would accord with what manufacturers would in reasonable hindsight do, some courts regard the consumer expectation and retrospective negligence approaches as equivalent. See, e.g., *Welch v. Outboard Motor Corp.*, 481 F.2d 252, 254 (5th Cir. 1973) ("We see no necessary inconsistency between a seller-oriented standard and a user-oriented standard when, as here, each turns on foreseeable risks. They are two sides of the same standard."); *Seattle-First Nat'l Bank v. Tabert*, 86 *Wash. 2d* 145, 154, 542 P.2d 774, 779 (1975) ("[i]n determining the reasonable expectations of the ordinary consumer [the court considers the] relative cost of the product, the gravity of the potential harm from the claimed

the ultimate design of the product. The objective of design defect litigation and standard-setting is the same—the establishment of a standard of reasonable safety. The method of setting a safety standard, however, differs from the process of reviewing a design decision. When a court decides a design defect case, it sets a standard in a negative fashion. If it holds the defendant liable, the court declares that the design is inadequate and that the product does not meet the minimum level of societal acceptability. Unlike an agency that sets affirmative standards by choosing among alternative designs, the court examines alternatives designs only to discover whether there is an economically feasible alternative that would provide greater safety than the design in question and that would have prevented the injury.<sup>21</sup>

The overwhelming consensus among courts deciding design defect cases is that risk-utility analysis should be used as either an exclusive or an alternative ground of liability.<sup>22</sup> Any such analysis

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defect and the cost and feasibility of eliminating or minimizing the risk"); *Phillips v. Kimwood Mach. Co.*, 269 Or. 581, 592, 525 P.2d 1033, 1037 (1974) ("a manufacturer who would be negligent in marketing a given product, considering its risks, would necessarily be marketing a product which fell below the reasonable expectations of consumers who purchase it"). See also *Birnbaum*, *Unmasking the Test for Design Defect*, *supra* note 1, at 614-18 (criticizing combined standard).

<sup>20</sup> See, e.g., *Consumer Product Safety Act*, 15 U.S.C. §§ 2051(a)(3), 2053(c) (1976); *Traffic and Motor Vehicle Safety Act*, *id.* § 1392.

<sup>21</sup> For a discussion of the differences between affirmative and negative standard-setting as they relate to the issue of polycentricity, see *Twerski, Weinstein, Donaher & Piehler*, *The Use and Abuse of Warnings*, *supra* note 1, at 524-28.

<sup>22</sup> See, e.g., *Dreisonstok v. Volkswagenwerk, A.G.*, 489 F.2d 1066, 1071-73 (4th Cir. 1974) (exclusive ground); *Caterpillar Tractor Co. v. Beck*, 593 P.2d 871, 885 (Alaska 1979) (alternative ground); *Barker v. Lull Eng'r Co.*, 20 Cal. 3d 413, 432, 573 P.2d 443, 445-56, 143 Cal. Rptr. 225, 237-38 (1978) (alternative ground); *Suter v. San Angelo Foundry & Mach. Co.*, 81 N.J. 150, 170-71, 406 A.2d 140, 150 (1979) (alternative ground); *Micallef v. Miehle Co.*, 39 N.Y.2d 376, 386, 348 N.E.2d 571, 577-78, 384 N.Y.S.2d 115, 121 (1976) (exclusive ground); *Wilson v. Piper Aircraft*, 282 Or. 61, 67-68, 577 P.2d 1322, 1326 (1978) (exclusive ground).

Still controversial, however, is how specific a court should be when instructing a jury on risk-utility factors. See *Turner v. General Motors Corp.*, 584 S.W.2d 844, 850 (Tex. 1979) (adopting risk-utility approach but expressly declining to enumerate specific factors in jury instruction). The failure to include relevant factors in the instruction could lead the jury to erroneous conclusions. For example, a charge directing the jury to balance utility and risk but omitting mention of the cost of improvement could lead the jury to exculpate the defendant when utility exceeds risk, even if the cost of improvement is quite small. Conversely, the same charge could lead the jury to find the defendant liable when risk exceeds utility even if the cost of improvement is excessive. See *Thibault v. Sears, Roebuck & Co.*, 118 N.H. 802, 807, 395 A.2d 843, 846 (1978); *Turner v. General Motors Corp.*, 584 S.W.2d 844, 854 (Tex. 1979) (Campbell, J., concurring). On the specificity of the jury charge generally, see *Birnbaum*, *Unmasking the Test for Design Defect*, *supra* note 1, at 631-36; *Donaher, Piehler, Twerski & Weinstein*, *The Technological Expert in Products Liability Litigation*, 52 *Tex. L. Rev.* 1303, 1308 n.29 (1974); *Keeton*, *Products Liability—Design Hazards*, *supra* note 1, at 314-16; *Wade*, *On Product "Design Defects"*, *supra* note 1, at 572.

involves making trade-offs that take into account design or performance requirements, the effects of those requirements on reducing hazards, the utility and cost of the product, and technological capabilities.<sup>23</sup>

<sup>23</sup> Extensive commentary identifies the factors necessary to a risk-utility or risk-benefit approach. Professor Wade suggests the following considerations:

(1) The usefulness and desirability of the product—its utility to the user and to the public as a whole.

(2) The safety aspects of the product—the likelihood that it will cause injury, and the probable seriousness of the injury.

(3) The availability of a substitute product which would meet the same need and not be as unsafe.

(4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.

(5) The user's ability to avoid danger by the exercise of care in the use of the product.

(6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions.

(7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price or carrying liability insurance.

Wade, *On Strict Liability*, *supra* note 19, at 837-38.

Professor Fischer proposes a more extensive list, including: (1) The ability of the consumer to bear loss; (2) The feasibility and effectiveness of the consumer's self-protective measures, such as the risks, ability to control the danger, and feasibility of deciding against use of the product; (3) The manufacturer's knowledge of the risk, the accuracy of prediction of losses, the size of such losses, the availability of insurance, the ability of the manufacturer to self-insure, the effect of increased prices on industry, the public necessity for the product, and the deterrent effect on the development of new products; (4) Safety incentives such as the likelihood of future product improvement, the existence of additional precautions that can presently be taken, and the availability of safer substitutes. Fischer, *Products Liability—The Meaning of Defect*, 39 *Mo. L. Rev.* 339, 359 (1974).

Professor Shapo, building upon his representational theory as the basis of products liability, offers 13 considerations relevant to establishing defect:

1. The nature of the product as a vehicle for creation of persuasive advertising images, and the relationship of this factor to the ability of sellers to generate product representations in mass media;

2. The specificity of representations and other communications related to the product;

3. The intelligence and knowledge of consumers generally and of the disappointed consumer in particular;

4. The use of sales appeals based on specific consumer characteristics;

5. The consumer's actions during his encounter with the product, evaluated in the context of his general knowledge and intelligence and of his actual knowledge about the product or that which reasonably could be ascribed to him;

6. The implications of the proposed decision for public health and safety generally, and especially for social programs that provide coverage for accidental injury and personal disability;

7. The incentives that the proposed decision would provide to make the product safer;

8. The cost to the producer and other sellers of acquiring the relevant information about the crucial product characteristic and the cost of supplying it to persons in the position of the disappointed party;

This confrontation between the limits of technology and the requirements of law in developing reasonably safe products suggests that risks of injury arising from the use of a product will always be present.<sup>24</sup> The product designer must, therefore, find some way to limit the risks associated with the product to an acceptable level without compromising the marketability and utility of the product. The law purports to stand as watchdog to ensure that product design decisions made by manufacturers do not expose product users to unreasonable risks of injury. Thus, in a design defect case, the issue is whether the manufacturer properly weighed the alternatives and evaluated the trade-offs and thereby developed a reasonably safe product; the focus is unmistakably on the *quality* of the decision and whether the decision conforms to socially acceptable standards.

9. The availability of the relevant information about the crucial product characteristic to persons in the position of the disappointed party and the cost to them of acquiring it.

10. The effects of the proposed decision on the availability of data that bear on consumer choice of goods and services;

11. Generally, the likely effects on prices and quantities of goods sold;

12. The costs and benefits attendant to determination of the legal issues involved, either by private litigation or by collective social judgment; and

13. The effects of the proposed decision on wealth distribution, both between sellers and consumers and among sellers.

Shapo, A Representational Theory of Consumer Protection: Doctrine, Function and Legal Liability for Product Disappointment, 60 Va. L. Rev. 1109, 1370-71 (1974).

Professors Montgomery and Owen have sought to compress many of the factors into a four-part formulation:

(1) The cost of injuries attributable to the condition of the product about which the plaintiff complains—the pertinent accident costs.

(2) The incremental cost of marketing the product without the offending condition—the manufacturer's safety cost.

(3) The loss of functional and psychological utility occasioned by the elimination of the offending condition—the public's safety cost.

(4) The respective abilities of the manufacturer and the consumer to (a) recognize the risks of the condition, (b) reduce such risks, and (c) absorb or insure against such risks—the allocation of risk awareness and control between the manufacturer and the consumer.

Montgomery & Owen, *supra* note 19, at 818; see Dickerson, Products Liability: How Good Does a Product Have to Be?, 42 Ind. L.J. 301, 331 (1967); Vetri, Products Liability: The Developing Framework for Analysis, 54 Or. L. Rev. 293, 305-14 (1975).

<sup>24</sup> The court in *Phillips v. Kimwood Mach. Co.*, 269 Or. 485, 495, 525 P.2d 1033, 1035 (1974), stated this principle clearly:

To some it may seem that absolute liability has been imposed upon the manufacturer since it might be argued that no manufacturer could reasonably put into the stream of commerce an article which he realized might result in injury to a user. This is not the case, however. The manner of injury may be so fortuitous and the chances of injury occurring so remote that it is reasonable to sell the product despite the danger. In design cases the utility of the article may be so great, and the change of design necessary to alleviate the danger in question may so impair such utility, that it is reasonable to market the product as it is, even though the possibility of injury exists and was realized at the time of the sale.

The thesis of this Article is that there has been altogether too much emphasis placed on the quality of the final design at the expense of ignoring the *process* by which critical decisions are made. If the law is to serve a prophylactic function and promote the goal of product safety, it must abandon this singleminded focus which forces courts to second-guess product safety decisions. Instead, we must place under judicial and administrative scrutiny the process by which the decisions are made. Our contention is that a structured, well-articulated, and highly visible standard-setting process performed by private industry or private consensus standard-setting groups can provide greater assurance of product safety than does the present system, which reviews only the quality of a manufacturer's decision on a particular product feature.

Thus, we propose a new defense in design defect litigation—a *process defense*. If a manufacturer defends an action by revealing a well-documented safety review process, the court should presume that the product is not defective.<sup>25</sup> If the process leading to a design decision has a high degree of integrity, the court should restrict its review of the design itself to instances in which the industry has clearly erred.<sup>26</sup> In short, judicial review of a product's design should shift the emphasis from the ultimate design to the process that brought the product into existence.

## I

### PROCESS LIABILITY—INTRODUCING THE THEME

To appreciate the significance of focusing on the process of product development, one must understand the complexity of the design process, the various stages at which critical decisions are made, and the array of competing interests and points of view that affect the decisions at each stage. As the product progresses along the stages of development—from initial concept through prototype, pilot line, and final production—financial and psychological commitments are made. Theoretically, the design can be modified, its market refined, or its price altered at any stage before, or even after, initial marketing. But the quality and the nature of the decisionmaking process change significantly as the product evolves. Additional safety features required to minimize hazards may be incorporated more easily if the need is discovered and identified in the concept or prototype stages of de-

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<sup>25</sup> See pp. 375-77 *infra*.

<sup>26</sup> See note 75 and accompanying text *infra*.

velopment than if recognized during pilot line production.<sup>27</sup> Decisions that may appear reasonable as responses to design problems appearing late in the design process may be unconscionable if considered in light of the wider range of possible alternatives available in the early stages of product development. On the other hand, we may be less willing to second-guess decisions made on the basis of limited alternatives if: (1) the alternatives were carefully considered at an early stage of product development; (2) the reasons for rejecting certain alternatives are clearly articulated; and (3) few viable alternatives were available. In fact, it may not be possible to undertake comprehensive risk-utility analysis of product design, whether in developing standards, designing products, or adjudicating products liability cases, without understanding the developmental process.

It is important at this point to question how a process-based approach would relate to the developing law of products liability. When we suggest that we turn our attention to process rather than to the final product, is this a return to the negligence standard and an abandonment of the hard-fought gains of strict liability? In strict products liability, the focus is on the *product* and not on the *conduct* of the manufacturer.<sup>28</sup> Process, however, speaks to *conduct*, which is the concern of negligence standards, rather than to the end result—the *product*.

The answer is both yes and no. To the extent that we propose to examine the conduct of a manufacturer, not with regard to the quality of particular decisions, but with regard to how those decisions were made, we beat a *partial retreat even from the strictures of the negligence doctrine*.<sup>29</sup> Successful operation of the defense, however, still permits the plaintiff to attack design defects on strict liability principles, subject to an increased quantum of proof.<sup>30</sup>

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<sup>27</sup> See Westinghouse Elec. Corp., Design Review Guidelines 2 (Booklet MB-3284) (n.d.): Why have Formal Design Reviews? . . . [P]roblems detected at predetermined points in the [manufacturing] process can be corrected more quickly and economically than problems which are detected after manufacture is complete. This is true of all complex processes—including the product engineering design process.

<sup>28</sup> See Restatement (Second) of Torts § 402A (1977).

<sup>29</sup> There is considerable support for a retreat from the strict liability doctrine in several areas of design defect litigation: cases of unforeseeable and unknowable harm, see, e.g., *Robbins v. Farmers Union Grain Terminal Ass'n*, 552 F.2d 788, 794 (8th Cir. 1977); *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076, 1088 (5th Cir. 1973), cert. denied, 419 U.S. 869 (1974); *Crocker v. Winthrop Laboratories*, 514 S.W.2d 429, 432-33 (Tex. 1974); and design defect and failure-to-warn cases generally, see, e.g., UPLA, *supra* note 5, § 104(B), (C), at 62,723-25; Birnbaum, *Unmasking the Test for Design Defect*, *supra* note 1, at 643-49; Epstein, *supra* note 1, at 651-54; Hoenig, *supra* note 1, at 125-37.

<sup>30</sup> See note 75 *infra* and accompanying text.

## II

## A CONCERN WITH PROCESS—SOME EARLY STIRRINGS

Recent legislative and judicial discussions of design standards have alluded to process-oriented guidelines. If the subject has not been presented with the clarity it deserves, it is only because process analysis has yet to be identified as an independent mechanism that can play an important role in judging the efficacy of both product design and product design safety standards.

*A. Process Values and the Consumer  
Product Safety Commission*

The importance of process in setting design standards received judicial expression in *Aqua Slide 'N' Dive Corp. v. Consumer Product Safety Commission*,<sup>31</sup> which reviewed the first safety standard promulgated by the Consumer Product Safety Commission (CPSC)—the swimming pool slide safety standard.<sup>32</sup> To reduce the risk of injuries incurred when sliding headfirst into a pool, this standard required manufacturers to include a sharply worded warning about the possibility of paralysis. It also mandated a ladder chain device to prevent children from sliding into deep water. The court overturned both of these requirements on the ground that the CPSC had not supported its findings by substantial evidence on the record taken as a whole.<sup>33</sup> The court was not convinced that the proposed requirements would actually reduce the risk of injury.<sup>34</sup> It also found that the CPSC had not properly assessed the economic impact that one of the warnings might have on slide sales.<sup>35</sup>

*Aqua Slide* warrants careful analysis. At one level, the court, after having decided that the "reasonable necessity" of a provision was governed by risk-utility criteria similar to those used in tort law,<sup>36</sup> merely ruled that it was unable to make a "substantial evidence" review without risk-utility evidence.<sup>37</sup> A closer reading of

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<sup>31</sup> 569 F.2d 831 (5th Cir. 1978). Courts frequently review the decisionmaking process in many areas of administrative law. See generally Administrative Procedure Act § 10(e)(2)(A), (C)-(E), 5 U.S.C. § 706(2)(A), (C)-(E) (1976); *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 487-88 (1951) (substantial evidence review of agency adjudicatory function); *WBEN, Inc. v. United States*, 396 F.2d 601, 610-14 (2d Cir.), cert. denied, 393 U.S. 914 (1968) (arbitrary and capricious standard for rulemaking); cf. *Camp v. Pitts*, 411 U.S. 138, 142 (1973) (per curiam) (arbitrary and capricious standard for informal decisionmaking).

<sup>32</sup> 16 C.F.R. § 1207 (1980).

<sup>33</sup> 569 F.2d at 843, 844.

<sup>34</sup> Id. at 840-44.

<sup>35</sup> Id. at 842-43.

<sup>36</sup> Id. at 839.

<sup>37</sup> Id. at 839-40.

*Aqua Slide*, however, leads to the conclusion that the court was unprepared to accept the value judgments of the CPSC because the court could not gauge the process by which the decisions to impose the requirements had been reached. Despite the court's manifest discomfort with the standard, it appears that if the CPSC had presented evidence demonstrating that it had performed risk-utility balancing, the court would have been prepared to accept the Commission's conclusions. Consider the court's initial criticism of the CPSC:

Except for the brief statement of basis and purpose accompanying the promulgated rule, there is little indication of the relative weight given to various documents by the Commission. The Commission's reliance on the [National Swimming Pool] Institute [a trade organization], the Institute's deference to its consultant . . . , and the Commission's use of yet another consultant . . . make the actual thread of reasoning relied on by the agency even more difficult to follow. . . .

In this context, the duty of the Court to discern "substantial evidence on the record as a whole" requires a look at both substance and procedure. While the ultimate question is whether the record contains "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion" . . . the inability of any court to weigh diverse technical data also demands an inquiry to determine whether the Commission "carried out [its] essentially legislative task in a manner reasonable under the state of the record before [it]." <sup>38</sup>

Later in the opinion, the court again emphasized process: "[T]he Court will defer to Commission fact-finding expertise, but it can do so only when the record shows the *Commission has made an actual judgment concerning the significance of the evidence.*" <sup>39</sup>

The thrust of the opinion is clear. Substance and procedure are hopelessly intertwined when courts, lacking technical expertise, review standards that require careful evaluation of risk-utility data. The clearer the evidence is that the expert has weighed the relevant data, the more the courts will defer to his opinion. <sup>40</sup> This does not

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<sup>38</sup> Id. at 837-38 (citations omitted).

<sup>39</sup> Id. at 838 (emphasis added).

<sup>40</sup> In a common law decision that has attracted much attention, the Oregon Supreme Court addressed the importance of examining the process of the Federal Aviation Administration (FAA) in determining whether to uphold the agency's safety standard. *Wilson v. Piper Aircraft Corp.*, 282 Or. 61, 577 P.2d 1322 (1978), was a wrongful death action brought as a result of an airplane crash. The allegation of design defect was premised on the manufacturer's use of a carbureted engine rather than a fuel-injected engine. The former was subject to icing; the latter was not. Justice Linde, in his concurring opinion, made the following observations on the approval of the carbureted engine by the FAA:



mean that careful adherence to an appropriate decisionmaking process will lead to total obeisance. Rather, a thorough process that is fully explained should raise a presumption of a valid decision.

### *B. The Draft Uniform Product Liability Law*

Process analysis has been considered in legislative proposals as well as in judicial decisions. In 1979, the Department of Commerce issued a Draft Uniform Product Liability Law (UPLL)<sup>41</sup> containing provisions that accounted for both governmental and nongovernmental<sup>42</sup> safety standards. Under the UPLL, compliance with such standards would have created a presumption that the product was not defective, as long as those formulating the standards had followed certain procedures. The drafters of the UPLL solicited responses and received extensive commentary and critique on the law from industry, consumer groups, insurers, practicing attorneys, and academics.<sup>43</sup> As

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[T]his aircraft is alleged to be defective not because it fell short of the safety standards set for its type, but on the ground that these standards provide insufficient safety for the whole series. But once the common-law premise of liability is expressed as a balance of social utility so closely the same as the judgment made in administering safety legislation, it becomes very problematic to assume that one or a sequence of law courts and juries are to repeat that underlying social judgment *de novo* as each sees fit. Rather, when the design of a product is subject not only to prescribed performance standards but to government supervised testing and specific approval or disapproval on safety grounds, no further balance whether the product design is "unreasonably dangerous" for its intended or foreseeable use under the conditions for which it is approved needs to be struck by a court or a jury *unless* one of two things can be shown: either that the standards of safety and utility assigned to the regulatory scheme are less inclusive or demanding than the premises of the law of products liability, or that the regulatory agency did not address the allegedly defective element of the design or in some way fell short of its assigned task.

It is these two questions, rather than a *de novo* evaluation of the safety of a design and the technological feasibility and costs of an even safer alternative, that properly become the issues for preliminary determination by a trial court in deciding whether a "design defect" claim against a product specifically tested and approved under government safety regulations should nevertheless go to a jury. In other words, it should be defendant's burden to show that a governmental agency has undertaken the responsibility of making substantially the same judgment that the court would otherwise be called on to make; and if so, it should then be plaintiff's burden to show that the responsible agency has not in fact made that judgment with respect to the particular "defect" at issue. When the product has been tested and approved by a federal agency, these issues can normally be decided simply by examining the statutory assignment of the agency (including relevant legislative history), the further standards adopted by the agency itself, and the records and reports underlying its approval of the product.

*Id.* at 83-85, 577 P.2d at 1334-35 (Linde, J., concurring) (footnotes omitted) (emphasis in original).

<sup>41</sup> 44 Fed. Reg. 2996 (1979) [hereinafter UPLL].

<sup>42</sup> See notes 3-4 *supra* for examples of nongovernmental groups involved in setting standards.

<sup>43</sup> UPLA, *supra* note 5, at 62,714.

a result, many provisions of the UPLL were modified in the final work product, the Department of Commerce Model Uniform Product Liability Act (UPLA).<sup>44</sup> While the UPLA retained the presumption concerning governmental standards, it eliminated the presumption concerning nongovernmental standards.

Section 106(e) of the UPLL provided:

A product seller may by a motion request the court to determine whether the injury-causing aspect of the product conformed to a non-governmental safety standard having the following characteristics:

- (1) It was developed through careful, thorough product testing and a formal product safety evaluation;
- (2) Consumer as well as manufacturer interests were considered in formulating the standard;
- (3) It was considered more than a minimum safety standard at the time of its development; and
- (4) The standard was up-to-date in light of the technological and scientific knowledge reasonably available at the time the product was manufactured.

If the court makes such a determination in the affirmative, it shall instruct the trier of fact to presume that the product was not defective. This presumption may be rebutted by clear and convincing evidence that in light of factors set forth in Sections 104(B) and (C), the product was defective.<sup>45</sup>

Section 107 of the UPLL, the provision relating to governmental standards, was nearly identical to section 106.<sup>46</sup>

It is clear that the process must be examined in detail to establish whether a standard possesses the four characteristics identified in

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<sup>44</sup> UPLA, *supra* note 5.

<sup>45</sup> UPLL, *supra* note 41, § 106(e), at 2999.

<sup>46</sup> *Id.* § 107 provided:

(a) A product seller may by a motion request the court to determine whether the injury-causing aspect of the product conformed to an administrative or legislative standard having the following characteristics:

- (1) It was developed as a result of careful, thorough product testing and a formal product safety evaluation;
- (2) Consumer as well as manufacturer interests were considered in formulating the standard;
- (3) The agency responsible for enforcement of the standard considered it to be more than a minimum safety standard at the time of its promulgation; and
- (4) The standard was up-to-date in light of the technological and scientific knowledge reasonably available at the time the product was manufactured.

(b) If the court makes such a determination in the affirmative, it shall instruct the trier of fact to presume that the product was not defective. This presumption may be rebutted by clear and convincing evidence that in light of the factors set forth in Sections 104(B) and (C), the product was defective.

sections 106 and 107 of the UPLL. By what other means could a court determine, for example, if there had been "careful, thorough product testing and a formal product safety evaluation"?

Although we believe that the emphasis on process is correct, two of the authors have criticized these provisions for their failure to provide guidelines defining good process,<sup>47</sup> require extensive documentation of the process,<sup>48</sup> and establish sanctions for falsifying documentation.<sup>49</sup> We expressed the following concerns with respect to both governmental and nongovernmental standards.

The data [are] so shallow and the art of standard setting so uncertain that without a clear definition with regard to what constitutes sophisticated standard setting, we ought not to place the plaintiff in the difficult position of rebutting a presumption by clear and convincing evidence that the standard is inadequate.<sup>50</sup>

The drafters, however, did not respond to these criticisms. Instead, under the UPLA, nongovernmental standards developed after exhaustive and careful evaluation will have little legal impact on a design defect case,<sup>51</sup> while governmental standards will be deemed meaningful without regard to the process that creates them.<sup>52</sup>

### III

#### PRODUCT DESIGN—FROM CONCEPT TO MARKETPLACE

Although the UPLL and *Aqua Slide* indicated some interest in the process by which safety decisions are made, they did not address the fundamental issue of how courts should evaluate designs for which no such external safety standard exists. A process-based approach to products liability offers a solution to this problem. A court using a process approach would not simply ask whether the inclusion or exclusion of a particular design feature makes the product unreasonably dangerous. Instead, it would consider such questions as:

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<sup>47</sup> See Twerski & Weinstein, *A Critique of the UPLL*, *supra* note 19, at 241-43 (footnotes omitted). In that Article, we alluded to the possibility of evaluating the manufacturer's design safety review process as well as the standard-setting process. *Id.*

<sup>48</sup> *Id.* at 241-42.

<sup>49</sup> *Id.*

<sup>50</sup> *Id.* at 243.

<sup>51</sup> See UPLA, *supra* note 5, § 107(c), at 62,728. The UPLA eliminated § 106(e), the process defense. The analysis of § 107 likened adherence to a nongovernmental safety standard to following industry custom. The drafters believed that the varied nature of voluntary standards prevents the standards from being accorded more weight in court. *Id.* at 62,728-30.

<sup>52</sup> See UPLA, *supra* note 5, § 108(A), at 62,730-31. See note 18 *supra* for a full discussion of this section.

Who are the decisionmakers? At what stage of product development was the decision made? How was the decision made? Has the decisionmaking process been documented? These sorely neglected questions provide the starting point for our discussion of the process of product design.

An example, to be discussed in the following sections of this Article, will help to illustrate this approach. Assume that XYZ Corporation, a manufacturer of power tools, seeks to develop a single-purpose tool—a lightweight electric screwdriver for home use. How should the process be structured to ensure that safety considerations are successfully incorporated into the development of the new product?

### *A. The Concept Stage*

A product begins as an idea born of an intended use: in our example, to drive screws with less effort. Although safety considerations also must be part of the conceptual development of the product, the attention of the product designer is drawn first to the function of the tool because that is the marketable aspect of the product. Safety concerns will not rise to the forefront of design discussions unless corporate attitudes thrust it upon product designers. Yet, the failure to incorporate a broad range of safety considerations at the concept stage may exclude from the process the most innovative approaches to potential problems. If the product concept contains unacceptable elements of danger, it should be abandoned before the manufacturer expends significant human and financial resources to develop it.

For example, suppose that in the concept stage of the electric screwdriver's development, the manufacturer decides to use a standard chuck to receive the screwdriver bits, without seriously considering the safety implications of that decision. The product then progresses to the pilot line stage. When tooling is already on line, and purchasing commitments have been made, someone realizes that many tools made for electric drills can also be inserted into the standard chuck. The potential hazards arising from using the screwdriver as a drill, grinder, sander, or polisher, when the basic design did not consider these uses, are frightening.

At this stage in the product's development the only feasible safety measure may be including an ineffective warning label with enormous liability potential.<sup>53</sup> Yet, had the manufacturer recognized

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<sup>53</sup> In a failure-to-warn case, the court evaluates whether the warning adequately informs the user of the high danger potential of the product. See *Jackson v. Coast Paint & Lacquer Co.*, 499 F.2d 809, 811-13 (9th Cir. 1974); *Murray v. Wilson Oak Flooring Co.*, 475 F.2d 129, 132-33

this safety problem during the concept stage, it might have been able to design a new and simple chuck that would accept only a specially designed head on the screwdriver bits, thereby eliminating the use of any other tools. The new chuck might have been less expensive and would have had the ancillary benefit of accepting only the manufacturer's screwdriver bits, thus ensuring a ready market for replacements. On the other hand, had it become apparent during the concept stage that a single-purpose chuck could not have been designed within the cost limitations, the potential hazards of marketing a tool whose use could not be controlled to ensure reasonable safety might have led the manufacturer to abandon the project.

For the design safety review process to be effective, a broad range of disciplines must interact, thereby allowing consideration of all perspectives on product design that influence safety decisions.<sup>54</sup> It is not possible to list all the groups that should be involved in the safety review process because safety considerations will differ depending on the special problems inherent in each industry or product line and because there are tens of thousands of products on the market. An illustrative assortment of specialists who should be involved in the safety review process includes: (1) a design engineer; (2) a marketing representative; (3) a test engineer; (4) a service representative; (5) a quality control engineer; (6) a production engineer; and (7) consultants or specialists in areas such as human factors, psychology, and technical writing.

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(7th Cir. 1973); *Burch v. Amsterdam Corp.*, 366 A.2d 1079, 1084, 1086-88 (D.C. 1976). Even if the warning is adequate, it is still necessary to determine whether the only realistic method of reducing the danger potential is through such a warning. A sharply worded warning will not always absolve the manufacturer of liability. See *Uloth v. City Tank Corp.*, \_\_\_\_ Mass. \_\_\_, 384 N.E.2d 1188, 1192 (1978); Noel, *Manufacturer's Negligence of Design or Directions For Use of a Product*, 71 Yale L.J. 816, 844-47 (1962); Twerski, Weinstein, Donaher & Piehler, *The Use and Abuse of Warnings*, *supra* note 1, at 506-07.

<sup>54</sup> To develop this sensitivity and commitment to product safety from concept to production, some innovative corporations have instituted safety design review procedures that begin at the concept stage and continue through to the prototype and production stages. See A. Weinstein, H. Piehler, W. Donaher & A. Twerski, *Final Report to National Science Foundation (NSF)*, app. I, at 86 (August 1980) (Research Grant no. APR. 76-18490) [hereinafter *Final Report*]. In some companies, the safety assignment is delegated to a committee with special and continuing responsibility for identifying the safety problems in the entire product line. See *id.* In others, the safety aspect is part of the responsibility of those engaged in the design of a specific product. See *id.* at 126, 134. Once completed, however, the design specifications usually are reviewed by a committee of specialists who are not members of the actual project team but are drawn from parallel groups within the company. See *id.* at 94, 111, 134-35.

The thoroughness and intensity of design safety review procedures vary significantly from company to company. It is important to note that the documentation of the design safety review process in the companies studied under the NSF grant did not meet the standards suggested by the authors. See *id.* at 97-103, 115-21, 132-33, 145-46.

It might appear that representatives of some of these disciplines are unnecessary to design safety review. Why, for example, should such a review include marketing, service, and quality control experts? The answer is suggested in part by reference to the hypothetical electric screwdriver to be marketed for home use. If young teenagers or older adults of both sexes comprise a significant part of the market for the screwdriver, the manufacturer must consider the needs of these groups in designing features such as the grip on the tool, the operating switch, accessibility, and ease of use. It is important also that the safety review process include an evaluation of the impact of safety features on the saleability, service, or production of the product. If the marketing division assesses the need for safety features only after significant investment has been made in pilot line or final production tooling, there may be fewer choices available. The serviceability of a tool and the likelihood that it will be the subject of amateur repair also must be assessed during the safety review process. It may be necessary to design parts not only to be fail-safe, but to fail in such a way that a consumer cannot repair the tool by minor tampering that could cause the product to fail catastrophically at a later point. Quality control information must also be included in the safety review process to ensure that the integrity of the tool is reproducible on the production line. An assessment of the quality control necessary to meet the desired standard for product integrity may lead to the choice of one design alternative over another. Ultimately, these confrontations among disciplines put the product to the test of meeting competing concerns within the parallel constraints of function, safety, marketability, serviceability, and cost.

### *B. From Prototype to Production*

The safety audit process does not end in the concept stage. The same product safety committee should undertake similar comprehensive reviews of the product at least twice more: at the prototype and pilot line production stages of product development.

During the prototype stage, a structured review of the design using a failure mode and effects analysis<sup>55</sup> may be necessary. This review may reveal safety problems that might arise from the failure of

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<sup>55</sup> A failure mode and effects analysis is a structural analytical technique that assesses the probabilities of failure for each element of a product and traces the subsequent probabilities of hazards or risks that can arise from each such failure. See, e.g., S. Halpern, *The Assurance Sciences: An Introduction to Quality Control and Reliability*, ch. 8 (1978). See generally B. Armstadter, *Reliability Mathematics: Fundamentals, Practices, Procedures*, chs. 9-10 (1971); N. Enrick, *Quality Control and Reliability* (1972).

product components. For example, the particular routing or attachment of electrical wires within our hypothetical screwdriver may expose the wires to rubbing or loosening, either of which may cause a shock hazard. At this point, the manufacturer must decide whether to alter the product design or implement more stringent quality control procedures, such as formal inspection of each product to ensure proper routing of the wires or tightening of the terminals to minimize the hazard. As in the concept stage, the trade-offs between a more costly design change and a more expensive quality control procedure can be argued and resolved more efficiently if all disciplines address the problems concurrently.

Because safety concerns will depend on the problems inherent in different products, it is not possible to articulate all the questions that a safety committee must address. At a minimum, the following considerations should be incorporated into the review:<sup>56</sup> (1) the scope of product uses; (2) the environments within which the product will be used; (3) the user population; (4) all possible hazards, including estimates of probability of occurrence and seriousness of resulting harm; (5) alternative design features or production techniques that could mitigate or eliminate the hazards; (6) warnings and instructions that could be used to minimize hazards and the manner in which these should be formulated to be most effective;<sup>57</sup> and (7) evaluations of alternative design features in light of the expected performance standards of the product. In turn, some factors relevant to this seventh consideration are: the creation of hazards that may be associated with a specific alternative; the effect of the alternatives on the usefulness of the product; the effect of the alternatives on the ultimate cost of the product; and comparison to similar products.

No one has yet formulated, nor is there likely to exist, an exact method for measuring the importance of individual criteria or for weighing the trade-offs. Indeed, the very process of identifying hazards and product misuses requires basic data, experience, brainstorming, and scenario-building by the safety review team. To the extent that input into any part of the design process is limited

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<sup>56</sup> See A. Weinstein, A. Twerski, H. Piehler & W. Donaher, *Products Liability and the Reasonably Safe Product*, ch. 10 (1978).

<sup>57</sup> The authors' investigation into the practices of product safety committees in major corporations reveals a surprising lack of attention paid to the effective formulation of warnings and instructions. Usually the task is left to a technical writer and reviewed by the project engineer, neither of whom is representative of the person who will use the product. There is no actual testing of the comprehension levels of the persons who will use the product, and there is no analysis of the literature available from educational sources. See Final Report, *supra* note 54, at 121-22.

and narrow, the process will reflect that shallowness. Thus, good process implies not only a structure of decisionmaking but also comprehensive evaluation of all safety considerations.

#### IV

##### DOCUMENTATION

Product safety review on an ad hoc, product-by-product basis probably will continue to be the manufacturer's approach to product safety. The strength of this approach is that it permits an in-depth and free-flowing inquiry into product safety. Because the process has so little formal structure, however, the nature of the decisionmaking and the reasons for the decisions should be readily accessible. Documentation serves this purpose in several ways. First, it allows the design safety review group to examine its risk-utility formulation at a later stage of product development when field-use information on the product is available. The group can, thus, monitor the efficacy of the decisionmaking process and fine-tune the process, thereby permitting its use by subsequent safety review groups and other professional staffs not directly involved in the task of review. Second, documentation aids reevaluations of the initial decisionmaking process, which may be triggered by serious complaints about a product. Third, documentation is a valuable source of decisionmaking information for industry-wide discussion<sup>58</sup> on the development, utilization, and refinement of in-house product safety review methodology.<sup>59</sup>

Admittedly, there are some dangers to documenting the design process. The potentially damaging impact of documenting safety trade-offs is readily apparent in light of the adversarial nature of

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<sup>58</sup> Conducting such discussions should not expose manufacturers to liability under the anti-trust laws. The industry-wide exchange of nonprice data sometimes can constitute an unreasonable restraint of trade, see L. Sullivan, *Handbook of the Law of Antitrust* § 97, at 274 (1977), and exchange of safety review methodology could, if it engendered uniformity of safety features, remove one element of product differentiation. Unless a clear anticompetitive effect could be demonstrated, however, the safety benefits of the exchange should suffice to protect the exchange under rule of reason analysis. In the context of vertical restraints on resale, practices more overtly anticompetitive than exchanges of product safety review data, the Supreme Court has stated that restraints designed to promote product safety can be approved if "they have no anticompetitive effect and . . . they are reasonably ancillary to the seller's main purpose of protecting the public from harm or itself from product liability." *National Soc'y of Professional Eng'rs v. United States*, 435 U.S. 679, 696 n.22 (1978) (dictum); accord, *Tripoli Co. v. Wella Corp.*, 425 F.2d 932, 938 (3d Cir.), cert. denied, 400 U.S. 831 (1970); see *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 55 n.23 (1977).

<sup>59</sup> See A. Weinstein, A. Twerski, H. Piehler & W. Donaher, *supra* note 56, at 142-44 for a discussion of the documentation appropriate to the design review process.



products liability litigation.<sup>60</sup> A manufacturer may fear that introducing such documents would unduly influence a jury if a manufacturer considered and then rejected safety features that would have caused a significant increase in costs while providing little additional safety. Furthermore, since safety features and the response to them are a matter of intense competition in many industries, a manufacturer may fear that disclosure of decisionmaking documents would threaten its product's marketability.<sup>61</sup> The risk of both liability exposure and increased competition may seem sufficiently great to render the idea of documenting all stages of product safety decisions an idealistic dream of ivory tower academics.

Yet, the risks of failing to record the process are even greater. The lack of meaningful data seriously hampers the investigation of product-related injuries by agencies or by industry itself. Although government's attempts to gather more data and make it available to industry<sup>62</sup> are worthwhile, raw data alone will not make corporate

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<sup>60</sup> The recent criminal prosecution of the Ford Motor Company in Indiana for defective design of the gasoline tank of the Pinto is the most publicized example of the use of in-house memoranda to damn a company for having made a cost-related safety decision. See *Stato v. Ford Motor Co.*, No. 79-5324 (Ind. Super. Ct., filed Feb. 2, 1979). The information gleaned from one memorandum which first surfaced in civil litigation in California revealed that Ford had known of the crashworthiness problems of the Pinto but had retained its original design because of cost factors. See *Grimshaw v. Ford Motor Co.*, No. 19-77-61 (Cal. Super. Ct., filed Feb. 6, 1978).

<sup>61</sup> In camera inspection or protective orders, however, may be used to protect trade secrets. See, e.g., Fed. R. Civ. P. 26(e).

<sup>62</sup> Many federal regulatory statutes provide for the reporting of raw data concerning safety-related defects. See, e.g., 16 C.F.R. pt. 1605 (1980) (regulation promulgated under Flammable Fabrics Act of 1953); 33 C.F.R. pt. 179 (1979) (regulation promulgated under Federal Boat Safety Act of 1971); 49 C.F.R. pt. 573 (1979) (regulation promulgated under National Traffic and Motor Vehicle Safety Act of 1966). The Consumer Product Safety Act of 1972 mandates the establishment of an Injury Information Clearinghouse to assemble and analyze injury data. 15 U.S.C. § 2054(a) (1976).

The most significant aspect of the Clearinghouse is the National Electronic Injury Surveillance System (NEISS). NEISS is a computerized data collection system connected to a large number of hospital emergency rooms throughout the United States. When an injury attributable to a consumer product is treated at one of these emergency rooms, the information is compiled along with details about the type of product involved and the severity of the injury. The CPSC Bureau of Epidemiology also performs in-depth studies on product categories that appear to create major hazards.

Yet, despite such available data, few agencies require interpretive or evaluative reports. One agency that appears to require such reporting is the Food and Drug Administration (FDA). See 21 U.S.C. § 355 (1976). This section has a definite emphasis on process. Many of the reasons for rejecting a new drug application turn on determination by the FDA that the applicant has not performed adequate testing of the drug, has used inadequate methods in manufacture and packing, or has not fully documented the test results. See 21 U.S.C. § 355(d) (1976); *Ubiotica Corp. v. FDA*, 427 F.2d 376 (6th Cir. 1970) (rejecting application for new drug for treatment of mongolism). Conclusions drawn from the drug area, however, for the most part do not apply to the products field as a whole. The research pattern for drugs is more settled and

decisionmakers more responsive to safety hazards. Such responsiveness depends on decisionmakers' having access to the interpretive reasoning of those who have translated sparse data into design changes, access that depends in turn on careful documentation of the decisionmaking process. It is simply folly to sacrifice the most significant source of safety information—carefully documented risk-utility product design analysis—because of concerns about business competition and liability exposure.

A second consideration compels comprehensive risk-utility documentation of the design process. Although documentation may be expensive for the manufacturer in the short run, we believe that in the long run documentation of the safety review process will reduce costs. As a practical matter, the onus of product design justification in products liability cases is now on the manufacturer.<sup>63</sup> Those

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has greater acceptability in the scientific community than the research pattern for most other products. See Shapo, *Public Regulation of Dangerous Products*, ch. 6 (1980). See generally Rheingold, *Products Liability—The Ethical Drug Manufacturer's Liability*, 18 *Rutgers L. Rev.* 947 (1964). The Toxic Substances Control Act, 15 U.S.C. §§ 2601-2629 (1976), regulates the manufacturing of chemical substances and mixtures, id. § 2601, and mandates documentation and reporting of test data concerning new chemical substances or mixtures, id. §§ 2604(a), (b), 2607(a)-(d); see 44 Fed. Reg. 59,763 (1979) (proposed rule).

<sup>63</sup> In *Barker v. Lull Eng'r Co.*, 20 Cal. 3d 413, 431-32, 573 P.2d 443, 455, 143 Cal. Rptr. 225, 237-38 (1978), the Supreme Court of California shifted the formal burden of proof from the injured plaintiff to the manufacturer to demonstrate that a product is not defective in design after the plaintiff had made a prima facie showing that the product's design had proximately caused his injury. The court's position has engendered vociferous criticism. See, e.g., *Wilson v. Piper Aircraft Corp.*, 282 Or. 411, 413, 579 P.2d 1287, 1287 (1978); Epstein, *supra* note 1, at 650-52; Keeton, *Products Liability—Design Hazards*, *supra* note 1, at 303-11.

One should not be blinded by the *Barker* burden-of-proof controversy to the realities of design defect litigation. Even without a formal shift of the burden of proof, practicality demands that the manufacturer come forward with evidence of design justification. Professor Gary Schwartz has described the pre-*Barker* trial procedure as follows:

[T]he plaintiff introduced evidence establishing the existence of a feasible design alternative that would have prevented his injury. At this point, whatever the law said, some juries expected the manufacturer to introduce whatever evidence it possessed showing that the plaintiff's design proposal would not have been a good idea—that it would have been too costly, would have unduly interfered with the product's performance, would have created additional safety hazards, or whatever. The jury's expectation in this regard obviously grew out of its intuitive perception of the sound access-to-information burden-of-proof criterion. Yet since the resulting practice also spared the manufacturer the obligation of proving a negative, it equally complied with the other valid criterion. Also, it avoided any overburdening of the proximate cause concept. So long as judges are willing to enter directed verdicts when the manufacturer's trade-off evidence is strong enough, this . . . pre-*Barker* practice seems an intelligent, balanced solution to the burden-of-proof problem . . . [T]he *Barker* rule should be either modified or "interpreted" to provide for its legalization. That is, once the plaintiff identifies a feasible design alternative which would have prevented his injury, the responsibility should rest on the manufacturer to show why that alternative would not have been risk-beneficial.

Schwartz, *Foreword: Understanding Products Liability*, *supra* note 1, at 470-71 (footnotes omitted).

manufacturers able both to document the complexities of design decisions and to demonstrate the sensitivity and intelligence of their decisionmaking processes generally have fared well at trial.<sup>64</sup> Thus, information evidencing careful deliberation is not only a sword for use against the manufacturer but also a shield against the costs of liability arising from improvident decisions.

Furthermore, the manufacturing community is concerned with government's moving from generic standard-setting to addressing itself to the details of individual product design and quality control. The spectre of this kind of governmental involvement already has caused great consternation.<sup>65</sup> To counter such official involvement, industry will have to demonstrate that its method of design evaluation has integrity. It will have to document the details of its decisionmaking process and demonstrate that it is attacking design problems with thoroughness and integrity. Government may not be satisfied with the results in every instance, but it is not likely to intrude for marginal gains. If, however, government is not convinced that the process is thorough, it will impose additional regulations that are both detailed and restrictive. Although documentation may pose immediate risks to manufacturers, in the long run both manufacturers and consumers will benefit from documentation of safety standard-setting that reveals the data, its interpretation, and the reasons for the decisionmaking.

One matter is certain. Unless the process of data interpretation is revealed, we shall gain precious little from the data that is vital to standard-setting. Industry will lack the data it needs to design the best new products or to redesign existing products. Governmental standard-setters will not, except in rare instances, be able to amass the resources to duplicate efforts of the private sector. Thus, if industry, under current standards of products liability law, fails to be sufficiently attentive to process, we must either provide a mechanism for revealing the decisionmaking and interpretive processes of the private sector or reconcile ourselves to the present system in which product judgments and safety standards are made largely in the dark.

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<sup>64</sup> See, e.g., *Hagans v. Oliver Mach. Co.*, 576 F.2d 97, 99-101, 103-04 (5th Cir. 1978) (defendant manufacturer of a power saw presented extensive documentation that the product exceeded industry safety practices as well as national and associational safety standards, that very few other manufacturers included such a guard in their designs, that no manufacturer produced a saw with a permanently affixed guard, and that a permanently affixed guard would undermine the saw's usefulness); *Garst v. General Motors Corp.*, 207 Kan. 2, 19-23, 484 P.2d 47, 53-63 (1971) (defendant manufacturer of earth-moving equipment presented highly technical and thorough documentation that other manufacturers were using similar designs; that a safer and feasible design was unknown; and that there had been adequate testing of the product).

<sup>65</sup> See note 17 *supra*.

## V

INDUSTRY, VOLUNTARY, AND  
GOVERNMENTAL STANDARDS

The standards set by governmental agencies,<sup>66</sup> private groups,<sup>67</sup> and trade associations<sup>68</sup> provide basic guidelines for product design for many major manufacturers. Even more importantly, smaller members of particular industries tend to rely on these standards as both minimum and maximum requirements for their products. Significantly, design defect litigation often calls attention to these standards.<sup>69</sup>

If the emphasis on process is correct, the standard-setting mechanisms of both governmental and private institutions will require the sort of scrutiny suggested above for industry.<sup>70</sup> The process of decisionmaking in the development of these standards will have to be documented so that its comprehensiveness and integrity can be evaluated and its efficacy judged. If a manufacturer—particularly a small one with little capacity for in-house design review—relies on such a standard and injury nevertheless results from a risk addressed by the standard, the ensuing litigation must focus on the efficacy of the standard itself. Unless those responsible for setting the standard come forward to demonstrate the comprehensiveness and integrity of the process by which the standard was developed, no determination of the issue of design defect can be made.

The same fears that motivate industry to bury its deliberative process<sup>71</sup> may, of course, affect private standard-setting groups and trade associations. If these groups and associations are to be a major source of standards for product litigation, however, they will have to reveal their decisionmaking processes. The fear that industry domina-

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<sup>66</sup> See note 2 *supra*.

<sup>67</sup> See note 3 *supra*.

<sup>68</sup> See note 4 *supra*.

<sup>69</sup> See *Simien v. S.S. Kresge Co.*, 566 F.2d 551, 557 (5th Cir. 1978) (standards of Flammable Fabrics Act); *Jones v. Hittle Serv., Inc.*, 219 Kan. 627, 630-31, 549 P.2d 1353, 1359 (1976) (standards of National Fire Protection Association); *Heise v. J.R. Clark Co.*, 245 Minn. 179, 184, 71 N.W.2d 818, 822 (1955) (rules of American Standard Safety Code); *McDaniel v. McNeil Laboratories, Inc.*, 196 Neb. 190, 199-201, 241 N.W.2d 822, 828 (1976) (standards of FDA); *Grammer v. Kohlhaas Tank & Equip. Co.*, 93 N.M. 685, 689-90, 604 P.2d 823, 827-28, 839 (1979) (standards of American Society of Mechanical Engineers); *Valentine v. Conchemco, Inc.*, 588 S.W.2d 871, 873 (Tenn. Ct. App. 1979) (standards of national Electrical Code). See generally Philo, *Use of Safety Standards, Codes and Practices in Tort Litigation*, 41 *Notre Dame Law. J.* 1, 7-10 (1965) (admissibility in evidence of safety codes, standards, and practices in negligence actions).

<sup>70</sup> For the legal effect currently given to governmental standards in products liability litigation, see discussion note 18 *supra*.

<sup>71</sup> See text accompanying notes 60-61 *supra*.

tion will merely perpetuate self-interest can be dispelled only by a process that involves a balanced and informed consensus and is given a high degree of visibility.

Even if standard-setters employ good procedures, however, they cannot provide an adequate substitute for well-developed and well-articulated in-house product safety review process. Externally set standards, whether established by government or voluntary standard-setting organizations, cannot focus on the full set of specific design considerations that industry uses to evaluate each aspect of a proposed product design. We do not mean to imply that governmental or voluntary standard-setting agencies that address generic issues of design safety do not play an important role. On the contrary, such external standard-setters will continue to be helpful in developing a baseline for product safety, but external standards cannot address all the risks posed by individual product designs. Moreover, broad standards tend to stifle ingenuity and creativity. Thus, although the individualized products will have to conform to agency standards, product safety must depend primarily on encouraging manufacturers to establish and carefully document their in-house product safety review processes.

## VI

### THE PROCESS LIABILITY PROPOSAL

The proposed legislative and judicial approaches to controlling design defect litigation have failed to recognize the central importance of encouraging good risk-reduction decisions. Instead, these proposals have focused on either excluding certain cases from the litigation process entirely<sup>72</sup> or providing manufacturers with additional defenses or presumptions of no defect that do not bear any relation-

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<sup>72</sup> For example, statutes of repose place an outside limit on the number of years from time of manufacture or sale within which a products liability action can be brought. See, e.g., *Ariz. Rev. Stat. Ann.* § 12-551 (Supp. 1957-1979); *R.I. Gen. Laws* § 9-1-13(b) (Cum. Supp. 1979); *S.D. Comp. Laws Ann.* § 15-2-12.1 (Supp. 1979); *Utah Code Ann.* § 78-15-3(1) (1977); UPLA, *supra* note 5, § 110(B), at 62,732.

Our proposal differs sharply from that of Professor Henderson, who suggests that all conscious design choice cases be removed from the litigation scene. See Henderson, *Judicial Review of Manufacturers' Conscious Design Choices*, *supra* note 1, at 1534. We took issue with the Henderson thesis, contending that the fact that the design choice was conscious did not mean that safety was a significant factor in the manufacturer's decisionmaking. Twerski, Weinstein, Donaher & Piehler, *The Use and Abuse of Warnings*, *supra* note 1, at 528. Our proposal demands that a court be fully apprised of whether a comprehensive review was central to product development. Absent such a perspective we see no reason for absolving a defendant of the consequences of its design choices.

ship to risk-reduction.<sup>73</sup> The plaintiffs' bar and consumer groups have attacked such proposals as unjust infringements of a process that has improved product safety.<sup>74</sup> Indeed, the proposals offer no guidance to manufacturers concerning the quality of their product decisions.

Our solution is not to remove some design defect cases from the courts, but instead to enable manufacturers to focus judicial inquiry on their decisionmaking processes. Under our proposal, a manufacturer could raise either a traditional defense or a defense based on process. Under a traditional defense, a manufacturer would argue that the challenged design feature was reasonable. The plaintiff's legal burden then would be to establish by a preponderance of the evidence that the design was defective. Alternatively, we would allow the defendant to reveal his entire safety review process. If the court determines that this process properly accounted for safety considerations, the resulting design is deemed presumptively nondefective. Such a presumption could be rebutted by evidence that the design is in fact defective. To assure the manufacturer whose process has integrity that close design decisions will not find their way to the jury, the plaintiff would be able to rebut the presumption only by producing clear and convincing evidence.<sup>75</sup>

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<sup>73</sup> Examples of such defenses and presumptions include: (1) a state of the art defense limiting a manufacturer's responsibility to safety features available or in use at the time of manufacture or sale, see note 10 *supra* and UPLA, *supra* note 5, § 107, at 62,728-29; (2) compliance with statutory standard as a defense to a design defect case, see note 10 *supra*; (3) a defense for unforeseeable misuse, see note 10 *supra*; and (4) a rebuttable presumption of no defect or a defense when there is unforeseeable alteration by someone other than the defendant, see notes 10-11 *supra*.

<sup>74</sup> See, e.g., Hearings Before the Senate Select Committee on Small Business on Product Liability Problems Affecting Small Business, 94th Cong., 2d Sess. 1584-97 (1976) (statement of Ralph Nader); Birnbaum, *Legislative Reform or Retreat? A Response to the Products Liability Crisis*, 14 Forum 251, 271-86 (1978); Johnson, *supra* note 5, at 680-92.

<sup>75</sup> A judge will direct a verdict for the defendant if the plaintiff fails to produce sufficient evidence such that a reasonable juror could find, by clear and convincing evidence, that the design was defective. See McCormick's Handbook of the Law of Evidence § 338, at 789-90 (2d ed. E. Cleary 1972).

The burden placed on the plaintiff will be twofold. The plaintiff must go forward with clear and convincing evidence and must persuade the jury by clear and convincing evidence. The first burden is that of producing evidence, satisfactory to the judge, of a particular fact in issue. The second is the burden of persuading the trier of fact that the alleged fact is true. See *id.* § 337, at 783-84. One might ask why we are changing the required level of proof if we are really attempting to alter the standard of liability. Our answer to this question is based on the extensive criticism concerning the difficulties in defining gross negligence and in distinguishing gross negligence from negligence. See W. Prosser, *supra* note 18, § 34, at 182; Green, *High Care and Gross Negligence*, 23 Ill. L. Rev. 4, 11, 17-29 (1928). Rather than adding to the existing confusion surrounding the definition of design defect by creating a standard of "gross" design defect, we have chosen to raise the evidentiary standard.

As our criticisms of the UPLL indicate,<sup>76</sup> process considerations should not be integrated into products liability law unless there is a clear understanding of the contours of good process. We have, therefore, discussed the stages of product design and the considerations that the manufacturer should take into account at each stage.<sup>77</sup> To meet our good-process standards, a defendant would have to show that the safety review process was thorough; that it analyzed the product at each critical stage of design; that it involved interaction among all the essential disciplines; that it honestly considered all relevant information and data; and that it carefully documented the entire process including the rationales for decisions on safety-related product features.<sup>78</sup>

Our proposal is both fair to and demanding of manufacturers. If the manufacturer decides to use the process defense, he must be willing to open his files completely to judicial scrutiny. Documentation at every stage of the decisionmaking process is essential since it provides the interpretive data for understanding design decisions.

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It may appear at first blush that we are recreating the burden-of-proof problem spawned by *Barker v. Lull Eng'r Co.*, 20 Cal. 3d 413, 432-33, 573 P.2d 443, 453, 143 Cal. Rptr. 225, 237 (1978), in which the California Supreme Court held that once the plaintiff makes a prima facie showing that the injury was proximately caused by the product design, the burden shifts to the defendant to establish that its product was reasonably safe. Professor Gary Schwartz has taken the *Barker* court to task on this point. He contends:

The heart of the problem is this: one simply cannot talk meaningfully about a risk-benefit defect in a product design until and unless one has identified some design alternative (including any design omission) that can serve as the basis for a risk-benefit analysis. If the *Barker* rule is read literally, however, it fails to require the plaintiff even to point to an alternative of this sort. Within the burden-of-proof jurisprudence, one respected canon is that the burden should be placed on the party who has control of or access to the relevant information; this is the canon upon which *Barker* properly relies. But another respectable canon is that the burden of proof should not be placed so as to require a party to prove a negative. This canon the *Barker* rule violates.

Schwartz, *supra* note 1, at 468 (footnotes omitted).

By requiring the defendant to establish a comprehensive process, our proposal might be read to require the manufacturer to negative every possibility of defect in the entire product. Admittedly, requiring the defendant to establish every aspect of the process with regard to every feature of the product would impose a heavy burden on the defendant. Our proposal, however, does not require such an undertaking. The manufacturer is not required to prove a negative, but only to convince the court of the comprehensiveness of the process and demonstrate how the process led to the particular design decision in question. Process thus is a defense to a specifically focused allegation of design defect. We suggest that the process defense presented in this paper may, in fact, provide a rational reading of the *Barker* opinion itself. The thrust of the defense is to require the defendant to explain risk-utility trade-offs by going beyond the narrow focus of the immediate design decision to affirmative proof of the integrity of the design process.

<sup>76</sup> See Twerski & Weinstein, *A Critique of the UPLL*, *supra* note 19, at 241-43; text accompanying notes 47-50 *supra*.

<sup>77</sup> See pp. 365-69 *supra*.

<sup>78</sup> See pp. 369-72 *supra*.

Additionally, the requirement that every stage of the process be documented provides a safeguard against abuse of the process approach. Other safeguards against abuse could include punitive damages for falsifying documentation.<sup>79</sup>

We have created a presumption that would shift both the production and persuasion burdens to the plaintiff after the manufacturer demonstrates good process because we believe that good process promotes good design decisions. A manufacturer that considers the full range of design alternatives is more likely to select the best design because it is more likely to be aware of potential hazards associated with any particular product. Unless a hazard is justified by increased utility, the manufacturer will choose a design that avoids that hazard. And the very circumstances under which a design would be so justified are those in which a risk-utility analysis probably would find the product nondefective.

The analysis of process that we propose is only in a limited sense a test of the manufacturer's conduct. If the process fails the test, for whatever reason, the product may or may not be unreasonably dangerous as decided by the jury on the basis of the alleged defect. When the process is valid, however, its validity rests not so much on the reasonableness of the specific design feature chosen, but on the fact that the process focused precisely on the premise of strict liability—considering the product in the real environment of its use.

If we are correct in our belief that good process promotes good design decisions, bad process should produce poor design decisions. Thus, evidence of bad process should create a presumption of defect. Although an in-depth analysis of the plaintiff's use of process is beyond the scope of this Article, the possibilities range from a permissible inference to a rebuttable presumption of defect that would shift the burdens of production and persuasion.

One further issue must be addressed: we believe that judges applying our proposal should reserve to themselves the question whether the manufacturer's process is sufficient to raise a presumption of no defect. Although this is not mandated by the process proposal, we believe there are compelling reasons supporting determination of the process defense by judges.

If the process proposal is to succeed in encouraging better risk-reduction decisions, we must provide manufacturers with specific guidelines on what constitutes good process. Feedback on the specific elements of good process with respect to particular products or indus-

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<sup>79</sup> See generally Note, *In Defense of Punitive Damages*, 55 N.Y.U.L. Rev. 303 (1980).



tries is important to ensure that manufacturers establish good safety review processes. A general jury verdict provides none of this information, and special interrogatories and special verdicts have been criticized on the ground that they may produce inconsistent results.<sup>80</sup> The prospect of inconsistent results is especially problematic in light of our goal of giving manufacturers guidance on how to style their safety review processes. A judge could, however, provide manufacturers with feedback by writing detailed findings and conclusions which would not pose the problem of inconsistent results.

There is another compelling reason for submitting the process defense to the judge. The purpose of the process presumption is to encourage manufacturers to adopt careful procedures for reviewing product safety. But if evidence regarding the manufacturer's full range of safety decisions is heard before the jury, such evidence may prejudice the jury's consideration of design questions. The threat of such prejudice could lead manufacturers to adopt a traditional defense, thereby undermining the effectiveness of the new defense.

The problem may be illustrated by returning to our hypothetical screwdriver.<sup>81</sup> Assume that the screwdriver is equipped with a slide switch to turn the tool on and off. This switch does not require the user to apply continuous pressure. Assume further that a purchaser of a screwdriver is injured when he drops the screwdriver and it continues to turn. The plaintiff will try to prove the availability of alternative designs that would have reduced the risk of injury; any alternative that was clearly infeasible, however, would be irrelevant to the question of defective design and therefore would not be admissible into evidence. Nonetheless, consideration of such an alternative is relevant to the issue of good process. For example, the manufacturer may have considered providing a spring-loaded pushbutton switch, which requires continuous pressure, to reduce the risk of injury. After careful evaluation, the manufacturer may have rejected this option for a combination of reasons, including long-term performance, use by older people, ease of repair, cost, and quality control concerns. Although evidence that the manufacturer evaluated infeasible alternatives is an integral part of demonstrating good process, it is not relevant to proving defective design. And, although a jury could be instructed to ignore evidence of the rejection of the safety device when deciding the design defect issue, there is a risk that this evi-

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<sup>80</sup> See *Hand v. United States*, 441 F.2d 529, 530-31 (5th Cir. 1971); *Missouri Pac. R.R. v. Salazar*, 254 F.2d 847, 847-48 (5th Cir. 1958); Note, *Special Verdicts: Rule 49 of the Federal Rules of Civil Procedure*, 74 Yale L.J. 484, 498-501 (1965).

<sup>81</sup> See p. 365 *supra*.

dence would influence the jury in its decision on design defect. This would be especially prejudicial if the manufacturer rejected the alternative as infeasible because it was too costly.

To further illustrate this problem, assume that an adult suffers an injury that could have been avoided by use of a specific safety device. In addition, assume that during the concept stage the manufacturer considered marketing the screwdriver for use by children. Although a risk-utility analysis conducted at that stage indicated that the safety device should be included in the product design, the manufacturer decided not to employ the device when it rejected the idea of marketing the screwdriver for use by children. Again, these decisions would be revealed if the manufacturer unveiled its decisionmaking process; they may not be relevant, however, to a decision concerning the reasonableness of the ultimate design—a screwdriver marketed for use by adults. Nonetheless, the risk of influencing the jury in its resolution of the design defect question might deter the manufacturer from raising the process defense. To avoid the unfair prejudice that could result from permitting the jury to hear such process evidence, judges should decide the process defense.<sup>82</sup>

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<sup>82</sup> We believe the judge's determination of the process defense does not offend the parties' right to a jury trial, as guaranteed by the seventh amendment, see U.S. Const. amend. VII, most state constitutions, e.g., Conn. Const. art. I, § 19; Me. Const. art. I, § 20; S.D. Const. art. VI, § 6; see 50 C.J.S. Juries § 10a (1947 & Cum. Supp. 1950); F. James & G. Hazard, *Civil Procedure* 347 (2d ed. 1977), and some state statutes and rules, see, e.g., Colo. R.C.P. 35; Wyo. R.C.P. 38.

Submitting the process defense to the judge is consistent with the general tendency of judicial control in design defect litigation. Professor Wade has argued that design defect cases fall in the middle of the spectrum between cases involving strict liability for abnormally dangerous activities and negligence cases. Wade, *On Strict Liability*, *supra* note 19, at 835-39; see *Phillips v. Kimwood Mach. Co.*, 269 Or. 485, 498-501, 525 P.2d 1033, 1039-40 (1974); *Roach v. Kononen*, 269 Or. 457, 461-65, 525 P.2d 125, 127-29 (1974). The decision that an activity is abnormally dangerous is made by the judge as a matter of law because social policy issues are involved in the determination that an entire class of activity falls outside the fault system. See Wade, *On Strict Liability*, *supra* note 19, at 838. See generally *Restatement (Second) of Torts* § 520 (comment 1) (1977). However, in negligence cases, the jury decides the issue of standard of care, a more factual determination which does not involve the same balancing of policy concerns. See Wade, *On Strict Liability*, *supra* note 19, at 838. Professor Wade argues that policy issues become important in design defect cases because they involve the classification of a whole group or type of products as unsafe due to the nature of the design. See *id.* Wade also distinguishes between design defect cases and production defect cases, arguing that production defect cases present more factual issues, do not involve broad social policy concerns, and are thus more suitable for jury determination. See *id.* On the other hand, Professor Wade argues, design defect cases lean more toward the abnormal activity side of the spectrum than toward the negligence side. See *id.* Therefore, in considering policy issues to decide whether the case should be submitted to the jury, judges exercise greater control over design defect cases by restricting the number of decisions they submit to the jury. See *id.* at 835-39.

The process determination itself is appropriately made by the judge because it involves a conclusion of law, and the right to a jury trial is implicated only when issues of fact are kept

In short, this proposal trades a relaxed standard of liability regarding the quality of design decisions for a higher standard of accountability in the decisionmaking process. The close-call choice among design alternatives will be removed from the jury because of our belief that such choices made by a manufacturer in the context of a process that has integrity are, in fact, reasonable. Decisions that are the product of such a rigorous process should not be subjected to the roll of the dice in the jury room.

## VII

### IMPLICATIONS OF A PROCESS-BASED THEORY

Although this Article has concentrated on developing a process defense for design defect litigation, a process approach has interesting implications for failure-to-warn and production defect cases.

#### *A. Failure-to-Warn Cases*

It is questionable whether the process defense should be available when a plaintiff contends that a product is defective because it

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from the jury. In a negligence suit, it is proper for the jury to determine whether a defendant was negligent since that determination entails an examination of the reasonableness of the defendant's actions. The process defense, however, is not made by reference to the hypothetical reasonable man standard, which is a "personification of a community ideal of reasonable behavior, determined by the jury's social judgment." W. Prosser, *supra* note 18, § 32, at 151; see pp. 364-71, 373-75 *supra*. Indeed, it is conceivable that the manufacturer could act reasonably although the process is legally insufficient to satisfy the process standard. Furthermore, the effect of the process determination is to set the plaintiff's burden of proof, a matter traditionally decided by the judge. Upon a finding of good process, the plaintiff is required to satisfy the higher burden of clear and convincing evidence, which replaces the preponderance of the evidence standard. See note 75 and accompanying text *supra*.

Although this is not absolutely necessary to the process defense, we suggest that the judge also decide the factual issues necessary to making the process determination. If the jury were to hear evidence admissible only for the purpose of determining process, the jury might be prejudiced in its determination of design defect. See text accompanying notes 81-82 *supra*. Furthermore, in order to provide manufacturers with guidance in designing their safety review processes, the jury would have to render special verdicts or answer special interrogatories. But these devices often produce inconsistent results which would thwart the goal of providing feedback. See cases cited in note 80 *supra* and accompanying text. For other areas of law in which judges decide factual issues in order to make a legal determination, see, e.g., *Sinclair v. Spato Co.*, 452 F.2d 1213, 1213 (9th Cir.), cert. denied, 409 U.S. 886 (1972) (judge may determine facts necessary to ruling on existence of diversity of citizenship); *United States v. Geaney*, 417 F.2d 1116, 1120 (2d Cir.), cert. denied, 397 U.S. 1028 (1969) (judge may determine preliminary issue of admissibility of evidence in conspiracy case even though it coincides with the ultimate issue of the defendant's guilt); *Matz v. United States*, 158 F.2d 190, 192 (D.C. Cir. 1946) (in bigamy prosecution, judge may determine whether first marriage was established for purposes of ruling on competency of second wife to testify); *Chance v. E.I. Du Pont De Nemours & Co.*, 57 F.R.D. 165, 169-71 (E.D.N.Y. 1972) (judge may determine preliminary issues of fact on which choice of law depends).

does not carry an adequate warning of the risks entailed in its use. Since the allegation is that the defendant had knowledge of a risk but did not share that information with consumers, a strong argument can be made for judging the reasonableness of the decision not to warn and prohibiting the use of the process defense. In general, the failure-to-warn problem is less polycentric<sup>83</sup> and less amenable to the argument that good faith trade-offs made by the manufacturer in close-call cases should not be a predicate of liability if the process has met the suggested standards.

Failure-to-warn cases in which the function of a warning is not to reduce the incidence of risk among consumers but to inform consumers of a nonreducible risk clearly should not be subject to the process defense.<sup>84</sup> Such cases do not pose polycentric risk-utility considerations but rather public policy questions concerning the consumer's right to choose the risk level at which he wishes to live. This is a societal decision based on values that stand apart from the formal design process. Use of the process defense would, therefore, be inappropriate.<sup>85</sup>

### *B. Production Defect-Design Defect—A Mirage*

A process orientation that probes into the risk-reduction decisions made by manufacturers and the choices available to them raises serious questions about the soundness of the sharp distinction drawn between production and design defects.<sup>86</sup> To prevail in a production

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<sup>83</sup> See Henderson, *Judicial Review of Manufacturers' Conscious Design Choices*, *supra* note 1, at 1559 n.121. Although in a rebuttal article the authors demonstrated that even warnings could raise polycentric issues, the thrust of our argument was that warnings had to be viewed as part of the overall design decision. Twerski, Weinstein, Donaher & Piehler, *The Use and Abuse of Warnings*, *supra* note 1, at 513-17. It is quite a different question whether the failure-to-warn claim should be subject to the process defense.

<sup>84</sup> We have analogized such failure-to-warn cases to informed consent cases. See Twerski, Weinstein, Donaher & Piehler, *The Use and Abuse of Warnings*, *supra* note 1, at 517-21.

<sup>85</sup> On the other hand, some of the authors believe that risk-reduction failure-to-warn cases—as distinguished from cases involving warnings that do not reduce risks—should be subject to the process defense. The argument in favor of providing the process defense is that risk-reduction warnings must be balanced against design alternatives and thus should be addressed by the process of product development. A process defense could demonstrate the careful consideration of the interplay between design and warning alternatives. To sever the two might cripple the process defense in these cases.

<sup>86</sup> See, e.g., *Barker v. Lull Eng'r Co.*, 20 Cal. 3d 413, 417-18, 573 P.2d 443, 446-47, 143 Cal. Rptr. 225, 228-29 (1978); *Cepeda v. Cumberland Eng'r Co.*, 76 N.J. 152, 169-70, 386 A.2d 816, 824 (1978); *Phillips v. Kimwood Mach. Co.*, 269 Or. 485, 491, 525 P.2d 1033, 1035-36 (1974); UPLA, *supra* note 5, § 104(A), (B), at 62,721; Henderson, *Judicial Review of Manufacturers' Conscious Design Choices*, *supra* note 1, at 1542-43. But see Phillips, *The Standard for Determining Defectiveness*, *supra* note 1, at 103-05; Weinstein, Twerski, Piehler & Donaher, *Product Liability: An Interaction of Law and Technology*, 12 Duq. L. Rev. 425, 432-33 & n.14 (1974).

defect case, a plaintiff need establish only that the product was defective in comparison to the nondefective products that come off of the assembly line. It is no defense that the cost to the manufacturer of improving quality control would be prohibitive.<sup>87</sup> On the other hand, the design defect case requires a risk-utility analysis in order to arrive at the conclusion that the product is unreasonably dangerous.

There is cause for concern that the structure of the law, which mandates strict liability for a production defect arising from quality control procedures but which permits risk-utility balancing for a design defect, might be counterproductive to risk-reduction. Given a choice between raising quality control standards and altering the design, a manufacturer might be led by the law to the wrong risk-reduction decision.

Assume that by rerouting the wires in the electric screwdriver,<sup>88</sup> the manufacturer could accomplish a design change that would eliminate the shock hazard present in the original design but that would create a different remote hazard, one that did not exist in the original design. Assume further that the estimated probability of injury from this remote hazard is 2 in every 100,000 uses. Alternatively, the manufacturer finds that by increasing quality control standards the shock level of the original design hazard could be reduced to 1 in every 100,000 uses. Despite the lower level of risk that would result from improved quality control, the manufacturer might choose a design change that gives it a risk-utility defense rather than a change in quality control standards which is not defensible on risk-utility grounds. Thus, it may be that the bases of legal liability are not synonymous with overall risk-reduction. If the soft (risk-utility) decision is easier to defend than the hard (quality control) decision, the manufacturer may be induced to choose the cosmetically attractive, albeit somewhat questionable, design alteration decision. Under current litigation practice, such a decision would not be revealed and would not be not open to challenge in the courts.

Another example of this phenomenon is the manufacturer's decision to increase the quality of his product by raising design standards. As a trade-off, the manufacturer might reduce his quality control standard under the theory that even a product that fails to meet the manufacturer's higher standard is still comparable to the standard of the industry with regard to that product part. If the part fails, is the manufacturer to be held to his higher design standard merely because

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<sup>87</sup> Restatement (Second) of Torts § 402A (1977).

<sup>88</sup> See p. 365 *supra*.

the product failed?<sup>89</sup> In many instances in which a product fails as a result of a production defect, the plaintiff may have a claim based on disappointed consumer expectations.<sup>90</sup> The consumer may have purchased from a particular manufacturer because the quality of his product surpasses industry standards. There are, however, situations in which consumers have no clear expectations concerning specific qualities of a product.<sup>91</sup> For example, the maker of a quality automobile could design and utilize a ball joint that fails when hitting a pothole at 65 mph. The industry standard might be 30 mph. Assume that because of a production defect, the ball joint on the quality automobile fails at 50 mph. Customers probably have no expectations of the conditions under which a ball joint meets or exceeds industry standards. There would seem to be no basis for imposing liability merely because the product did not meet the manufacturer's own superior standards.

It is clear that the manufacturer's choice between a design change or an increase in quality control standards should be made on the basis of sensible risk-reduction. The distinction between defect types exists in the minds of legal scholars. Engineers just do not think in those terms.

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<sup>89</sup> In a different context, the authors of the UPLA tried to respond to this argument. See UPLA, *supra* note 5, § 104(A) Analysis, at 62,722, 62,723.

<sup>90</sup> See *Barker v. Lull Eng'r Co.*, 20 Cal. 3d 413, 429-32, 573 P.2d 443, 454-56, 143 Cal. Rptr. 225, 236-38 (1978); *Aller v. Rodgers Mach. Mfg. Co.*, 268 N.W.2d 830, 835-36 (Iowa 1978); *Seattle-First Nat'l Bank v. Tabert*, 86 Wash. 2d 145, 154, 542 P.2d 774, 779 (1975).

The process defense is not applicable when the plaintiff alleges a production defect based on the product's failure to meet consumer expectations. In such cases, the test for liability is not contingent on risk-utility analysis. In these cases, the consumer expectation test posits a standard of liability that has its origins in values other than sensible risk-reduction. When the focus of attention is on the product, however, and not on consumer expectations, the entire decisionmaking process must be examined carefully before concluding that liability automatically follows when an injury is caused by the product's failure to meet the manufacturer's internal standards.

The same reasoning applies to the use of the consumer expectation test in design defect cases in which risk-utility considerations do not play a role in judging defective design. Some commentators, however, have argued that the defendant should be permitted to rebut the inference of defective design based on the product's failure to meet consumer expectations by demonstrating that the design met risk-utility guidelines and was not unreasonably dangerous. See Keeton, *Products Liability—Design Hazards*, *supra* note 1, at 310; Schwartz, *supra* note 1, at 453-54. If one agrees with the argument that risk-utility factors should be considered as a defense in design defect cases based on the product's failure to meet consumer expectations, the process defense should be applicable in these cases also.

<sup>91</sup> See, e.g., *Heaton v. Ford Motor Co.*, 248 Or. 467, 472-73, 435 P.2d 806, 803-09 (1967) (truck's collision with rocks is sufficiently beyond the average person's experience for jury to decide what an ordinary consumer would expect); UPLA, *supra* note 5, § 104(B) Analysis, at 62,724; Wade, *On Strict Liability*, *supra* note 19, at 829 (consumer cannot form expectation when he does not know how safe a product can be made).

## CONCLUSION

It is with considerable trepidation that we suggest a defense to a products liability action based on evidence that the decisionmaking process was comprehensive and well-articulated. The obvious questions that will be raised are: If the process was so good, why did the product cause injury? Does not the fact that the product caused an injury in a design defect case demonstrate that safety dimensions were not properly considered? The answer to these questions is that there are cases in the middle range of product liability litigation in which the judgment of defectiveness is a very close call. If the design decision was made in a careful and intelligent manner, the manufacturer should be entitled to defend its product without jeopardy that the close-call case will inevitably find its way to a jury. We believe that a legal system that rewards intelligent, open, and comprehensive design safety decisions ultimately will promote greater safety in the marketplace. We will be setting clearly delineated and attainable goals for manufacturers rather than second-guessing design decisions in close-call cases.

The potential for abuse of the process defense is substantial. There is a threat that manufacturers could create paper records solely for litigation. However, it is hard to conceive of an idea that cannot be abused by the unscrupulous. For the fair, conscientious manufacturer, our proposal offers the assurance that the courts will judge the entire design safety review process, rather than a single design decision removed from the context in which it was made. To the extent that the process is held up to scrutiny, the beneficiaries will be the consumers.